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The use of electrically assisted bicycles for promoting active transport and health

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June 2021

A dissertation submitted to the University of Bristol in accordance with the requirements for award of the degree of Doctor of Philosophy in the Faculty of Social Sciences and Law.

Word Count: 79,911

Abstract

Background: Over the past 20-years there has been little change in global physical activity (PA) behaviour despite substantial advocacy efforts. E-cycling has become increasingly popular for personal travel and may offer a means through which to weave PA into daily life.

Aim: The overall aim of this thesis was to explore the use of e-bikes in improving health through increased PA.

Method: Three studies addressed this aim, exploring different, but complementary questions. Study one was a systematic review of the research examining the impact of e-cycling on PA and health. Study two was a scoping review of the evidence examining how and why people use e-bikes and the impact of their use on travel behaviour. Study three was a randomized controlled pilot study to examine the feasibility and acceptability of conducting an e-cycling intervention for individuals with type 2 diabetes mellitus (T2DM).

Results: Study one found that e-cycling is a moderate intensity activity that could increase cardiorespiratory fitness in inactive adults. The impact of e-cycling on health outcomes beyond fitness was inconclusive and required further investigation. Study two showed that e-cycling increased the frequency and duration of cycling and could substitute for motorised transportation. However, current evidence relies on self-reported, retrospective measures and objective longitudinal data are needed. Addressing research gaps identified in Studies one and two, Study three demonstrated that conducting an e-cycling intervention is feasible with a 87.5% retention rate, 87.5% attendance at data collection sessions and 62.5% attendance at intervention sessions. Instructors were comfortable delivering the intervention. The intervention provided some evidence of positive clinical, physiological, and behavioural effects.

Conclusion: The findings of this thesis support the use of e-cycling as a means of increasing PA behaviour, with promise to positively impact physical and mental health in inactive and clinical populations. Efforts should be made to ensure that e-cycling is accessible to everyone.

Acknowledgements

This research would not have been possible without financial support from the Bristol Biomedical Research Centre, Nutrition Theme. The centre has provided me with fantastic learning opportunities, and I have benefited from the multidisciplinary team. I am hugely thankful for the caring work environment the centre has created and I have been lucky to make good friends during my time here. In addition, to all the individuals that took part in this research, thank you! I appreciate all the time and effort you have given. Research would not be possible without people like you.

I would like to thank my supervisors, Professor Ashley Cooper and Professor Angie Page, for their belief in me from the start. Your support, encouragement and challenging questions have been invaluable to this PhD and my development as a researcher. I look forward to continued discussions about research and outdoor pursuits. To the most recent addition to the supervisory team, Professor Charlie Foster, I have already learnt so much from you and your help getting me closer to the finish line is hugely appreciated. Dr. Sam Leary and Dr. Clare England, thank you for your academic and personal support over the past four years. It has been a pleasure working with you both. Thank you to Dr. Paul Kelly, you have been generous in providing me with opportunities to collaborate and have always been willing to answer my many questions.

To my parents Michael, Gigi, and Roger, thank you for always pushing me to challenge myself and providing me with the support to enable me to do so. You have instilled a strong work ethic in me, for which I am forever grateful. To my daughter Phoebe, who was born during this PhD, your good humour and laughter is infectious and has kept me grounded during this, sometimes overwhelming, adventure. I am extremely proud of the confident young women you have already become. Lastly, but by no means least, thank you to my wonderful husband Alex for being there every step of the way. Your unconditional love and encouragement have made this PhD possible. Your ability to understand scientific concepts well outside your field is admirable and I am so grateful for all those late-night work conversations. I hope I can provide you with the same level of support as you continue your PhD journey.

Author’s declaration

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's *Regulations and Code of Practice for Research Degree Programmes* and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

SIGNED: .... DATE: 09.06.2021

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Dissemination of academic work

Publications from this thesis and statements of contribution

Publication 1: Bourne, J. E., Sauchelli, S., Perry, R., Page, A., Leary, S., England, C. & Cooper, A. R. (2018). Health benefits of electrically assisted cycling: a systematic review. *International Journal of Behavioral Nutrition and Physical Activity,* 15 (116).

Author contributions: JEB conceptualised the review. JEB, RP, ARC and AP contributed to design and search strategy. JEB, SS, ARC and RP contributed to screening, data extraction and quality assessment. JEB drafted the full manuscript. All authors read and approved the final manuscript.

Publication 2: Bourne, J. E., Cooper, A. R., Kelly, P., Kinnear, F. J., England, C., Leary, S. & Page, A. (2020). The impact of e-cycling on travel behaviour: A scoping review. *Journal of Transport and Health, 19*, doi.org/10.1016/j.jth.2020.100910

Author contributions: JEB conceptualised the review. JEB and PK contributed to the design and search strategy. JEB, CE, ARC, FJK contributed to screening and data extraction. JEB drafted the full manuscript. All authors read and approved the final manuscript.

Publication 3: Bourne, J. E., Page, A., Leary, S., Andrews, R. C., England, C., & Cooper, A. R. Electrically assisted cycling for individuals with type 2 diabetes mellitus: protocol for a pilot randomized controlled trial. *Pilot and Feasibility Studies , 5*(136), doi: 10.1186/s40814-019-0508-4

Author contributions: JEB designed the trial. AP, ARC, SL, CE and RA provided feedback on the design of the trial. JEB drafted the full manuscript. All authors read and approved the final manuscript.

Conference proceedings related to work of this thesis

Bourne, J. E., Searle, A., Cooper, A., Leary, S., England, C. & Page. A. S. (2021) ‘If I had long hair I’d flick it’: Experiences of e-cycling among individuals with type 2 diabetes’ Oral presentation at the *International Society of Behavioral Nutrition and Physical Activity* conference, online, June 2021.

Bourne, J. E., Cooper, A. R., Searle, A., Leary, S., England, C. & Page, A. S (2021). Feasibility of an e-cycling intervention for individuals living with type 2 Diabetes. Oral presentation at the *UK Society of Behavioural Medicine,* online, January 2021

Bourne, J. E., Sauchelli, S., Perry, R., Page, A., Leary, S., England, C. & Cooper, A. R. (2018). Health benefits of electrically-assisted cycling: a systematic review. Oral presentation at the *International Society of Behavioral Nutrition and Physical Activity* conference, Prague, June 2019.

Common Abbreviations and Acronyms Used in this Thesis

ACM	All-cause mortality
AT	Active travel
BCT	Behaviour change technique
BMI	Body mass index
BNSSG	Bristol, North Somerset, and South Gloucestershire
CB	Conventional bicycle
CCG	Clinical commission group
CI	Confidence interval
CO_2	Carbon dioxide
CO2e	Carbon dioxide equivalent: a standard unit for measuring the carbon footprint of different greenhouse gases
COM-B	Capability, opportunity, motivation-behaviour
CONSORT	Consolidated Standard of Reporting Trials
COVID-19	Coronavirus disease first identified in December 2019
CVD	Cardiovascular disease
DEXA	Dual energy X-ray absorptiometry
E-bike	Electrically assisted bicycle
ED	Emergency department
EOI	Expression of interest
ES	Effect size
EPHPP	Effective Public Health Practice Project Quality Assessment Tool
FT	Full time
GP	General practitioner
GPS	Global positioning system
HbA1c	Glycated haemoglobin
HDL	High density lipoprotein
HOMA-IR	Homeostasis model assessment for insulin resistance
HOMA-B	Homeostatic model assessment for β-cell function
HR	Hazard ratio
Hr	Heart rate
HRA	Health Research Authority
HRQoL	Health related quality of life
LCUK	Life Cycle UK
iAUC	Incremental area under the curve
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
$IGI_{0\text{-}30}$	Original insulinogenic index
$IGI_{0\text{-}120}$	Total insulinogenic index
IMD	Index of multiple deprivation
ISPAH	International Society of Physical Activity and Health
ISSI-2	Insulin secretion-sensitivity index-2
IQR	Interquartile range

LDL	Low density lipoprotein
LPA	Light intensity physical activity
MET	Metabolic equivalent: The MET is an expression of energy cost and is calculated from rest where one MET is estimated to equal 3.5ml/kg/min
mCSA	Muscle cross-sectional area
MRC	Medical Research Council
MPA	Moderate intensity physical activity
MVPA	Moderate to vigorous intensity physical activity
NCD	Non-communicable disease
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NIHR	National Institute for Health Research
NTS	National travel survey
OGTT	Oral glucose tolerance test
OR	Odds ratio
PA	Physical activity
PEDAL1	A feasibility study of e-cycling study titled 'Promoting electrically assisted cycling in people with type 2 diabetes'
PIC	Participant identification centre
PPI	Patient and public involvement
pQCT	Peripheral quantitative computer tomography
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PT	Part time
REC	Research ethics committee
RCT	Randomized controlled trial
RR	Relative risk
SD	Standard deviation
SDG	Sustainable development goals
SMD	Standardised mean difference
SRQR	Standards for Reporting Qualitative Research
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TDF	Theoretical domains framework
UK	United Kingdom
USA	Unites States of America
VPA	Vigorous intensity physical activity
VO_{2max}	maximum oxygen intake value attainable for an individual
VO_{2peak}	the highest oxygen intake value obtained on a specific test
WHO	World Health Organisation

1. Chapter 1: Introduction, literature review and thesis aims

1.1 Overview

In this chapter the key concepts of this thesis are introduced, and the objectives of this PhD research stated. The chapter provides an overview of the history of physical activity (PA) research and its measurement, the impact of PA on health, PA prevalence and the costs associated with physical inactivity. The use of active travel (AT) as a means of increasing PA behaviour is discussed and strategies through which to increase AT reviewed. Given the low rates of engagement in AT, particularly cycling, the use of electrically assisted bicycles (e-bikes) is introduced as a potential means through which to increase AT.

1.2 Physical activity

1.2.1 Definitions of PA

PA is defined as 'any bodily movement produced by skeletal muscles that results in energy expenditure' (1). This contrasts with exercise which represents a planned, structured, and repetitive form of PA. PA is part of a continuum of movement (Figure 1.1) that categorises behaviour based on energy expenditure, often defined as the metabolic equivalents of a task (METs). One MET is the energy equivalent expended by an individual while seated at rest and is classified as one kcal per kg of body mass per hour. Sedentary behaviour is defined as any waking behaviour of 1.5 METs or less while sitting, reclining, or lying. Light intensity PA (LPA) is defined as PA that requires an energy expenditure of between 1.6 to 2.9 METs, leading to no substantial raise in heart rate (Hr) or breathing rate. Moderate-intensity PA (MPA) is defined as PA requiring an energy expenditure of between three and less than six METs, causing increased breathing rate and Hr but the individual can hold a conversation. Vigorous intensity PA (VPA) is classified as PA requiring an energy expenditure of six or more METs, causing the heart to beat rapidly and heavier breathing making it difficult to carry a conversation (2).

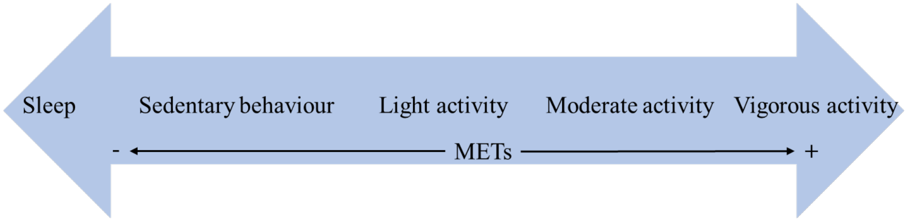

Figure 1.1 The continuum of movement behaviour. Adapted from Tremblay et al (3).

1.2.2 Measurement of PA

Measuring PA behaviour is important to monitor population PA levels and evaluate the need for, and effectiveness of, PA interventions. However, measuring PA behaviour is challenging and a variety of different tools have been used (see Figure 1.2).

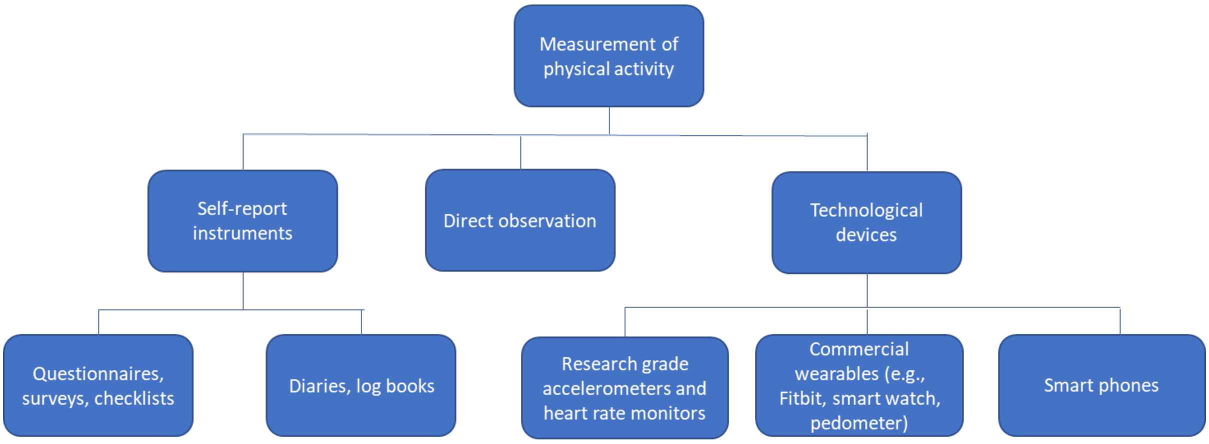

Figure 1.2 Main methods of measuring PA. Reproduced and adapted from Biddle et al (4)

Self-reported questionnaires or surveys are the most common method of PA assessment, relying on individuals to recall their behaviour. They can take different forms (e.g., paper and pencil, online or interview) and vary in what they measure (e.g., mode, duration, frequency), the type of activities they measure (e.g., habitual activity, recent activity, leisure, and non-leisure activity) and how data are reported (time, kilocalories) (4). Questionnaires and surveys suffer from issues of recall and response bias (e.g., social desirability) and fail to capture all levels of activity including unstructured lifestyle activity and LPA (5). While they are low cost and readily accepted by participants (6) the criterion validity and reliability of these measures are inconsistent (5). Self-report diaries or logbooks aim to measure PA in real-time, capturing more detailed data and overcoming some of the issues of self-report questionnaires (7). However, diaries and logbooks are a burden to participants, and may not be completed in real time as intended.

Direct observation, in which an independent observer monitors and records PA, is realistically only feasible when activity is performed in a single location (e.g., a classroom). While observation captures detailed activity and contextual information it takes considerable time to complete and may cause individuals to change their behaviour if they know they are being observed (8, 9).

Over the past few decades technological advances have led to the development of objective devices, such as accelerometers, pedometers, and Hr monitors, to measure PA. These devices remove issues of recall and response bias and can determine the volume and time spent in different PA intensities as well as energy expenditure. They display criterion validity in comparison to doubly labelled water or indirect calorimetry (10-14), acceptable inter-instrument reliability and strong test-retest reliability (15). However, programming, processing, and analysing these data relies heavily on subjective researcher decisions for which there are currently no agreed upon methods (16). Furthermore, they are unable to accurately assess some types of everyday activities (17).

Despite these limitations, objective measures provide more accurate measures of PA and less variability than self-reported measures (15, 18) and therefore represent the next step in accurately measuring PA prevalence and change over time. Use of such devices has increased dramatically in high-income countries and as the cost of these devices decreases their use globally in large scale epidemiological studies becomes more feasible (19). However, if these devices are to be used more globally then standardisation of data collection methods, data processing and analysis is required (20, 21).

Recently, commercially available wrist worn devices, with integrated accelerometers and Hr sensors, have gained popularity (e.g., Fitbit, apple watch). However, when compared to research grade measures there is substantial variability in their ability to accurately assess energy expenditure in the laboratory and free-living settings (22-24). A meta-analysis of wrist and arm worn devices reported that research grade devices were more accurate than commercial devices for estimating total energy expenditure (24).

In addition to wrist worn devices the use of smartphones with inbuilt accelerometers has been proposed as a method of measuring PA on a large scale due to their increased global use (25). They have been reported to reliably estimate sedentary and moderate-to-vigorous intensity physical activity (MVPA) (26). In addition, smartphones have been used to conduct ecological momentary assessment studies (EMAs) in which the type, location and context of PA is recorded through repeated assessment of behaviour and context based on time or events (27). While EMA has increased in popularity it faces issues of content validity (28).

1.2.3 PA and adult health

There is a strong body of evidence that engaging in regular PA lowers the risk of developing many non-communicable diseases (NCDs) and improves mental health and wellbeing. This evidence is outlined in Table 1.1.

Conversely, physical inactivity (defined as failing to meet the PA guidelines) is associated with an increased risk of developing type 2 diabetes mellitus (T2DM), coronary heart disease and breast and colon cancer after adjusting for confounders (29). Recently, physical inactivity has been identified as a risk factor for developing severe COVID-19. A study of 48,440 adults found that individuals who were inactive (0-10 minutes of self-reported MVPA per week) were at greater risk of hospitalisation (OR[95%CI], 2.26[1.81, 2.83]), admission to intensive care (OR[95% CI], 1.73[1.18, 2.55]) and mortality (OR[95% CI], 2.49 [1.33, 4.67]) due to COVID-19 compared to individuals who were consistently meeting the PA guidelines (30). Regarding mental health, a cross-sectional study of 902 UK adults found that lower levels of self-reported daily MPVA reported from late March 2020 were negatively associated with poor mental health (OR[95% CI], 0.88[0.80, 0.97]) after adjusting for covariates, with similar results reported for anxiety and depressive symptoms (31).

Table 1.1 Evidence of the impact of PA on mortality, morbidity, and general health

Condition	Evidence
ACM and CVD mortality	There is strong evidence across multiple meta-analyses of an inverse relationship between PA and ACM and CVD mortality, with the greatest benefits seen in the least active individuals (32).
CVD	Kyu and colleagues (33) meta-analyses of 174 prospective cohort studies found that moderately active individuals (4000-7999 MET minutes/week) had a 23% lower risk of ischemic heart disease (RR[95%CI], 0.77[0.70, 0.84] and 19% lower risk for ischemic stroke (RR[95%CI], 0.81[0.69, 0.94]) compared to insufficiently active individuals (<600 MET minutes/week).
Hypertension	Huai and colleagues (34) meta-analysis of 13 prospective cohort studies reported a 19% and 11% reduction in risk of developing hypertension among individuals who reported high and moderate levels of PA respectively, compared to those engaging in low levels of PA (RR[95% CI], high vs low 0.81[0.76, 0.85], moderate vs. low 0.89[0.85, 0.94]).
T2DM	Aune and colleagues (35) meta-analysis of 14 cohort studies reported a risk reduction for T2DM of 35% for high compared to low total activity (RR[95%CI], 0.65[0.59, 0.71]).
Cancer	There is strong evidence that greater amounts of PA are associated with reduced risk of bladder, breast, colon, endometrial, oesophageal, gastric and renal cancer (32).
Weight gain	There is strong evidence that greater amounts of PA, particularly >150-minutes of MVPA per week, can attenuate weight gain in adults (32).
Cognitive functioning	Northey and colleagues (36) reported that PA led to improvements in cognitive function in adults over 50-years (ES[95%CI]: 0.29[0.17, 0.41]).
Cognitive impairment	Sofi and colleagues (37) meta-analysis of 15 prospective studies, with follow-ups between one to 12 years, reported that high levels of PA were significantly protective against cognitive decline at follow-up (HR[95%CI], 0.62[0.54, 0.70]. While engaging in low-to-moderate PA was somewhat protective against cognitive impairment (HR[95%CI], 0.65 [0.57, 0.75]. Beckett et al (38) meta-analysis of 9 prospective longitudinal studies reported a significant reduction in risk of Alzheimer's disease in physically active older adults compared to non-active older adults (RR[95%CI], 0.61[0.52, 0.73]). Of note Kivimaki and colleagues (39) suggest that studies with follow-up of <10-years maybe capturing declines in the early stages of dementia, a period associated with declines in PA, rather than demonstrating a causal link between PA on dementia risk.

Depression	Ashdown-Franks and colleagues (40) meta-review of 8 meta-analysis found consistent evidence that structured MVPA had a positive impact on symptoms of depression. In non-clinical populations, Rebar and colleagues (41) meta-analysis found that PA reduced depressive symptoms (SMD[95%CI], -0.50[-0.93, -0.06]).
Anxiety	Ensari and colleagues (42) meta-analysis of 36 RCTs found the PA led to a reduction in state anxiety following acute exercise (Hedges' g=0.16). Regarding long term anxiety Schuch and colleagues (43) meta-analysis of 13 prospective studies found that adults with high self-reported PA were at reduced odds of developing anxiety (adjustedOR[95%CI], 0.81[0.69, 0.95]) compared to those with low PA. In non-clinical populations, Rebar and colleagues (2015) meta-analysis found that PA reduced symptoms of anxiety (SMD[95%CI], -0.38 [-0.66, -0.11]).
Quality of life	Park and colleagues (44) meta-analysis of 18 RCTs found that exercise programmes in older adults led to improvements in quality of life (SMD[95%CI], 0.86,[0.11, 1.62]).

ACM=all-cause mortality; CVD=cardiovascular disease; CI=confidence interval; ES=effect size; HR=hazard ratio; MET=metabolic equivalent; MVPA=moderate to vigorous intensity physical activity; OR=odds ratio; PA=physical activity; RCT=randomized controlled trial; RR=relative risk; SMD=standardised mean difference; T2DM=type 2 diabetes mellitus

1.2.4 Dose response relationship

Understanding the minimum and maximum dose of PA at which health benefits can be accrued is essential to inform PA guidelines. There is evidence of an inverse curvilinear dose-response relationship between the volume of PA and risk of all-cause mortality (ACM), cardiovascular disease (CVD) mortality, cancer-specific mortality, as well as incidence of T2DM, CVD and several cancers (Figure 1.3) (32).

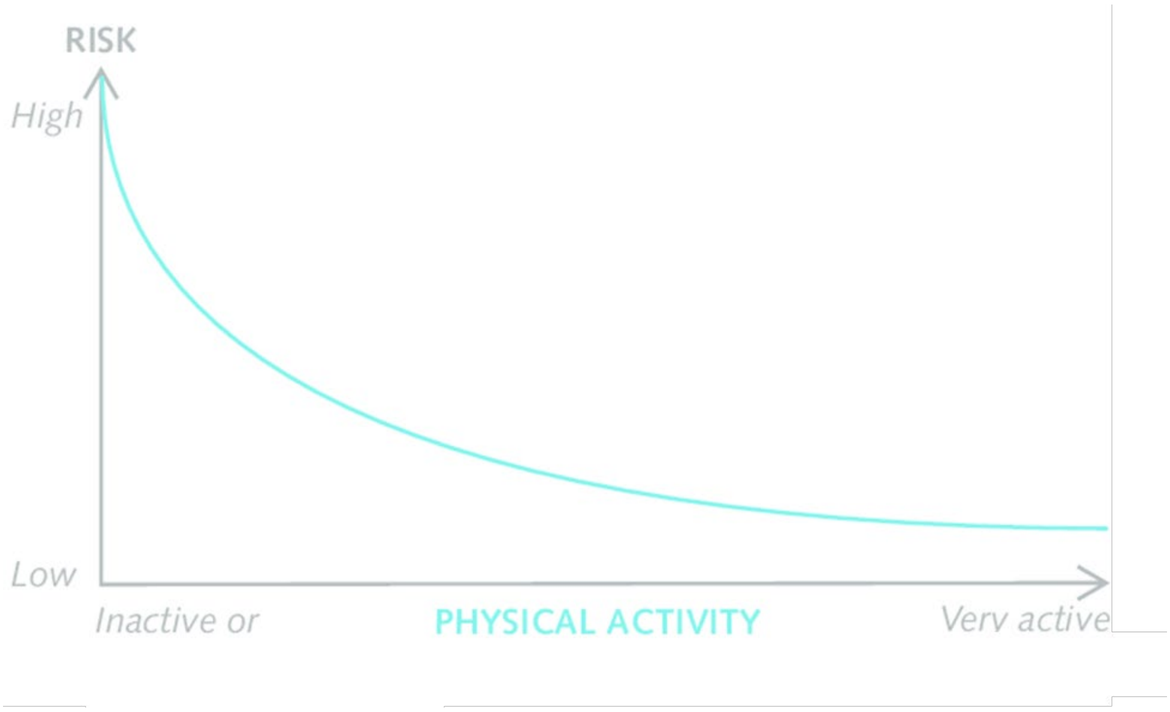

Figure 1.3 Graphical representation of the inverse curvilinear relationship between PA and risk of disease. Reproduced from the 2011 Chief Medical Officer's report on PA (45).

Until recently dose-response relationships had been based on self-reported measures of MVPA used in longitudinal cohort studies. However, these measures are unable to capture information on total PA and LPA (46) and are subject to reporting errors previously highlighted. With the use of objectively measured PA, it has become clear that LPA contributes to lowering CVD risk factors, independent of those provided by MVPA (47). A recent meta-analysis of eight prospective cohort studies with a median follow-up of 5.8 years (range 3 to 14.5 years) reported that greater volumes of total PA at any intensity, as measured using accelerometery, was beneficial for health compared with the least active referent group (referent, 1.00) (48). Specifically, adjusted hazard ratios of 0.48 (95%CI, 0.43, 0.54) for the 2nd quartile; 0.34 (95%CI, 0.26, 0.45) for the 3rd quartile; and 0.27 (95% CI, 0.23, 0.32) for the 4th quartile (the most active) were reported. As such, activity of any intensity is beneficial to health, with no lower limit for benefit.

In addition, engaging in greater volumes of activity, at higher intensity, has been found to be beneficial to health. Blond and colleagues (49) meta-analysis of 48 prospective studies found that, compared to the recommended level of PA (750 MET/minutes per week), mortality risk was lower at higher levels of PA until 5000 MET minutes/week for ACM (HR[95%CI], 0.86[0.78, 0.94]) and CVD mortality (HR[95%CI], 0.73[0.51, 0.95]). The authors concluded that 10 to 12 hours of weekly VPA is not harmful to longevity.

It is important to note that PA comes with risks, the most common of which are musculoskeletal injury or sudden cardiac death (50). However, risk of a sudden cardiac event due to PA engagement is rare (32) and the long term benefits of VPA, such as running, outweigh the risks (51). Regarding musculoskeletal injury a review found that while leisure-time PA was unfavourably associated with musculoskeletal injuries it was favourably associated with risk of fracture and onset of knee or hip osteoarthritis (52). It is largely accepted that the benefits of engaging in PA outweigh the risks.

1.2.5 PA calls to action

As the strength of the evidence linking engagement in PA and protection against NCDs has grown, so have PA advocacy. In 2008 the International Society of Physical Activity and Health (ISPAH) was founded. Soon after its inception the organisation released the *Toronto Charter for Physical Activity* (53). With a shift away from identifying the epidemiological links between PA and health, the charter outlined nine key principles to encourage sustainable and inclusive PA. Recognising a need for interventions to increase PA behaviour the '*Non communicable disease prevention: Seven investments that work for physical activity'* publication accompanied the Charter (54).

With increased advocacy and a rapidly growing evidence base came increased publication of PA research in key medical journals such as The Lancet with the first series dedicated to PA published in 2012. In this series the prevalence of physical inactivity was identified as a global pandemic with far reaching consequences (55). Following this series in 2013, the World Health Organisation (WHO) Global Action Plan for NCDs was published in which member states agreed to a 10% relative reduction in the prevalence of physical inactivity by 2025. This represented the first global initiative urging member states to tackle physical inactivity as one of nine key components in preventing and controlling NCDs (56).

However, recognising the slow progress towards reaching this global reduction in physical inactivity, in 2016, ISPAH released the *Bangkok Declaration for Physical Activity* calling for greater investment in and implementation of actions to decrease physical inactivity (57). As part of this declaration the society identified strong links between PA and its contribution to helping achieve 8 of the 17 United Nations 2030 Sustainable Development Goals (SDG) which were developed to promote global prosperity (58). The contribution of PA to the SDGs was also recognised by the *2018 Global Action Plan for Physical Activity (GAPPA) 2018-2030 More Active People for a Healthier World* (59). Specifically, investing in initiatives to promote PA was said to contribute to 13 of the 17 SDGs, as outlined in Figure 1.4.

Figure 1.4 Economic, social, and environmental co-benefits of policy action to increase PA. Reproduced from ACTIVE: a technical package for increasing physical activity (60)

The 2018 GAPPA, devoted solely to PA, came with a new global target of a 15% reduction in global physical inactivity by 2030. GAPPA called for a whole system approach to ensuring PA opportunities are accessible to all and outlined four strategic objectives and 20 evidence-based policies that could be applied and adapted to all country contexts to achieve this target. The four strategic objectives included active societies, active environments, active people, and active systems. Complementing this action plan ISPAH released an updated version of the investments that work for PA document to assist with the development of interventions to promote PA (61).

1.2.6 PA guidelines

Alongside strategies to promote PA engagement has been the publication of PA guidelines. Physical activity guidelines offer recommendations for the volume, duration, frequency and type of PA that should be conducted to significantly reduce the risk of negative health outcomes (62). Recommendations to encourage engagement in regular PA first appeared in 1995, representing a shift away from exercise promotion toward a focus on PA for improved health (63). In 2010 global public health guidelines for PA were published by the WHO. The guidelines recommended that adults aged 18 to 64 engage in at least 150-minutes of moderate-intensity or 75-minutes of vigorous-intensity aerobic PA, or a combination of the two, throughout the week in bouts of at least 10-minutes. In addition, muscle strengthening should be conducted on two or more days per week (64). Similar recommendations were released by the UK in 2011 (45).

Ten years on from the original WHO global PA guidelines, 2020 saw the release of updated guidelines. These built on a substantial body of evidence of the positive impact of PA on health, including mental health (65). The guidelines continue to promote engagement in at least 150-minutes of moderate-intensity or 75-minutes of vigorous-intensity aerobic PA per week and muscle strengthening on at least two days per week. However, the updated guidelines emphasise that *'some PA is better than none'* and as such the requirement that PA be conducted in minimum continuous bouts of 10-minutes has been dropped. These changes are based on device-based measurements showing that any duration of PA and reductions in sedentary time are associated with improved health outcomes as reported in section 1.2.4 (48, 66-68). The updated guidelines reflect those released by the UK (62) and the USA (69). Figure 1.5 shows the evolution of the PA guidelines.

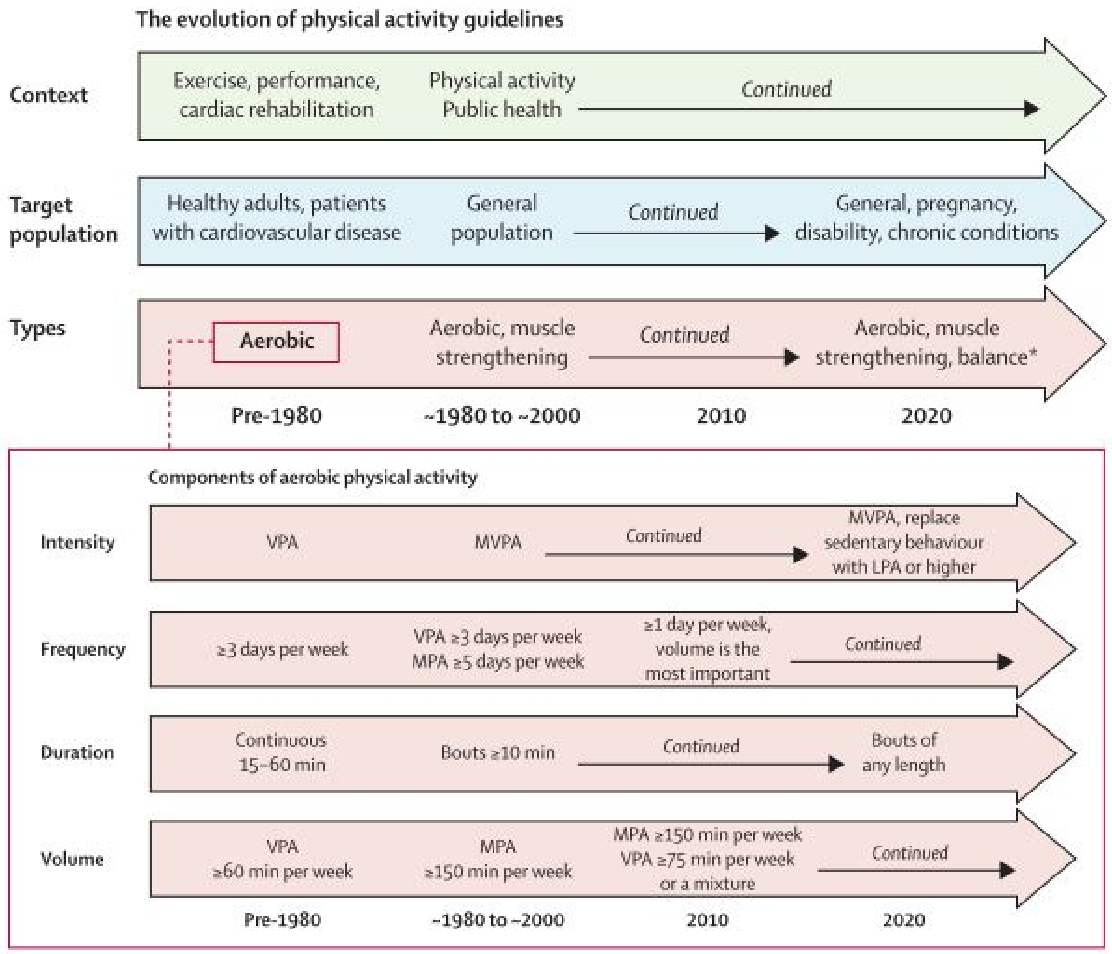

Figure 1.5 The evolution of physical activity guidelines, reproduced from Ding et al (65). LPA=light-intensity physical activity; MPA=moderate intensity physical activity; MVPA=moderate-to-vigorous physical activity; VPA=vigorous intensity physical activity. *primarily in older adults.

1.2.7 PA prevalence

Translating these global physical inactivity reduction targets into practice has proven difficult. Analyses of trend data from 1.9 million people, across 168 countries found that 27.5% of the global adult population was insufficiently active in 2016, similar to levels reported in 2001 (70). Men were found to be more active than women in most countries (prevalence of physical inactivity in men [95%CI], 23.4%[21.1, 30.7%] vs. women [95%CI], 31.7%[28.6, 39.0%]). In addition, high-income countries reported higher prevalence of physical inactivity (36.8% [95%CI, 35.0, 38.0]) than low-income countries (16.2% [95%CI, 27.1, 37.2%]). Rates of physical inactivity rose in high-income countries between 2001 to 2016 despite a time of increased advocacy and knowledge of the benefits of PA. In England specifically, the prevalence of physical inactivity was found to be higher than global estimates with 33% of men and 42% of women failing to meet the guidelines in 2016 (71).

Similarly, 2018/19 data from Sport England's Active Lives Adult survey revealed that physical inactivity in England was 35% of men and 39% of women (72).

1.2.8 Burden of physical inactivity

In 2013, analyses of data from 142 countries, estimated that the direct health care costs of physical inactivity on five major NCDs and ACM was INT$53.8 billion dollars globally (73). Indirectly, physical inactivity related deaths cost INT$13.7 billion dollars in productivity loss. High-income countries bore a larger portion of the economic burden than low-income countries, however, low-income countries had a larger proportion of the disease burden due to the varying levels of development and associated health care expenditure (73).

In the UK in 2006/07, physical inactivity related illness from five NCDs (ischaemic heart disease, stroke, breast cancer, colon/rectum cancer, diabetes mellitus) cost the NHS £0.9 billion (74). Specifically in Scotland in 2010/11, physical inactivity related to the same five diseases cost the NHS an estimated at £94.1 million (75).

Investment in PA promotion has been predicted to have positive returns on investment, due to prevention of NCD, in several countries over 15-years (76). Presenting the data in a more gain-framed manner, a recent study estimated that across 168 countries, 3.9 million deaths per year (95%CI: 2.5, 5.6) are prevented from current prevalence levels of PA (78). As such, investment in PA is still considered the 'best buy for public health' as stated by Jerry Morris in 1994 (77).

1.2.9 Increasing PA behaviour

As previously stated, despite the mounting evidence of the health benefits of engaging in regular PA there has been limited PA behaviour change over the past 20 years. A systematic review of the PA literature revealed a continual strong focus on research exploring the physical health benefits of PA and the individual and inter-personal level correlates and determinants of PA (79). It has been suggested that this research focus is compromising the need for research in areas in which there is less evidence including PA interventions and policy (68). Ramirez and colleagues (79) found that between 1950 to 2019 only 3.9% of studies published related to PA policy and 8.3% to interventions. Developing effective, sustainable interventions are key to promoting PA in adults (80). Historically, PA promotion initiatives have focused on encouraging individuals to engage in structured recreational PA (81, 82). However, there are a number of barriers to recreational activity including lack of facilities, lack of time, cost, feeling too tired or weak and having no one to exercise with (83).

It is now widely recognised that weaving activity into everyday life, known as incidental PA, is imperative for PA promotion (59).

1.3 The potential of active travel

An alternative to recreational PA, which may alleviate some of the associated barriers, is AT (primarily walking or cycling for the purpose of functional rather than recreational travel). Travel is an integral part of everyday life which takes a considerable amount of people's daily time, however, most of the trips completed are of short duration. The 2019 England National Travel Survey (NTS) reported that 68% of all trips were under five miles in length and the majority of these were made by car (84). Given that individuals report a willingness to travel distances of 0.5 to 2 miles on foot (85) and 1.5 to 4.7 miles by bike (86), it is feasible that these short motorised journeys could be replaced by active means and subsequently increase PA (87). The promotion of AT has been identified as an effective, evidence-based means of increasing PA behaviour (61) with positive environmental benefits (88) and is endorsed by the WHO and National Institute of Health and Care Excellence (NICE) (59, 89).

1.3.1 Measurement of travel behaviour, including AT

Historically, individual travel behaviour data were collected using paper or telephone recall surveys in which individuals describe their travel behaviour on an average or specific day. However, this retrospective method is subject to high recall error (90, 91). In the late 90s the use of paper travel diaries increased in popularity enabling researchers to collect travel data in real time, capturing data on trip duration, length, purpose and mode over several days. Travel diaries accurately capture contextual information about trips including purpose and mode (92, 93) and as well as specific information about the travel environment (94). However, when compared to global positioning systems (GPS) they lead to under reporting of trip frequency (95-98) and over estimation of trip duration (99). Furthermore, travel diaries are commonly completed retrospectively making them similarly prone to recall error (100) and are of considerable burden to participants which can lead to reporting fatigue (101). As such, GPS monitoring has become a popular method of assessing trip frequency, duration, and speed, providing more objective and accurate travel behaviour data than self-report measures, though this method cannot determine travel purpose.

The use of GPS monitoring has been trialled in large scale city and statewide travel surveys (95, 97, 102, 103). In some countries and states GPS monitoring has been successfully incorporated (e.g., Australia, New Zealand, California, New York City, Jerusalem) while in others, such as France and the UK it has not proliferated. A review of the NTS in 2017 noted that while GPS monitoring enabled collection of accurate data the cost and the logistical difficulties of distribution and collection of devices meant it was unfeasible (104).

In the context of AT, GPS devices are unable to determine the intensity of PA associated with travel behaviour. Information on intensity is important to determine the contribution of AT to meeting the PA guidelines. Combining both accelerometery and GPS monitoring can provide useful information on AT behaviour and associated intensity. GPS data can be time-matched with accelerometer data and visualised in geographical information software (e.g., QGIS or ArcMap). Following this, trip information such as start and end time can be manually segmented, or algorithms applied to identify departure and arrival points. Information on travel mode and purpose can be collected using travel diaries completed alongside the GPS and accelerometer data collection (105) or using GPS-based prompted recall surveys in which trip information is segmented and fed back to the participant (106, 107) to provide accurate travel information and understand the context of the behaviour. Efforts have been made to move away from a reliance on any self-reported measures with researchers developing algorithms to predict transport mode and/or purpose and associated levels of PA solely from GPS and accelerometery data (107-111). However, these methods lack accuracy and the use of self-reported measures for validation of objective measures is currently recommended.

It is important to highlight that the methods of assessing AT discussed above focus on individual level behaviour. Travel behaviour can also be assessed using observational methods such as traffic surveys involving counts of pedestrians, cyclists and/or vehicles. These observational methods are commonly used to assess the impact of infrastructure changes and counts of use or ticket sales to monitor public transport. The challenges faced in evaluating the impact of built environments interventions on AT are discussed by Aldred and colleagues (112).

1.3.2 AT and PA

After controlling for demographic differences, individuals who engaged in AT for either commuting or non-commuting purposes engaged in an additional 320.9 and 279.4 minutes of self-reported PA per week respectively compared to individuals who travelled solely by motorised transportation (113). Following this with longitudinal analyses, Sahlqvist and colleagues (114) reported that a change in AT was associated with a change in total PA in the same direction. In addition, an increase in AT was not associated with a greater decrease in recreational PA compared to individuals whose AT decreased or remained the same. These findings are supported by research by Foley and colleagues (115) and suggest that individuals who increase their AT behaviour do not compensate with a decrease in recreational PA.

Analysis of data from Sport England's Active People Survey revealed that individuals who self-reported cycling for transport were four times more likely to meet the PA guidelines than those who did not cycle for transport (adjustedOR[95%CI], 4.08[3.88, 4.39]) (116). While data from the Health Survey for England revealed that walking made a significant contribution to meeting PA guidelines across all age-groups (range: 26 to 45%) (117). Therefore, promoting the substitution of motorised travel for AT presents a low-cost, time-efficient method of increasing PA behaviour.

1.3.3 AT and health

Beyond an increase in PA, engagement with AT is associated with health benefits. A meta-analysis of 21 cohort studies (14 for walking and 7 for cycling) reported that engaging in 11.25 MET hours per week of cycling or walking (i.e., 150 minutes of MVPA per week estimated at 4.5METs per minute) was associated with a reduced risk of ACM by 10% (95%CI, 6, 13%) and 11% (95%CI, 4, 17%) respectively (229). This relationship held after adjusting for leisure time PA suggesting that the beneficial effects of AT are independent of engagement in other forms of PA.

Specifically exploring commuting, analyses of data from the UK Biobank cohort (26,3540 participants) found that retrospective self-reported cycle commuting was associated with a significantly lower risk of ACM (HR[95%CI], 0.59[0.42, 0.83]), CVD incidence (HR[95% CI], 0.54[0.33, 0.88]) and mortality (HR[95% CI], 0.48[0.25, 0.92]) and cancer incidence (HR[95% CI], 0.55[0.44, 0.69]) and mortality (HR[95% CI], 0.60[0.40, 0.90]) compared with non-active commuting (118). Walk commuting was associated with a significant reduction in CVD incidence (HR[95%CI], 0.73[0.54, 0.99]) and mortality (HR[95%CI], 0.64[0.45, 0.91]) compared to non-active commuting. However, the UK Biobank sample are healthier than the general population and, with a short length of follow-up data available (median: 5 years), a low number of events were recorded (118, 119). Using linked census data from 1991 and 2011 Patterson and colleagues (120) reported that cycle commuting was associated with a reduced rate of ACM (HR[95%CI], 0.80[0.73, 0.89]), CVD mortality (HR[95%CI] 0.76 [0.61, 0.93]), cancer mortality (HR[95% CI] 0.84[0.73, 0.98]) and incident cancer (HR[95%CI] 0.89[0.82, 0.97]) compared to commuting by private motorised vehicle. While walk commuting was associated with a 7% reduced rate of cancer incidence (HR[95%CI] 0.93[0.89, 0.97]). However, this study was unable to control for a range of potentially confounding variables including recreational PA, smoking, dietary intake, and adiposity. A 2019 meta-analysis of 23 prospective studies (531,333 participants) reported that individuals who engaged in active commuting had significantly lower risk of ACM (RR[95%CI] 0.92[0.85, 0.98]), CVD incidence (RR[95%CI] 0.91[0.83, 0.99]) and T2DM (RR[95% CI] 0.70[0.61, 0.80] than those who did not actively commute. However, there was no association between active commuting and CVD mortality and cancer. Subgroup analysis revealed that cycle commuters had a significantly lower risk of ACM, CVD incidence, cancer mortality and T2DM compared to walkers (121). Collectively these findings suggest that cycle commuting may be associated with greater health benefits than walking. This is potentially due to the higher energy expenditure per unit of time than walking with potentially greater impacts on fitness (122).

In addition to direct impact of AT on morbidity and mortality, both walking and cycling for transport have been longitudinally associated with benefits on intermediate risk factors including cardiorespiratory fitness, blood pressure, body composition and weight management (123-126). Cycle commuting has been shown to be associated with improved mental wellbeing compared to those who do not cycle commute (127). Furthermore, shifting from inactive to active commuting to work has been associated with less severe depressive symptoms at follow-up than those who remained inactive (128).

Despite the positive health benefits associated with AT there is a risk of injury and exposure to pollution (129). However, a health impact assessment of AT concluded that the benefits of shifting from passive to active modes of transportation outweighed the detrimental effects from air pollution exposure and traffic incidents (130). In addition, 50% of all health benefits experienced through shifting from passive to active transportation were a result of increased PA, in place of the sedentary activity associated with passive transportation. Furthermore, the benefit-to-harm ratio increases with age as the risk of disease increases (131).

1.3.4 Environmental impact of AT

Investing in AT has the potential to reduce carbon emissions and traffic congestion through reduction in use of motorised vehicles (132, 133). Several studies have sought to estimate the potential emission reductions due to AT through generating scenarios in which a specific percentage of journeys are substituted by active means (133-137). For example, a health impact assessment of six European cities found that increasing cycling to 35% and walking to 50% among commuters would lead to reductions in carbon dioxide (CO_2) emissions of between 1,139 to 26,463 metric tonnes per year (133). In the UK, Woodcock and colleagues (134) estimated that if the percentage of the English population who regularly cycling increased from 5 to 25% there would be a reduction in CO_2 emissions of 2.2% per person per week.

Analyses of longitudinal data from seven European cities found that engaging in more cycling and walking at follow-up was associated with a reduction in mobility-related CO_2 emissions (138). The authors stated that if the average person engaged in one cycling trip per day and drove one less trip per day for 200 days of the year there would be a decrease in transport-related CO_2 emissions of approximately 0.5 tonnes per person over the year. Given that the average CO_2 emissions from transport (excluding shipping and aviation) was 1.8 to 2.7 tonnes of CO_2 per person per year in the included cities this represents a sizeable decrease in emissions. Collectively, both scenario/modelling research and empirical data suggest that AT can reduce transport-related CO_2 emissions.

1.3.5 Engagement in AT

Despite widespread endorsement of AT as a practicable method through which to incorporate PA into daily life, rates of engagement in AT in the UK and around the world are low (139-141). In Scotland in 2019, 22% of all journeys were made on foot and 1.2% by bicycle (142) while in England in the same year, 26% of all trips were made by walking and 2% by cycling, accounting for 4% of all distance travelled (84). In England, an average of 250 walking trips were made per person, per year with an average duration of 17-minutes. While for cycling, 16 trips were made per person per year on average, with an average duration of 23-minutes (139). In comparison in the Netherlands, men and women achieved an average of 24-minutes and 28-minutes of PA per day, respectively, from transport related walking and cycling (143).

Regarding commuting, 15% of individuals surveyed in England in 2019 reported walking (11%) or cycling (4%) to work (139). Similarly in Scotland, 12% of individuals walked and 3% cycled to work in 2019 (142). Census data from England and Wales revealed little change in active commuting between 1991 to 2011 (144). Equally, data from the NTS reveals little change in overall AT since 2002 (139).

It is important to note that the COVID-19 pandemic, and enforced social distancing measures in over 100 countries, has had a significant impact on global travel behaviour. The impact of COVID-19 on PA and AT will be discussed in detail in Chapter 9.

1.3.6 Interventions to increase AT through cycling

As previously reported, AT through cycling has the potential to impact health to a greater extent than walking, however, rates of engagement in cycling are significantly lower than for walking. There are many individual, social and environmental barriers that impact cycling engagement including physical constraints associated with hilly terrain, distance to the destination and lack of infrastructure as well as poor physical fitness and lack of time (145, 146). An extensive discussion of the range of determinants of cycling has been provided elsewhere (147, 148). To address barriers to engagement, interventions to increase cycling can be targeted at multiple levels (149). Aligning closely with the social-ecological framework (80) onto which the determinants of cycling engagement can be mapped, the levels at which interventions are targeted have been classified as:

1. Individual (i.e., targeting individual psychological and biological factors)
2. Social (i.e., targeting community, cultural, family or group factors)
3. Physical Environment (i.e., making changes to infrastructure or access to facilities)
4. Policy (i.e., funding, national strategies, or legislation to make changes) (149)

Policy level initiatives are the least developed area of understanding (149). The introduction of low traffic neighbourhoods has been associated with increases in AT (150) while the evidence regarding the impact of the introduction of national 20mph zone is mixed (151). A review of policy to promote cycling reported that AT related policy acts at various levels of the socio-ecological framework and are more likely to be effective when implemented as packages across different levels (152). More data collection and monitoring of policy related initiatives is required.

There is a consistent body of longitudinal evidence that altering the physical environment at the macro level (i.e., making changes to infrastructure including provision of cycling infrastructure or pedestrianisation of streets) is effective at increasing AT, including cycling (153-156). Furthermore, there is growing evidence that micro-physical environmental changes (i.e., showering facilities and installing bike parking) can increase cycling (149, 157). However, while interventions focused on the physical environment are important, they are not sufficient to boost cycling alone due to a range of individual and societal barriers to riding (158, 159).

Evidence of the impact of individual and social interventions on cycling is less developed (149). Workplace interventions such as one-off cycling events, workplace challenges and workplace transport planning report conflicting results (149, 155, 158). In the community, bicycle skills training in adults has been found to lead to increases in cycling behaviour, however large differences in their effectiveness have been reported between studies (160). Individual level interventions have focused on developing personalised travel plans, education campaigns and financial incentives. The creation of personalised travel plans has been found to lead to modest but consistent increases in AT (155, 161). There is little evidence that education and awareness campaigns are effective at increasing AT by themselves (149, 162) and the findings relating to the impact of financial incentives to engage in cycling are mixed (149). It is important to note that many individual interventions involve accompanying social and physical environment actions (149), and therefore it is difficult to establish the impact of these interventions in isolation. Furthermore, evaluation of the effectiveness of individual and social level cycling interventions has been poor with a recent review highlighting that there is currently 'little robust evidence' of what works to increase cycling in low cycling nations, such as the UK (158). As such, more controlled trials are needed to determine what works at the individual and social levels to increase cycling. Furthermore, many studies fail to report in depth information on the context and implementation of interventions (155, 160). Detailed information on intervention design, content and delivery are required to be able to fully evaluate such trials. Kelly and colleagues (163) provide an overview of individual and social level actions that are feasible for use in initiatives to increase cycling and can be used to inform intervention design.

Given the limited success of current individual and social level interventions to increase cycling and the numerous barriers to engaging in cycling it is important to identify novel methods of encouraging novice exercisers to engage in AT that is enjoyable and can encourage long-term adherence. This is particularly important among adults with chronic disease who engage in less PA than their healthy counterparts (164), but for whom PA engagement is an essential part of disease treatment and/or management (165).

1.4 The potential of e-bikes to increase PA

E-bikes are one of the fastest growing sectors of the transport industry (166). Commercially available e-bikes originated in Japan in the 1980's but became increasingly popular in the early 2000s with technological advances in the batteries and motors and reduced weight of the bikes (167). There are a wide variety of e-bikes available on the market which differ based on maximum speed and the main method of control (i.e., throttle control or pedal assistance) (166). In China, the predominant style of e-bike is a scooter style bike which uses a throttle to provide power and does not require pedalling. Pedals are present at the point of sale for regulatory purposes and are often removed by the consumer. In Europe, North America and Australia the term e-bike predominantly refers to a bicycle that has an electric motor but requires pedalling for assistance to be provided (166). These pedal assisted e-bikes are sometimes referred to as pedelecs. The electrical assistance is provided by the motor when sensors detect pedalling speed and force. Pedal assisted e-bikes are legally classified as bicycles in most countries with motors ranging from 250 to 750 Watts and top speeds of between 25 to 32km/hr (166). In Europe and the UK, the maximum power output for an e-bike is 250 Watts and a top speed of 25km/hr. It is these bicycles that require human power through pedalling but provide electrical assistance that are the focus of this thesis.

In recent years e-bike use in European countries has increased substantially for both leisure and active commuting (166, 168). However, despite the increase in popularity, e-bike related research is only just beginning and there is currently a lack of epidemiological research exploring the impact of e-cycling on health and behaviour.

1.4.1 E-bikes, PA, and health

Emerging research suggests that e-cycling is associated with increases in PA. In Norway, Sundfør and Fyhri (169) reported an increase of 353.5 minutes of self-reported PA per week following the provision of an e-bike, while in the UK, the provision of an e-bike led to a perceived increase in PA (170). As such, e-bikes have been highlighted as a potential alternative to the traditional AT modes of walking and cycling as a means of increasing PA. However, little is known about the intensity of activity elicited through e-cycling or additional health outcomes associated with this activity. A recent feasibility study in adults with T2DM found that the provision of an e-bike for five months was associated with an self-reported riding of approximately 21km per week and an increase in maximum power output of 10% (171). Furthermore, e-cycling elicited an average Hr of 75% of maximum during riding equating to MPA and was perceived as enjoyable, with 14 out of 18 participants purchasing an e-bike at the end of the study. This study highlights the acceptability and potential utility of e-bikes in this clinical population which requires further examination given their high rates of physical inactivity (172, 173).

1.4.2 How and why e-bikes are used

While the evidence suggests that e-cycling may lead to increases in PA, how e-bikes are used (i.e., for recreational activity or AT) and the reasons for their use (i.e., the determinants) are less clear. While the determinants of engagement in walking and cycling as a means of AT are similar, the extent to which these factors influence behaviour varies between modes (148). As such, it is reasonable to assume that the determinants of e-cycling differ in existence or weight to conventional cycling due to the electrical assistance provided.

Retrospective surveys with e-bike owners suggest that e-bikes may overcome several barriers to conventional cycling including overcoming topographical obstacles, reducing travel time, the ability to carry a heavy load and allowing those with reduced physical fitness to cycle (174, 175). As such, the provision of electrical assistance has the potential to increase the diversity of people cycling and warrants further investigation.

Regarding the purpose of e-bike use, survey data suggests that 52.2% of older adults (55+years) used an e-bike for recreational purposes while 45.9% of younger adults (<55years) used an e-bike for commuting (175). While these retrospective surveys give us some insight into how e-bikes are generally used by different populations little is known about how e-bikes are used in daily life and whether access to or ownership of an e-bike is associated with changes in AT or recreational activity. For those that engage in e-cycling for recreation, it is important to ascertain whether use of an e-bike replaces alternative, potentially more active forms of PA or if it replaces sedentary activities. Similarly, regarding AT it is important to determine whether e-cycling replaces motorised transportation, a sedentary activity, or physically active transport modes such as conventional cycling. If e-bikes serve to replace motorised transportation this could impact not only individual health but also have positive environmental outcomes through a reduction in traffic and carbon emissions.

1.4.3 E-bikes and safety

Early research suggested that e-cycling led to more traffic incidents, of greater injury severity, than conventional cycling (176, 177). Specifically, collation of emergency department (ED) injury treatment data from 13 Dutch hospitals found that e-bikes users were more likely to be involved in a crash that required ED treatment than conventional bike users after controlling for age, gender and cycling frequency (176). A 2018 replication of this study (178) reported similar findings with the odds of being treated in the ED following a crash being greater among e-bike users than conventional bike users (OR[95%CI] 1.24[1.03, 1.48]). However, when additionally controlling for distance travelled per year by bicycle (i.e., the amount of exposure to risk) the difference in ED treatment between the two bike types was minimal (OR[95%CI] 1.01[0.83, 1.22]). Similarly, in a survey of Norwegian cyclists, no differences in crash severity between e-bike and conventional bike users was found after controlling for exposure (179).

Regarding incident risk, after controlling for exposure e-bike users were no more frequently involved in incidents than conventional bike users (178, 179). However, female e-cyclists were more likely to be involved in a crash (179) and sustain more serious injuries (180) than men. Increased incident risk among females has been attributed to lack of familiarity with the bicycle (179), which may disproportionally affect e-bike statistics given that e-cycling attracts novice users to cycling, particularly women (181). Notably, while e-bike users are generally older, report more chronic disease, medication use and have a higher body mass index (BMI) than conventional bike users, these factors are not associated with increased accident risk or severity (179, 180, 182, 183). As such, e-cycling appears to be an appropriate method of increasing PA in older adults and those in poor health with no differences in incident risk and crash severity compared to a conventional bicycle.

1.5 Conclusion

Engaging in PA is essential for physical and mental health. However, rates of engagement are low, and it is now believed that weaving PA into everyday life is necessary to increase engagement. AT represents one method through which to build PA into everyday life and is associated with numerous health benefits. However, rates of engagement in AT, particularly cycling, are low and it is unclear how best to intervene to increase this behaviour. Common barriers to cycling include lack of fitness, topographical constraints, and the distance to travel. E-bikes are becoming an increasingly popular form of personal travel that have the potential to overcome barriers to conventional cycling and positively impact levels of PA. However, research into the potential health benefits of e-cycling is only just beginning and there is a need to synthesise the current evidence pertaining to the role of e-bikes in relation to individual health outcomes. Furthermore, research exploring the ability of e-cycling to increase PA and positively impact health in clinical populations is needed as these individuals are less physically active than their healthy counterparts and are less likely to engage in AT. To date few studies have investigated the potential utility of e-bikes to improve health in clinical groups.

In addition, it is important to ascertain how and why e-bikes are used in daily life and their impact on other behaviours, for example, whether using e-bikes replaces previously sedentary (e.g., driving) or active (e.g., walking, conventional cycling) activities. This information will contribute to the evidence base for the role of e-cycling in health promotion.

1.6 Thesis aims and objectives

The overall aim of this PhD is to **explore the use of e-bikes in improving health through increased PA.** Based on this aim the following three thesis objectives were developed:

1. Investigate whether e-cycling is associated with an intensity of PA consistent with the development of improved health outcomes in adults.
2. Explore how and why people use e-bikes and the impact of e-bike use on changing travel behaviour.
3. Utilise e-bikes in an intervention aimed at increasing PA in adults with T2DM to explore the feasibility of conducting a randomized trial and examine the association between the intervention and a range of clinical, physiological, and behavioural outcomes.

2 Chapter 2: PhD guiding framework, studies and methods

Chapter 2 outlines the guiding framework for this PhD, the rationale for using this framework, and provides an overview of how it is applied to the thesis to address the objectives. An overview of the studies conducted, methods chosen and rationale for them is provided.

2.1 Complex health interventions

Many diseases can be prevented, or progression slowed, through the modification of behavioural risk factors (184). As such, these factors have been the focus of many public health initiatives. As highlighted in Chapter 1, physical inactivity is a commonly targeted behavioural risk factor owing to the extensive body of evidence of the multiple health benefits of regular PA (185-189). With little change in the global prevalence of physical inactivity over the past 20-years there is an urgent need to find innovative ways to tackle the physical inactivity pandemic. Physical inactivity is a complex issue (190) and as such, interventions designed to tackle physical inactivity can be considered complex (191, 192). This is in comparison to pharmacological interventions which have simpler causal pathways often not requiring individual behaviour change (193).

There is no clear boundary that separates simple and complex interventions. Important factors to consider when determining whether an intervention should be classified as complex include: the number of interacting components, the number and difficulty of behaviours to be targeted by the intervention, the groups, or levels of an organisation towards which the intervention is directed, the number and variability of outcomes and the degree of tailoring permitted (193). PA interventions can be targeted at different levels of society (i.e., the individual, the community or the population) all of which may be influenced by a range of factors within the society including the individuals, communities, resources, environment, infrastructure and economy (59, 61, 190). As such, PA interventions cannot be expected to work in isolation from other influences, and it is important to understand the factors that interact with the intervention to impact effectiveness. Therefore, interventions wanting to change behaviour need to go beyond the gold standard randomized controlled trial (RCT) for assessing intervention effectiveness to understand *how, when, why* and in what *contexts* the intervention is effective. As such, understanding the target behaviour and factors that influence it is essential for intervention development and evaluation (193, 194). With the complexity of health behaviour interventions, including PA, widely accepted specific guidance has been created to help guide the development and evaluation of such interventions.

2.2 UK Medical Research Council framework

The UK Medical Research Council (MRC) published influential guidance on the processes involved in carefully developing and evaluating complex interventions. Since its publication in 2000 the framework has been updated in 2008, with further guidance anticipated in spring 2021 to address a need for greater clarity on how to practically apply the framework (195-197).

The 2008 framework outlines four important components in the development and evaluation of an intervention: 1) development, 2) feasibility and piloting, 3) evaluation and 4) implementation (Figure 2.1). While the process is believed to move systematically in a clockwise direction around figure 2.1, in reality researchers move back and forth between components and certain activities may be constrained by factors outside of the researchers control including political and/or financial issues.

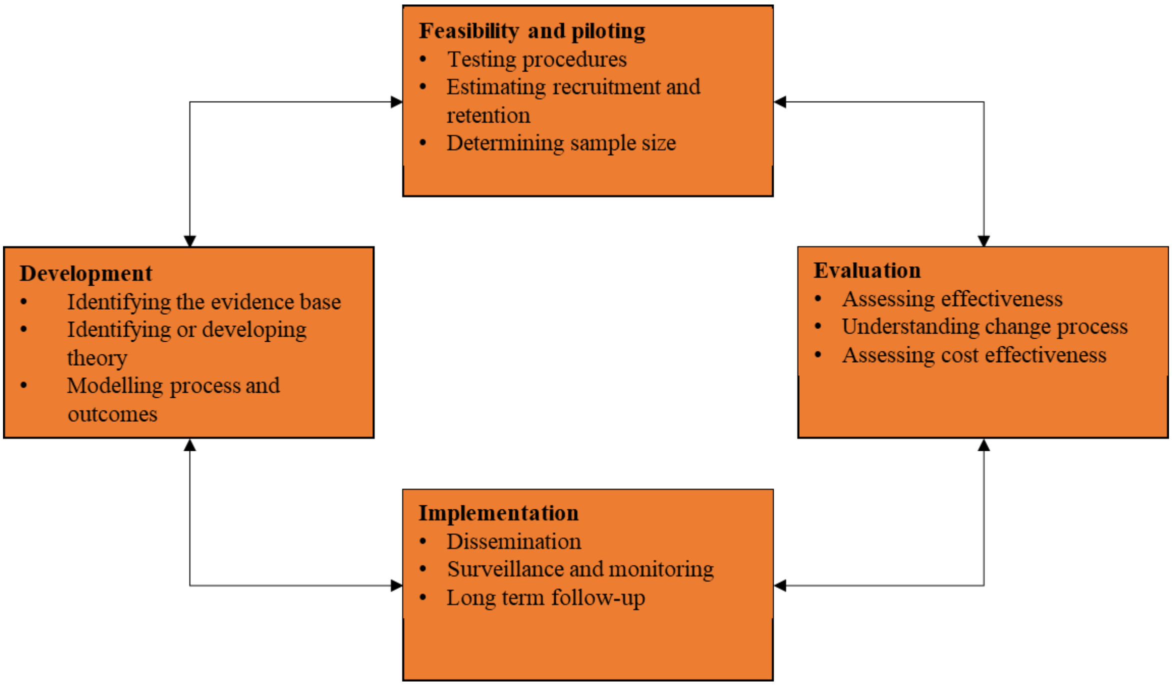

Figure 2.1 MRC Framework for developing and evaluating complex interventions, Reproduced from Craig et al (193)

The *development* component emphasises the importance of designing interventions using the best available evidence and appropriate theory. Craig and colleagues (193) highlight that *'the intervention must be developed to the point where it can reasonably be expected to have a worthwhile effect'* (p9). Prior to conventional intervention development, preparatory work should be conducted to identify the current evidence that can provide insight as to whether the potential intervention may have a worthwhile effect on the outcome of interest. If no such work exists, systematic reviews of the literature should be conducted to collate the evidence (193). In addition, where possible the theoretical processes through which the intervention is likely to impact the outcomes of interest should be examined through existing evidence and theory. This will help maximise the chances of intervention effectiveness.

Following development, interventions should undergo *feasibility and piloting* prior to full scale evaluation. This enables the researcher to address key uncertainties pertaining to intervention delivery, testing procedures, recruitment strategies, recruitment numbers and participant retention. Feasibility testing can also be used to gain insight into contextual factors that impact intervention effectiveness which may not have been previously considered (198). Following this, researchers must decide whether to a) return to the development stage to refine the intervention before more feasibility testing, b) proceed to the *evaluation* phase and conduct a fully powered trial to examine effectiveness or c) conclude that the intervention does not warrant further evaluation (191, 198). As such, feasibility testing is a valuable activity that can help reduce costs associated with carrying out large trials which may be unsuccessful due to ineffective recruitment strategies, poor retention and/or intervention implementation issues (199).

Developing interventions in this systematic and transparent way enables researchers to examine *if* an intervention is effective but also the underlying *how, when* and *why* processes that may explain intervention success or failure. This includes assessments of the causal mechanisms of change, intervention implementation and identification of contextual factors that may impact the outcomes. Evaluation of the processes through which an intervention impacts the outcomes provides insight into necessary refinements and the potential for implementation at scale (200). This information will inform the development of a comprehensive *implementation* strategy to ensure the research findings are disseminated widely, increasing the likelihood of translating evidence into practice, if appropriate.

2.3 Application of the MRC framework to this PhD

The exploration of e-cycling as a public health strategy is a new area of research. Utilising the MRC framework components of *development* and *feasibility and piloting* provides a systematic approach to exploring the potential of e-cycling as an effective PA intervention and will help address the objectives of this thesis. If deemed appropriate, the results of this work can be used to refine an e-cycling intervention and trial design for use in a fully powered RCT evaluating intervention effectiveness and guide a comprehensive process evaluation. Figure 2.2 outlines how the three studies of this thesis map onto the MRC framework.

2.3.1 Study one

As research exploring the intensity of PA associated with e-cycling and its impact on health begins to grow there is a need to synthesise this evidence. Synthesising this literature will give a clearer understanding of the current evidence pertaining to e-cycling and health and identify whether the development of an e-cycling intervention is likely to positively impact health outcomes. Study one, therefore, comprises a systematic review of all current evidence that has been conducted to explore the intensity of PA associated with e-cycling and assess the impact of e-cycling on health outcomes. Experimental and observational research is collated, and the quality of the evidence evaluated. Study one addresses the first objective of this thesis.

A systematic review is the most appropriate review typology given the specific focus on health outcomes and the desire to collate and critically appraise the evidence (201, 202). A systematic review utilises detailed, transparent, and reproducible methods to draw conclusions from the best available evidence. The standardised appraisal of study quality allows for consistent comparisons across the literature and an objective judgement to be made about the level of confidence in the review findings. This can help guide future research to address methodological and quality concerns. As such, the findings of this review provide insight into whether there is sufficient evidence, of appropriate quality, to warrant the development of an e-cycling intervention and what additional evidence is required to address current gaps in the literature.

2.3.2 Study two

In addition to establishing the potential health benefits to be gained from e-cycling it is essential to establish if individuals engage in e-cycling when they have access to an e-bike and to understand how and why individuals chose to engage, or not, in e-cycling. Understanding the behaviour and identifying potential causal mechanisms of change is necessary preparatory work which can be used to inform future interventions (194, 203). In the context of the promotion of e-cycling as a means of increasing PA, understanding the impact of e-cycling on other transportation use is important to ascertain whether e-cycling substitutes for passive or active modes of transport. This knowledge will determine whether the promotion of e-cycling is a worthwhile endeavour with the potential to reduce sedentary transportation or whether individuals shift from one mode of active transport to another.

Study two comprises a scoping review to collate the current evidence examining how and why e-bikes are used and their impact of travel behaviour. This will directly address objective two of this thesis. Given the novelty and rapid growth of research in this area, a scoping review is the most appropriate method of collating the literature. While there is no agreed upon definition of a scoping review (204), this method is characterised by its ability to provide a comprehensive overview of a broad topic through systematically collating a diverse range of literature, often with different study methods (205). The breadth and flexibility provided with scoping reviews is less feasible with traditional systematic reviews and meta-analyses which comprise more narrowly focused research objectives (204, 206). The end product consists of an overview of the extent, nature and range of the current research from which gaps in the literature are identified and future research recommendations are made (205). Scoping reviews have become increasingly popular since 2000 and have been used in a wide range of health disciplines (207).

Collectively, studies one and two provide guidance as to whether the promotion of e-cycling is a meaningful and viable pursuit through greater understanding of their impact on PA, health, and travel behaviour. Identification of factors associated with e-bike use will guide the design of an e-cycling intervention to increase the likelihood of effectiveness. These studies will form the evidence base on which the value of developing an e-cycling intervention to promote PA will be determined.

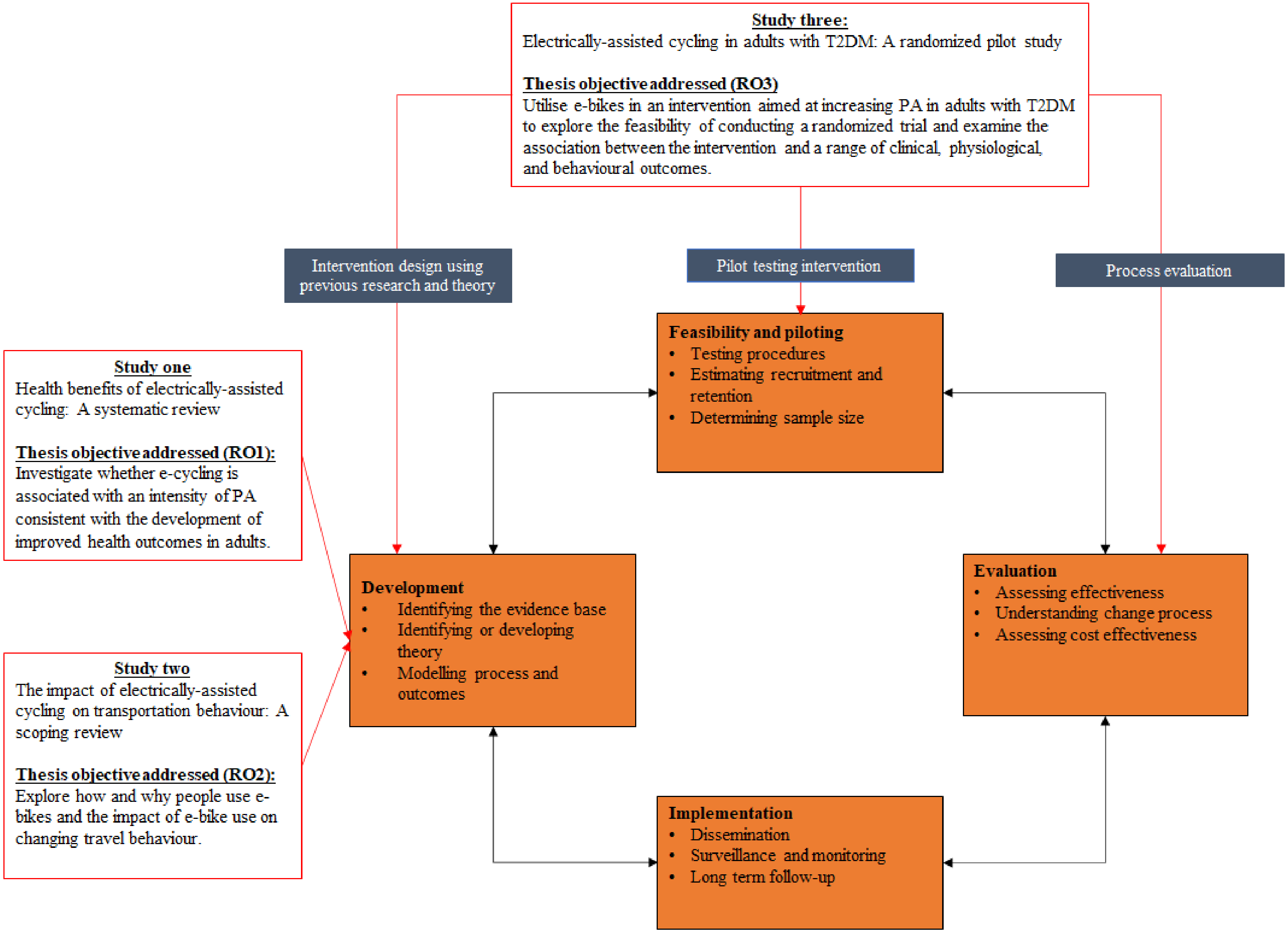

Figure 2.2 The application of the MRC framework as a guide to this PhD thesis

2.3.3 Study three

Drawing on method limitations identified in study one and the research gaps identified in study two, study three consists of the *development*, *testing* and *process evaluation* of an e-cycling intervention for individuals with T2DM. This population have previously been identified as being highly receptive to e-cycling, with some potential health benefits (171). However, work is needed to systematically refine and detail an e-cycling intervention based on this previous research and factors identified as impacting e-bike use. Systematic intervention development provides an explicit report of the mechanisms targeted within the intervention and how they are targeted enabling in depth evaluation in the future (193, 198). Following this, the potential impact of the intervention and factors that may influence its effectiveness are explored through pilot testing as encouraged by the MRC guidance. This piloting addresses a range of uncertainties associated with conducting a large-scale trial and examines the potential impact of the intervention on PA, health outcomes and travel behaviour. Therefore, study three directly assesses objective three of the thesis. The process and rationale of intervention development, piloting, and evaluation of study three are described in more detail below.

2.3.3.1 Intervention design

To design an effective intervention, it is important to understand the potential mechanisms that impact the target populations decision to engage in the desired behaviour (196, 198). This can be achieved through qualitative examination (196). As part of their feasibility work Cooper and colleagues (171) conducted qualitative interviews with 18 individuals with T2DM immediately following and six months after a 20-week e-bike loan. These interviews were analysed with the aim of identify the barriers and enablers to e-cycling. This behavioural analysis was guided by the Theoretical Domains Framework (TDF) (208) and the Behaviour Change Wheel (203), enabling the identification of the most appropriate methods through which to intervene (i.e., education, training, environmental restructuring) and selection of specific behaviour change techniques (BCTs) for inclusion in the intervention. This theory driven approach to intervention development provided a systematic method of designing and detailing the current intervention. This information can be used to interpret findings of effectiveness by exploring how and why the intervention was or was not successful (193, 194, 198, 209).

2.3.3.2 Use of theory in intervention design and evaluation

Researchers have proposed several benefits of using behavioural theory in intervention design and evaluation (193, 194, 198, 209, 210). However, systematic reviews exploring the impact of using behavioural theory in intervention development on PA intervention effectiveness report comparable effects between interventions that have an explicit theoretical underpinning and those that do not (211-214). While this may lead some to conclude that theory is not necessary when designing PA interventions, there are several explanations for these findings.

Firstly, numerous theoretical frameworks have been developed and used in intervention development and it is unlikely that a single theory captures the wealth of potential determinants of behaviour change. (210, 215, 216). Therefore, a selected theory may omit key determinants influencing the behaviour of interest. Secondly, the use of theory is commonly poorly applied and reported making it hard to determine the theoretical constructs targeted (211, 216-218). Thirdly, atheoretical interventions, to which theoretically developed interventions are compared, are not nonsensible interventions. Specifically, atheoretical interventions will use specific strategies that the developers believe will be effective at changing behaviour. As such, interventions developed without theory are likely to incorporate some specific BCTs that could be considered akin to the use of theory and classification based on explicit use of theory may obscure the effects of the types of intervention. More recently researchers have sought to classify the content of interventions to determine which BCTs are associated with positive change and identify the processes through which this change occurs (209, 214, 219). Therefore, it is recommended that complex interventions be developed based on a theoretical understanding of the target behaviour and influencing factors from which appropriate BCTs are selected and can then be evaluated (194, 198, 209, 218). This approach was taken in the development of the current intervention.

2.3.3.3 Feasibility and pilot testing

Following intervention development, the MRC framework encourages the use of pilot and feasibility studies prior to full scale evaluation. However, the two terms are not clearly distinguished from one another in the guidance, with the authors stating that pilot testing *'need not be a 'scale model' of the planned main stage evaluation'*, p3 (193). In contrast, NIHR published definitions suggest that the two are mutually exclusive with pilot studies defined as *'a smaller version of the main study used to test whether the components of the main study can all work together'* and feasibility studies commonly preceding pilot studies to explore aspects of uncertainty which could impact a trial (220). These differences of definition led to confusion in guidance as to the appropriate research to be conducted prior to a full-scale trial as well as for the reporting of trials (221, 222). To address this, Eldridge and colleagues (221) developed a conceptual framework for defining pilot and feasibility studies which is now widely applied to the design and reporting of such trials. Based on expert consensus and validation from a systematic review, the authors specified that feasibility studies represent any study that assesses whether a future study can be done. As such, pilot studies represent a specific type of feasibility study designed to assess if a study protocol can be conducted. Pilot studies can be either randomized (a smaller scale version of the future trial is conducted to determine if it can be done) or non-randomized (the study is conducted as it would be in a future trial without the randomization of participants). Feasibility studies, that are not pilot studies, involve the exploration of specific questions related to a specific element of a future trial. As such, the intervention or certain study procedures may not be implemented or evaluated. The current trial used a randomized pilot study design.

2.3.3.4 Rationale for carrying out a randomized pilot feasibility study

Pilot testing, prior to conducting a large trial, enables the researcher to explore trial uncertainties including a) the appropriateness or ability to conduct testing procedures, recruitment strategies, recruitment numbers and participant retention throughout the study and/or b) intervention implementation and acceptability. Pilot study results can be used to determine the appropriateness of conducting a fully powered trial and associated evaluation and allows the researcher to make changes to the study procedures and/or intervention ahead of the large-scale trial. As such, pilot studies can help reduce costs associated with carrying out large trials which may be unsuccessful due to implementation issues or ineffective recruitment strategies and/or poor retention (199). In addition, pilot testing can assist researchers in identifying the primary outcome for a future trial and provide data to determine the appropriate sample size to detect an effect on the primary outcome. Randomized pilot studies are appropriate when an intervention has been found to demonstrate promise, through preliminary feasibility work, but where there is insufficient evidence to support a full-scale RCT. Previous work conducted by Cooper and colleagues (171) demonstrated that individuals with T2DM rode e-bikes and reported some positive health benefits. This warrants further investigation into the potential of e-cycling as a means of increasing PA in this population. However, there is considerable uncertainty surrounding the ability to conduct a large-scale randomized e-cycling trial in this population, and which outcome measures are appropriate for inclusion. Therefore, a randomized controlled pilot feasibility study is the appropriate next step to explore uncertainties pertaining to recruitment, retention, study procedures, identification of appropriate outcomes measures and sample size for use in a future fully powered RCT.

2.3.3.5 Process evaluation

As part of the feasibility and piloting phase, the MRC guidance encourages the researcher to conduct a process evaluation (193, 198). Process evaluations are designed to evaluate the processes through which an intervention may or may not be effective. This includes examination of intervention implementation, understanding the process through which the intervention impacts the behaviour (i.e., the causal pathways) and examining the contextual factors that affect the intervention (198). At the feasibility stage, Moore and colleagues suggest that the process evaluation focuses on establishing the feasibility and acceptability of delivering the intervention as planned (198). This can be achieved through a combination of quantitative measures of intervention implementation and qualitative measures to identify factors impacting intervention implementation that can be used to refine future iterations (193, 198). The use of qualitative research in general, as part of the feasibility testing phase enables researchers to interpret their findings and identify intervention or design improvements for future trials (223).

The current trial gathers quantitative data on intervention dose (the quantity of intervention implemented), fidelity (whether the intervention was delivered as intended) and adaptations made. Qualitative interviews with participants and instructors are conducted to provide information on the acceptability of intervention delivery (instructors) and content (participants and instructors). While qualitative information regarding the trial procedures is collected to provide insight into the quantitative data obtained.

While no formal quantitative examination of causal mechanisms or the influence of contextual factors is required as part of a feasibility study, qualitative research can be used to examine potential mechanisms of impact and contextual factors which impact the intervention (198). This can help to develop hypothesis about which determinants and contextual factors are most influential on e-cycling behaviour and guide the selection of quantitative measures to examine potential mediating or moderating effects (224). One-to-one interviews are conducted with participants in the current trial to examine enablers and barriers to e-cycling in this population.

2.4 Study presentation in this thesis

Studies one (Chapter 3) and two (Chapter 4) are presented as per manuscripts that have been published. Where changes to the original manuscripts have been made that promote understanding these have been made explicit. Study three is separated into four chapters; Chapter 5 provides a review of the literature of community-based PA interventions for individuals with T2DM, the research questions proposed and a detailed description of the methods. Chapters 6 to 8 are presented as introduction, method, results, and discussion based on the research questions. Specifically, Chapter 6 reports on the feasibility of conducting an e-cycling trial in adults with T2DM. Chapter 7 reports on the association between the intervention and a range of clinical, physiological and behaviour outcomes to determine whether the intervention shows promise in these areas. Chapter 8 qualitatively examines the experiences of e-cycling with a focus on identifying the barriers and enablers to e-cycling. Chapter 9 provides an overall discussion of this research, discusses implications for practice and policy and identifies some key strengths and limitations.

2.5 Schematic of this thesis

Figure 2.3 provides an overview of the thesis. The schematic demonstrates how the thesis objectives were developed from the current literature and the gaps in the literature. How the studies address the research questions, the main findings and the way in which the preceding studies informed subsequent research is shown.

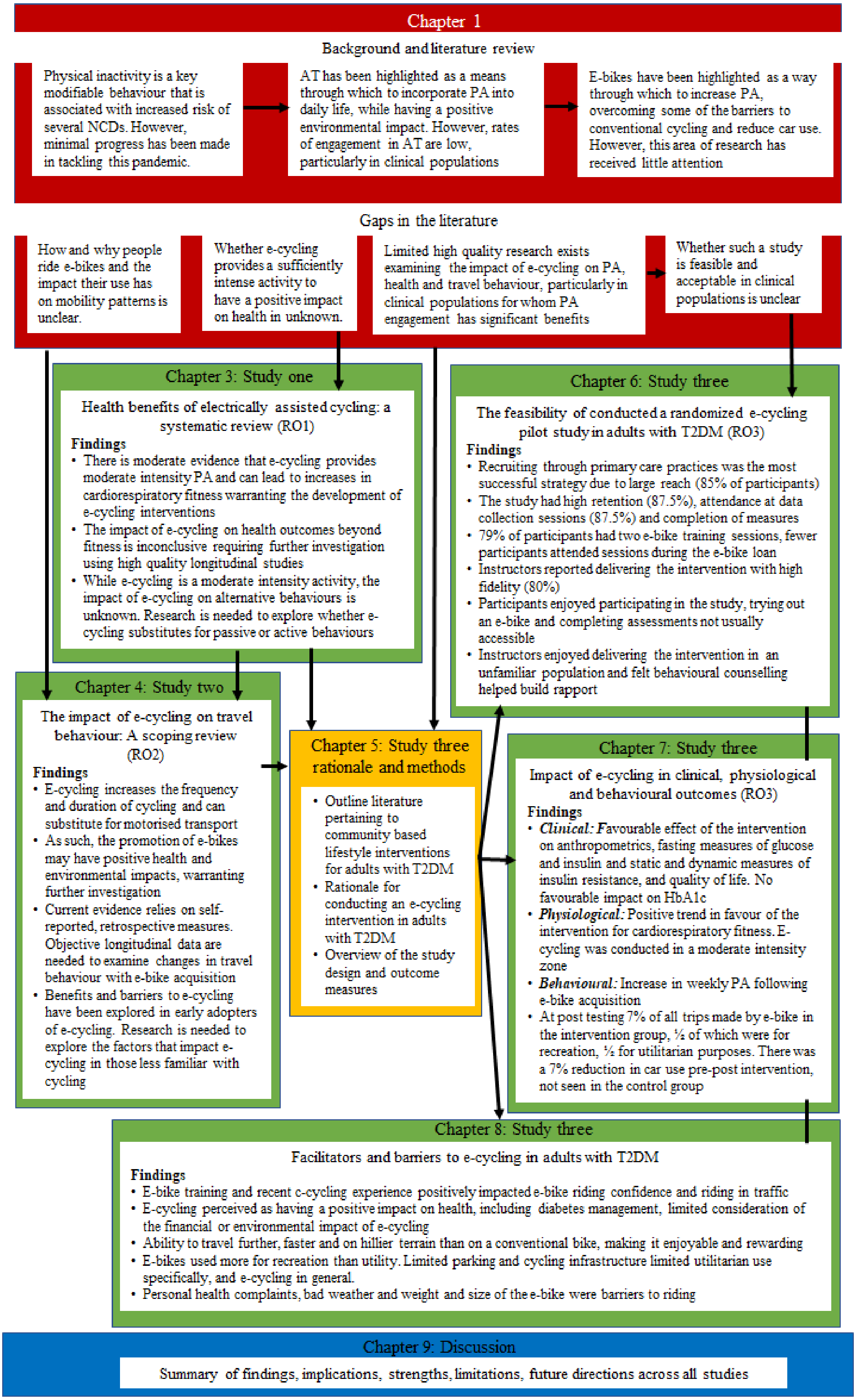

Figure 2.3 Schematic of the thesis
RO=research objective, T2DM=type 2 diabetes mellitus, PA=physical activity, NCD=non-communicable disease

3 Chapter 3. Health benefits of electrically assisted cycling: a systematic review

3.1 Overview

This chapter outlines study one, a systematic review of observational and experimental research assessing the intensity of activity associated with e-cycling and the impact of e-cycling on a range of health outcomes. Study one addresses the first objective of this thesis: to *investigate whether e-cycling is associated with an intensity of PA consistent with the development of improved health outcomes in adults.* The protocol for the review was registered on the PROSPERO database: Registration number CRD42018086544 (http://www.crd.york.ac.uk/prospero) and is provided in Appendix 3.1. The review was conducted in accordance with the protocol. The study is presented as a reproduction of the accepted version of the manuscript provided in Appendix 3.2, with more detailed rationale provided where appropriate. An explanation of how this research contributes to the overall thesis is discussed at the end of the chapter.

3.2 Introduction

Given the high rates of global physical inactivity (225) a growing body of research has focused on the potential of AT to increase PA behaviour and potentially lead to population health benefits. Engagement in AT, specifically commuting, has been shown to be predictive of a lower BMI (226) and reduced risk of diabetes diagnosis (227). A recent prospective study reported that active commuting, involving cycling, was associated with a lower risk of ACM and cancer incidence and mortality (118). In addition, commuting by bicycle or on foot was associated with a lower risk of CVD incidence and mortality (118). The greatest gains in health outcomes from active commuting are reported in the least active individuals (228, 229).

Travel is an essential part of everyday life for most people, and the adoption of AT represents an efficient way to increase daily PA. Falconer and colleagues (226) found that active commuting was associated with an additional 73 weekly minutes of MVPA in men and 105 weekly minutes in women with T2DM, compared to those commuting using motorised transport. With half of all car journeys in the UK being between one and five miles in length (230), the substitution of many car journeys by walking and/or cycling may be an achievable aim.

Due to a growing body of evidence, the UK NICE now endorse AT, with a particular focus on commuting, as a feasible method to incorporate PA into daily life (89). However, rates of active commuting are low (231). Common barriers to cycle commuting include the physical constraints associated with hilly terrain, poor physical fitness, lack of time and the distance to work (174).

E-bikes have been highlighted as an alternative method of AT that could overcome some of the commonly reported barriers to cycle commuting (166). The term e-bike includes a range of designs including throttle-controlled bikes which do not require the rider to pedal and electrically assisted bikes which provide electrical assistance only when the rider is pedalling (166). It is through pedalling that electrically assisted cycling may serve to increase PA. With lower motor power and maximum speeds compared to throttle-controlled e-bikes, e-bikes are legally classified as bicycles (166). For this review the term e-bike is used exclusively to refer to electrically assisted bicycles which require the rider to pedal.

In recent years e-bikes have become commonplace in European countries (166) with projected global sales of 47.6 million by the end of 2018 (232). E-bikes are increasingly used for both leisure and commuting purposes (168). The assistance provided has been reported to motivate novice cyclists and increase the likelihood that these individuals will continue to cycle in the future (174). Given the increasing interest in e-bikes, and their use for AT, there is a need to understand their potential to promote PA of a sufficient intensity to gain clinical benefit (i.e., moderate-to-vigorous intensity (233)) and to examine their impact on broader health outcomes. Such research is required to inform relevant health economic assessments and public health policy regarding the appropriateness of e-bike promotion. To date, no such review has been conducted. As such, the aim of this review is to collate and summarise the current evidence on the PA intensity and health outcomes associated with e-cycling. These aims will be achieved by answering the following research questions:

1. What is the intensity of PA associated with riding an e-bike?
2. Does the use of an e-bike lead to changes in health outcomes including cardiorespiratory, metabolic, or psychological outcomes?
3. Do physiological responses to riding an e-bike differ to those generated by other modes of active transportation (i.e., walking, and conventional cycling)?

3.3 Methods

A systematic review of the literature was conducted according to the guidelines outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (234).

3.3.1 Search strategy

The following databases were searched from their inception to November 2017: PsychINFO, MEDLINE and Embase (via Ovid), ISI Web of Science, CINAHL complete, SPORTDiscus and Scopus. Scopus and Web of Science search several databases while PsychINFO, MEDLINE, Embase, CINAHL complete and SPORTDiscus represent key medical and psychological databases. Search terms focused exclusively on the intervention component of the study to maintain search breadth. Thee search terms were *'pedelec', 'e-bike', 'electrically assisted bicycle', 'electrically assisted cycle', 'electrically assisted bike', 'pedal-assist', 'electric bicycle', 'electric bike', 'electric cycle', 'electric mobility'* (see Appendix 3.3 for example search strategy). Reference lists from all selected articles were hand-searched for relevant studies. Grey literature was searched to identify unpublished reports or papers to help reduce the potential impact of publication bias on results. Using overlapping search methods maximises the chances that relevant information is found (235). As such, OpenGrey and Google Scholar (first 20-pages) were searched using the term '*electrically-assisted bicycle'*. Hand-searching occurred until June 2018.

3.3.2 Inclusion criteria and selection process

Studies were eligible for inclusion if they met the following criteria:
1) participants: adults ≥18 years of age,
2) the e-bike must have pedals and be operated by the individual, with assistance available from an electric motor,
3) at least one of the following outcomes: objective measure of PA intensity whilst e-cycling (e.g., metabolic equivalents, energy expenditure), cardiorespiratory, metabolic or quality of life (as a measure of psychological health),
4) type of study: experimental or observational studies.

Studies could be published or unpublished in any language as preliminary literature reviewing suggested that a considerable amount of research originates from non-English speaking countries. For articles in a language other than English the title and abstract were translated using Google Translate. If full text screening was required, the article was translated by an individual fluent in the language. Studies were excluded if they reported using bicycles that did not require the individual to pedal to provide power, were review articles or commentary pieces, and/or used self-reported measures of PA. Title and abstract screening was conducted by two reviewers independently (JEB. and SS). There was a 93% agreement between reviewers on title and abstract screening. Discrepancies were discussed and a third reviewer (ARC) was consulted if consensus could not be reached. Full texts were screened by the two reviewers independently and any discrepancies were discussed.

3.3.3 Quality assessment and strength of the evidence

The quality of included studies was assessed using the Effective Public Health Practice Project Quality Assessment Tool (EPHPP; (236)). The tool appraises studies on six components: 1) selection bias, 2) study design, 3) control of confounders, 4) blinding, 5) reliability and validity of data collection methods and 6) withdrawals and dropouts. Each component was rated as; strong, moderate, or weak for each study based on outcomes of interest.

A global rating for each study was then determined based on the criteria; 1) strong when no weak ratings were reported, 2) moderate when one weak rating was reported, and 3) weak when two or more components were rated as weak. This tool was chosen as it provides a generic measure of the quality of included studies and has been deemed suitable for use in systematic reviews (237), demonstrating content and construct validity (238). In addition, it has been used in a previous review examining the impact of cycling on health (228). The blinding component was not included in the overall study rating as participants are unable to be blinded to condition allocation following randomization in PA interventions. The overall strength of the evidence was assessed based on previously specified best evidence synthesis criteria (239) (Appendix 3.4).

3.3.4 Data extraction and synthesis

Members of the review team (JEB and either SS or ARC) independently extracted data for each study. Quality assessment was confirmed by a fourth reviewer (RP). Data were extracted using an adapted version of a Cochrane Data Extraction Form, which was piloted prior to use. Discrepancies regarding data extraction were resolved through discussion between reviewers. Data extracted included study design, characteristics of participants, outcomes measured, and results. Due to the heterogeneity of study design and outcomes reported, a meta-analysis was not deemed appropriate (240). Specifically, many studies did not report an estimate of the impact of e-cycling on the outcome of interest, the e-bike exposure lengths varied greatly between studies and similar outcomes were often assessed in different ways. As such, data were synthesised and presented narratively. The effect of the intervention on PA and health outcomes for each study was summarised based on reported statistical evidence and effect size, both within group (pre-post) and between group where possible, or by examining means or medians when no hypothesis testing was conducted.

3.4 Results

A total of 4399 articles were identified through initial searches (Figure 3.1). After removing duplicates 2894 titles and abstracts were screened, resulting in 119 studies which underwent full text screening for inclusion. Sixteen articles met the criteria for inclusion plus one included after author contact. Eleven studies assessed the acute response to e-cycling (i.e., one bout of e-cycling), and six examined the longitudinal effect of e-cycling (i.e., more than one bout of e-cycling, including pre-post measurements). Reasons for exclusion included no measure of specified outcomes, study not related to e-bikes, studies focused on the engineering of e-bikes, qualitative studies or not presenting original research. Three studies were identified through clinicaltrials.gov but were excluded for the following reasons: 1) data not published, 2) currently recruiting, 3) authors were unreachable.

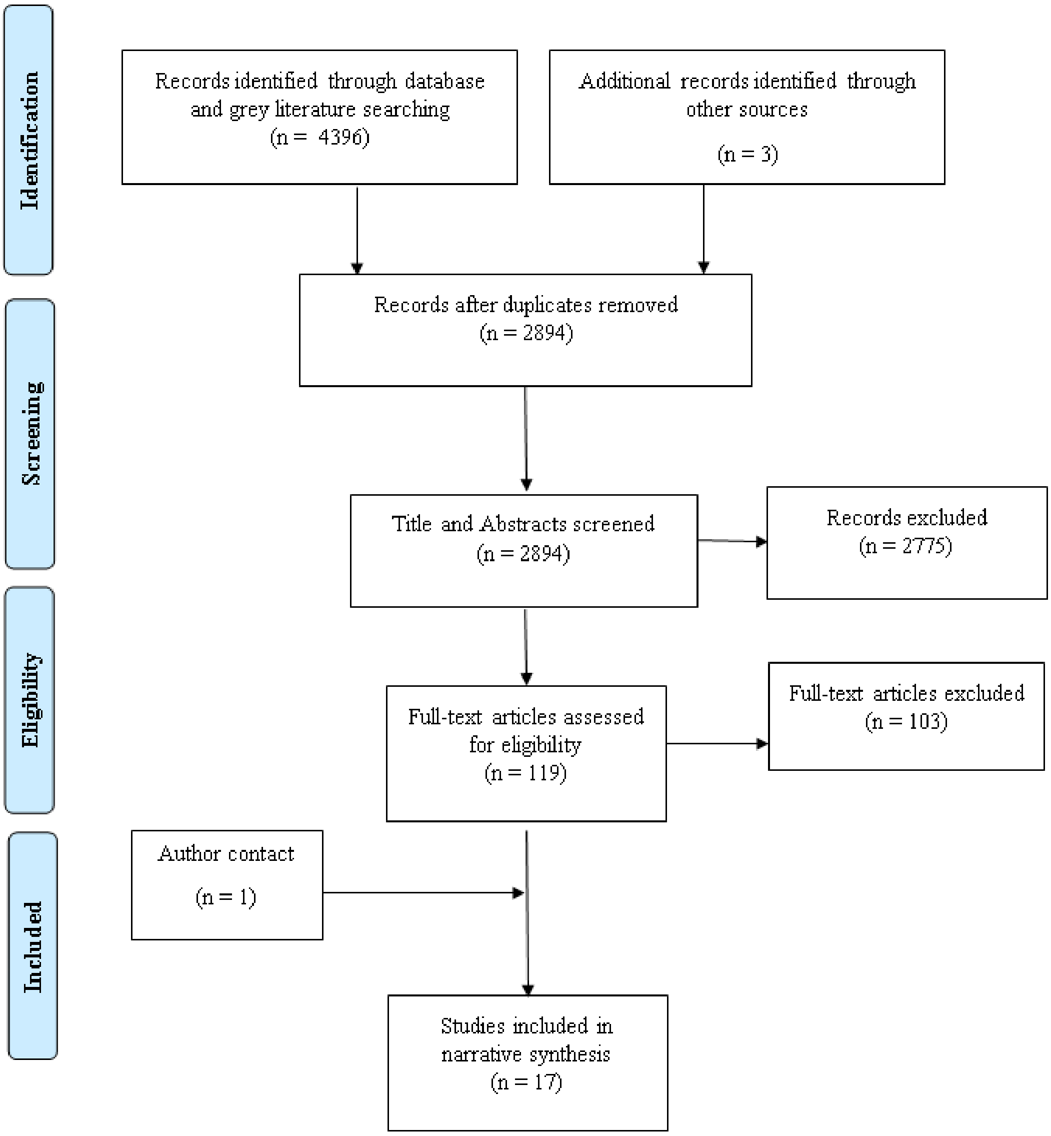

Figure 3.1 Flow chart of literature search

3.4.1 Study characteristics

3.4.1.1 Acute physiological studies

Eleven studies examined the acute physiological impact of e-cycling using cross over designs, five of which were randomized (Table 3.1). Nine studies were conducted in Europe and two in the USA. Sample sizes ranged from three to 22 with a total of 147 participants. Participants were aged between 20 and 70. Three studies recruited physically inactive individuals (241-243) and one study included individuals with coronary artery disease (244). Six studies compared e-cycling to conventional cycling (241, 244-248) and five compared e-cycling with assist to e-cycling without assistance (242, 243, 249-251). Two studies included walking as a comparator (241, 246).

Rest periods between conditions ranged from two minutes to one month and distance ridden from 3.5 to 27.0km. Nine studies were conducted in a natural setting with topography ranging from flat to elevations between 33.5 and 260.0m. Four studies specifically examined the impact of topography on physiological outcomes by separating rides into different topographical sections (Appendix 3.5). Four studies required participants to stop and go during rides to simulate typical riding conditions (243, 249) or delivering mail (247, 248). In seven studies participants were instructed to ride at a self-selected pace.

Table 3.1 Summary of included studies

First author, year, country	Study design	Participants; gender (%female); Age, years (mean, SD); BMI, kg/m^2 (mean, SD)	Clinical status	Exposure conditions	Length of intervention	Ride characteristics Distance, km; Topography; Distinctive features; Ride instructions
Acute studies						
Bernsten, 2017(245), Norway	Randomized cross over	N=8, 25.0% Age (Median, IQR): 39.0 (13.0) BMI (Median, IQR): 24.0 (5.0)	Active adults	E-bike vs. CB *(4 conditions, hilly vs. flat terrain)*	Trials conducted on same day, two-minute break between trials	Route one: 8.1km, Flat route Route two: 7.1km, one hill climbed twice 130m elevation gain. Self-selected intensity
Gojanovic, 2011(241), Switzerland	Non-randomized cross over	N=18, 33.3% Age: 35.7 (9.7) BMI: 24.0 (3.3)	Inactive adults	E-bike LA vs. E-bike HA vs. CB vs. walking	Trials conducted over two days. 30-minute break between trials conducted on same day	Biking: 5.1km, 178m elevation gain, average gradient 3.4%. Instructed to ride at comfortable pace maintaining 60rpm Walking: 1.7km, Uphill, 110m elevation gain, average grade 6.5%
Hansen, 2017(244), Belgium	Randomized cross over	N=17, 13.0% Age: 64.0 (7.0)	Coronary artery disease	E-bikes LA vs. E-bike HA vs. CB	Trials conducted on separate days (three to four days between)	10km, 102m elevation change No traffic or stop and go points Instructed to cycle at self-selected pace on prespecified mode
La Salle, 2017(249), USA	Randomized cross over	N=12, 50.0% Age: M=25.0 (1.0), F=22.0 (1.0) Body Fat %: M=16.8 (1.9), F=23.4 (3.3)	Active adults with cycling experience	E-bike pedal assist vs. E-bike NA	Trials conducted in same day. Average time between trials 12-minutes	3.54km, Hill 0.64km 11% gradient Seven pedestrian crossings participants required to dismount and walk. Self-selected pace
Langford, 2017(246), USA	Non-randomized cross over	N=17, 35.0% Age: <20yrs=3, 20-30yrs=10, 31-40yrs=2, >50yrs=2 BMI: M=26.1, F=23.1	Adults, part of e-bike sharing system	E-bike vs. CB vs. Walking	Trials conducted on separate days (minimum 24hours rest)	4.4km, 1.6km downhill (-33.2m), 1.8km flat (-0.3m), 1.0km uphill (+33.5m). Self-selected pace
Louis, 2012(250), France	Randomized cross-over	N=20 (T=10, UT=10) Age: T=38.7 (14.8), UT=28.9 (6.3) BMI: T=22 (1.1), UT=22.2 (3.7)	Highly active adults (T) Recreationally active adults (UT)	E-bike NA vs. E-bike LA vs. E-bike HA	Trials conducted on same day. Five-minute breaks between trials	Completed on indoor trainer. Instructed to pedal at specified mode for total of 45-minutes at pre-specified speeds: 15-minutes at 16km/hr, 21km/hr and free speed totally 45-minutes.
Meyer, 2014(251), Germany	Non-randomized cross over	N=3, 0.0% Age: 25, 25, 27 Weight (kg): 74.0, 71.0, 79.0	Active adults, recreational cyclists	E-bike pedal assist vs. E-bike no assist	Trials conducted on separate days, one day apart.	27km track divided in five sections
Simons, 2009(243), Netherlands	Non-randomized cross over	N=12, 50.0% Age: 52.2 (8.7), range 32 to 60 BMI: 24.5 (2.6)	42% inactive adults 58% recreationally active adults	E-bike NA vs. E-bike LA vs. E-bike HA	Trials conducted in same day. One-hour rest between trials.	4.3km, Flat route, two stop and go section participants required to dismount and restart. Self-selected pace on pre-specified intensity

Sperlich, 2012(242), Germany	Randomized cross over	N=8, 100% Age: 38.0 (15.0) BMI: 25.3 (2.1)	Inactive adults	E-bike pedal assist vs. E-bike no assist	Trials conducted in same day. One-hour rest between trials.	1.9km x 5=9.5km, 200m uphill one, 5.9%, 700m downhill, 300m uphill two, 5.8%, 700m flat. Self-selected pace and gear
Theurel, 2011(247), France	Non-randomized cross over	N=22, 18.0% Age: M=41.0 (11.0), F=34.0 (9.0) Weight (kg): M=68.0 (18.0), F=76.0 (10.0)	Active postal workers	E-bike vs. CB	Trials conducted on same weekday, one month apart	Postal route, one group completed rides in residential neighbourhood, the second completed the ride in downtown location
Theurel, 2012(248), France	Non-randomized cross over	N=10, 50.0% Age: F=30.0 (12.0), M=35.0 (14.0)	Active adults	E-bike vs. CB	Trials separated by one week	30-minutes of intermittent cycling on inside track alternating cycling of 10 seconds duration and recovery of 20 seconds. Aimed to complete 60m in 10 seconds (average speed=21.6km/hr).
Longitudinal studies						
Cooper, 2018(171), UK	Single group feasibility	N=20 (report on 18) Age: 58.1 (7.9) BMI: 30.2 (4.4)	T2DM	One group e-bike	Up to five months	E-bike training provided. Provision of e-bike for up to five months. Support for mechanical issues provided. No instruction on how or when to ride bike
De Geus, 2013(252), Belgium	Non-randomized cross over	N = 24, 46.0% Age: M=47.0 (7.0) F=43.0 (6.0) BMI: M=27.0 (2.8), F=24.7 (4.6)	Inactive adults[a]	E-bike vs. Control	Control=four weeks E-bike=six weeks	Instructed to ride e-bike at least three times per week to commute to and from work
Hochsmann, 2017(253), Switzerland	Pilot randomized controlled trial	N=32, 13.0% Age (Median, IQR): F=35.0 (34.0, 45.0), M=43.0 (38.0, 45) BMI, (Median, IQR): E-bike=29.0 (27.0, 31.0), regular bike=28.0 (26.0, 29.0)	Inactive adults	E-bike vs. CB	Four weeks	Instructed to use bike for active commute to work on at least three days per week, over 6km. Self-selected pace
Malnes, 2016(254), Norway	Single group pilot	N=25, 72.0% Age: 42.0 (12.0) BMI: M=25.4 (12.3), F=28.7 (15.8)	Inactive adults	One group e-bike	Up to eight months	Three sites: two provided e-bikes for up to eight months, one e-bike up to three months. Instructed to use bike as desired. In two centres if e-bikes not used they were withdrawn from participant. Group was separated into high and low fitness groups based on baseline testing
Page, 2017(255), UK	Non-randomized two group	N=31, 80.0% Age Range: 21-55years	Unclear	E-bike commuting vs. passive commuting	Data reported mid-way into intervention – two months	No instructions on how to ride bike, full roadside assistance provided.
Peterman, 2016(168), USA	Single group	N=21, 70.0% (of 20 in analysis) Age: 41.5 (11.5)	Inactive adults	One group e-bike	Four weeks	Instructed to ride e-bike at least three days per week for at least 40-minutes for commuting

[a] report as sedentary but do not specifically measure moderate to vigorous physical activity; T=trained (engage in endurance sport at least four times per week); UT=untrained (moderately active but less than 4x per week); Inactive, <150min/week of moderate to vigorous physical activity; Active, ≥150min/week of moderate to vigorous physical activity; BMI=body mass index; CB=conventional bike; F=female; HA=high assistance; IQR=interquartile range; LA=low assistance; M=male; NA=no assistance; SD=standard deviation; T2DM=type 2 diabetes mellitus

3.4.1.2 Longitudinal studies

Six studies examined the longitudinal impact of e-cycling, using a variety of study designs (Table 3.1). All studies were conducted in high income countries including Belgium, Switzerland, Norway, the UK (n=2) and the USA. Sample sizes ranged from 20 to 32, with a total of 153 participants. Most participants were between 30 and 50 years of age. Four studies recruited physically inactive individuals (168, 252-254). One study included individuals with T2DM (171) and for one study the health status of individuals was unclear (255). Interventions ranged from four weeks to eight months in length. One study included published data from mid-point of the intervention, but no post intervention data (255). Three studies provided participants with guidelines on minimum riding requirements, all of which specified riding the e-bike for commuting purposes at least three times per week (168, 252, 253).

3.4.2 PA intensity

Studies reported a range of outcomes related to PA intensity. Given the heterogeneity between studies regarding route length and topography, mean values and/or percent of maximum values during conditions are reported to enable comparison between studies. Physiological outcomes reported in the manuscript include oxygen uptake, METs, energy expenditure per minute, Hr and power output (Table 3.2). Additional outcomes are reported in Appendices 3.6 and 3.7.

3.4.3 Oxygen uptake

Eight studies reported oxygen uptake (241, 242, 244-246, 248-250). Riding an e-bike led to a relative mean oxygen uptake of 14.7 to 29.0ml/min/kg or 51.0 to 74.0% of maximum oxygen uptake. E-cycling required lower oxygen uptake than conventional cycling (19.3 to 37.0ml/min/kg) or e-cycling with no assistance (22.9 to 23.4ml/min/kg), with statistical differences reported in four studies, one of which reported an cohen's d effect size of 1.73 (242). Walking elicited lower oxygen uptake compared to self-selected e-cycling (246) and e-cycling on low assist (241).

Table 3.2 Physical activity intensity outcomes of interest measured during rides*

Study	Outcomes	Results; mean (SD)				
		E-bike	**Comparison one**	**Comparison two**	**Comparison three**	**Significance testing, *p value***
Bernsten, 2017(245) [a]	*(Median, IQR)*	**E-bike**	**CB**			
	Percentage VO_{2max}	51 (27.0)	58.0 (28.0)			NC
	Measured METs	8.5 (3.1)	10.9 (2.7)			NC
	Estimated METs	6.9 (2.1)	8.4 (1.8)			NC
Cooper, 2018(171)		**E-bike**	**Walking**			
	Mean Hr	125.2 (18.1)	107.6 (15.8)			NC
	Men	121.2 (17.2)	103.2 (14.1)			NC
	Women	132.6 (18.9)	116.5 (16.9)			NC
	Percentage Hr max	74.7	64.3			NC
Gojanovic, 2011(241)		**E-bike HA**	**E-bike LA**	**CB**	**Walking**	
	Mean absolute VO_{2peak}	1.5 (.04)	1.8 (0.5)	2.0 (0.4)	1.6 (0.3)	<0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
	Percentage VO_{2peak}	54.9 (11.0)	65.7 (8.1)	72.8 (6.4)	59.0 (9.1)	<0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
	Mean estimated METs	6.1 (1.4)	7.3 (1.0)	8.2 (1.3)	6.5 (0.8)	<0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
	Mean Hr	138.4 (18.0)	149.0 (17.7)	157.0 (11.2)	132.7 (17.4)	<0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
	Percentage Hr max	74.5 (8.7)	80.3 (8.7)	84.6 (5.2)	71.5 (9.2)	<0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
Hansen, 2017(244)		**E-bike HA**	**E-Bike LA**	**CB**		
	Mean absolute VO_2	1.7 (0.5)	1.9 (0.6)	1.9 (0.5)		.02 overall, .04 LA vs. HA, > .05 CB vs. LA, CB vs. HA
	Percentage VO_{2peak}	68.0 (7.1)	74.0 (6.2)	73.0 (4.6)		.01 overall, .03 LA vs. HA, > .05 CB vs. LA, CB vs. HA
	Mean estimated METs	6.0 (1.8)	6.6 (2.0)	6.4 (1.6)		.02 overall; .027 HA vs. LA; >.05, CB vs LA, CB vs. HA
Hochsmann, 2017(253)	*(Median, IQR)*	**E-bike**	**CB**			
	Percentage Hr max[+]	74.9 (67.4, 82.8)	73.3 (67.7, 78.2)			NC
Langford, 2017(246) [a,c]		**E-bike**	**CB**	**Walking**		
	Mean relative VO_2	16.9 (5.2)	19.3 (5.5)	15.1 (5.4)		NC
	Mean relative EE per minute	0.1 (0.03)	0.1 (0.02)	0.1 (0.03)		NC
	Mean estimated METs	5.1	5.8	4.5		NC
	Mean Hr	121.4 (17.0)	127.5 (18.2)	115.3 (14.4)		NC
	Mean power output	63.3 (22.9)	73.1 (35.8)	NA		NC
La Salle, 2017(249) [a]		**E-bike**	**CB**			
	Mean absolute VO_2	2.3 (0.1)	2.5 (0.1)			.45
	Percentage VO_{2max}	66.4 (2.6)	68.0 (2.8)			NR
	Mean estimated METs	8.3 (0.5)	8.5 (0.6)			.65
	Mean Hr	147.0 (5.0)	149.0 (5.0)			.064
	Percentage Hr max	79.1 (2.4)	80.4 (2.6)			NR
	Mean power output	115 (11.0)	128.0 (11.0)			.38
Louis, 2012(250) [b]	***Trained***	**E-bike HA**	**E-bike LA**	**E-bike NA**		
	Mean relative VO_2	14.7 (2.0)	19.5 (2.4)	22.9 (2.2)		< .05, all comparisons
	Mean estimated METs	4.2 (0.6)	5.6 (0.7)	6.5 (0.6)		< .05, all comparisons
	Mean absolute EE per minute	5.1 (0.8)	7.6 (0.8)	7.8 (0.5)		< .05, all comparisons
	Mean Hr	77.7 (11.0)	89.4 (10.2)	92.8 (11.6)		< .05, all comparisons
	Mean power output	47.3 (9.1)	83.6 (4.0)	104.2 (4.2)		< .05, all comparisons

	Untrained	**E-bike HA**	**E-bike LA**	**E-bike NA**		
	Mean relative VO_2	15.0 (2.0)	21.7 (4.2)	23.4 (3.6)		< .05, all comparisons
	Mean estimated METs	4.3 (0.6)	6.2 (1.2)	6.7 (1.0)		< .05, all comparisons
	Mean absolute EE per minute	4.9 (0.8)	6.7 (0.8)	7.5 (0.9)		< .05, all comparisons
	Mean Hr	96.8 (16.8)	116.8 (21.7)	116.7 (16.2)		< .05, all comparisons
	Mean power output	40.0 (7.1)	79.8 (4.8)	99.9 (6.9)		< .05, all comparisons
Meyer 2014(251) [a]		**E-bike**	**E-bike NA**			
	Mean Hr	94.7	131.3			NC
Peterman, 2016(168)		**E-bike**				
	Mean estimate METs	4.9 (1.2)				
	Mean absolute EE per minute	6.5 (1.9)				
	Percentage Hr max	72.1 (5.4)				
Simons, 2009(243)		**E-bike HA**	**E-bike LA**	**E-bike NA**		
	Mean estimated METs	5.2 (1.4)	5.7 (1.2)	6.1 (1.6)		<.05 HA and NA, >.05 HA vs. LA, LA vs. NA
	Mean Hr	112.4 (22.9)	116.2 (22.4)	123.8 (23.2)		<.05 NA vs. HA; NA vs. LA, >.05 HA vs. LA
	Percentage Hr max	67.1 (14.1)	69.3 (13.5)	73.9 (14.5)		<.05 NA vs. HA; NA vs. LA, >.05 HA vs. LA
	Mean absolute power	94.2 (29.2)	101.8 (24.8)	118.2 (30.9)		<.05 All comparisons
Sperlich, 2012(242) [a]		**E-bike**	**CB**			
	Mean relative VO_2	18.0 (3.8)	25.5 (4.8)			<.05, ES=1.73
	Mean absolute VO_2	1.3 (0.4)	1.8 (0.4)			< .05, ES=1.12
	Mean estimated METs	5.2 (1.7)	7.1 (1.4)			<.05, ES=1.22
	Mean Hr	105.0 (20.0)	133.0 (19.0)			<.05, ES=1.53
	Mean absolute power	363.0 (23.0)	415.0 (28.0)			<.05, ES=2.02
Theurel, 2011(247)		**E-bike**	**CB**			
	Mean absolute EE per minute	5.6 (1.3)	5.9 (1.8)			NR
	Mean Hr	NR	NR			.02, 3.0% lower with e-bike
Theurel, 2012(248)		**E-bike**	**CB**			
	Mean relative VO_2	29.0 (5.0)	37.0 (5.0)			< .001
	Mean Hr	136.0 (23.0)	167.0 (17.0)			<.001

*Given the difference in the cycle routes conducted mean values or percentage of maximum for outcomes related to PA intensity are reported (e.g., Mean VO_{2peak}, mean Hr, mean EE). For additional PA related outcomes reported in the studies see Appendix 3.6; [+] reported for only a subsample of the group (n=5 e-bikes; n=4 CB)

CB=conventional bike; EE=energy expenditure; ES=effect size measured as Cohen's d; HA=high assistance; Hr=heart rate; LA=low assistance; METs=metabolic equivalent; NA=no assistance; NC=not conducted; NR=not reported; SD=standard deviation; VO_2=volume of oxygen; VO_{2max}=maximum oxygen intake value attainable for an individual; VO_{2peak}=the highest oxygen intake value obtained on a specific test.

Relative VO_2, VO_{2max} and VO_{2peak} measured as ml/min/kg; *Absolute* VO_2, VO_{2max} and VO_{2peak} measured in l/min; *Mean absolute EE* measured in kcal/min; *Mean relative EE* measured in kcal/kg/min; *Mean Hr* measured in beats per minute (bpm); *Mean power output* measured in Watts, *Estimated METs* measured using assumption that resting energy expenditure (i.e.,one MET)=3.5ml/kg/min; *Measured METs* measured through assessed individual resting EE

[a] Results are reported to total cycle routes. Studies separated results for different route topography. See Appendix 3.5 for details on different cycling topography; [b] Participants completed same activity at three different speeds, self-selected speed reported as like other studies reported; [c] Total sample analyses not conducted, see additional material for analyses between ride segments.

3.4.4 Metabolic equivalents (METs)

Nine studies reported mean estimated METs while riding an e-bike at a self-selected intensity (168, 241-246, 249, 250), which ranged from 4.9 to 8.3 METs. Overall, e-cycling led to a lower mean MET score than conventional cycling or e-cycling without assistance. However, the significance of the difference was inconclusive. One study reported a difference in mean METs between walking and e-cycling only during uphill sections (246), while another study reported no difference between walking and e-cycling over varied terrain (241).

3.4.5 Energy expenditure per minute

Four studies assessed energy expenditure per minute (168, 246, 247, 250). On an indoor trainer, energy expenditure per minute was lower on an e-bike with assistance (high or low) compared to an e-bike without assistance in physically active adults (250). In outdoor trials two studies reported no difference in energy expenditure per minute between e-cycling and conventional cycling, though mean values were consistently lower for e-cycling (246, 247). Absolute energy expenditure per minute while riding an e-bike ranged from 4.9 to 6.5kcal/min.

3.4.6 Heart rate

Twelve studies reported Hr while e-cycling (168, 171, 241-243, 246-251, 253). During e-cycling the percentage of maximum Hr ranged from 67.1 to 79.1%. Overall, mean Hr while riding an e-bike was lower than riding a conventional bike or an e-bike with no assistance. Hr showed a trend towards being lower while walking compared to e-cycling (171, 241, 246).

3.4.7 Power output

Five studies assessed power output during conditions (242, 243, 246, 249, 250). Mean power output was lower while riding an e-bike compared to a conventional bike or e-cycling with no assistance. Riding an e-bike on high assistance compared to low assistance led to significantly lower power outputs.

Overall, e-cycling was performed at a moderate intensity, but the intensity was lower than during conventional cycling. Most studies reported significant differences in the associated outcomes between e-cycling and conventional cycling. However, one study found no differences in physiological markers of intensity between e-cycling and conventional cycling

(249). While the evidence is limited, e-cycling appears to be performed at a greater intensity than walking.

3.4.8 Impact of topography

Five studies directly compared the impact of e-cycling in varying topographies (Appendix 3.5). The energy cost during e-cycling and conventional cycling uphill ranged from 5.2 to 6.8 and 7.2 to 8.5 METs respectively. Examination of means and medians suggested that energy expenditure (METs) during downhill and flat sections were lower while e-cycling compared to conventional cycling, but that this difference in energy cost was less distinct than during uphill sections. Across all studies, greater elevation gains in routes led to higher energy cost for both e-cycling and conventional cycling compared to flat routes or those conducted indoors. Differences in Hr between e-cycling and conventional cycling appear to be greater during uphill sections, except for one study (242) that reported similar differences in Hr between cycling conditions across all topographies.

3.4.9 Physical fitness

A pilot randomized control trial of physically inactive individuals reported an increase in peak oxygen uptake (VO_{2peak}) of 10.0% (equating to an increase of 3.5ml/kg/min) following four weeks of e-cycling compared to a 6.0% increase (equating to 2.2ml/kg/min) following four weeks of conventional cycling (253) (Table 3.3). As such, after controlling for baseline values there was no difference in fitness post intervention between the e-bike and conventional bike groups (253). In a similar population, using a single-group quasi-experimental design, one study reported an 8.0% increase (0.18L/min) in VO_{2peak} following four weeks of e-cycling (168) and another reported a 7.7% increase (2.4ml/kg/min) in VO_{2peak} following three months of e-cycling (254). When separated into low and high fitness groups a significant increase in VO_{2peak} was reported only in individuals with low levels of fitness, with a 9.6% increase compared to a 1.5% increase in high fitness individuals (254). Gender differences were reported in one study following six weeks of e-cycling with a 2.0% and 7.0% increase in VO_{2peak} in physically inactive men and women respectively (252). Gender differences were also reported in maximum power output with women reporting lower increases in maximum power than men following a six-week and five-month intervention (171, 252).

3.4.10 Health outcomes

Three studies examined the impact of e-cycling on health outcomes beyond fitness (Table 3.3), for which the outcomes assessed were heterogeneous. After four weeks of e-cycling there were no changes in systolic or diastolic blood pressure at rest (168, 253). There was no evidence of a difference in blood pressure whilst cycling between conventional cycling and e-cycling (253). Peterman and colleagues (168) reported no changes in insulin resistance or lipid profiles following four weeks of e-cycling. However, a significant reduction in two-hour post plasma glucose concentration was reported. No changes were reported in the one study examining quality of life following eight weeks of e-cycling (255).

3.4.11 Quality assessment and quality of the evidence

The global rating of acute studies yielded six moderate and five weak ratings according to the EPHPP tool (Table 3.4). Ten studies were rated as weak for representativeness of the target population, often due to a failure to report how participants were recruited. Methods of assessment were rated as strong. The repeated nature of conditions ensured the control of confounders, therefore yielding a strong rating. Overall there was moderate evidence that e-cycling could lead to PA at an intensity associated with beneficial health outcomes (233). A global rating of strong was given to one longitudinal study, moderate was given to four studies and weak to one study. There was moderate evidence that e-cycling could lead to increased fitness. The evidence related to the impact of e-cycling on additional health outcomes was inconclusive.

Table 3.3 Results of longitudinal intervention studies

Study	Outcomes	Results, mean, SD *(95% CI)*				
		Intervention		**Control**		**Significance, *p-value***
		Pre	**Post**	**Pre**	**Post**	
		E-bike				
Cooper, 2018(171)	Max absolute power	157.5 (55.7)	174.3 (70.8)			NC
	Men	182.1 (51.5)	206.2 (64.9)			NC
	Women	118.9 (38.9)	124.3 (49.0)			NC
		E-bike		**NE**		***Within groups***
De Geus, 2013(252)	Absolute VO_{2peak}					
	Men	2.6 (0.4)	2.6 (0.4)	2.6 (0.5)	2.6 (0.4)	>.0.025 E-bike, NE
	Women	1.9 (0.4)	2.1 (0.4)	1.9 (0.4)	1.9 (0.4)	>.0.025 E-bike, NE
	Relative VO_{2peak}					
	Men	30.2 (4.3)	30.7 (5.6)	30.8 (4.9)	30.2 (4.3)	>.0.025 E-bike, NE
	Women	30.0 (6.0)	32.3 (6.5)	29.4 (5.1)	30.0 (6.0)	>.0.025 E-bike, NE
	Absolute max power					
	Men	169.5 (19.9)	192.1 (28.7)	173.8 (27.1)	169.5 (19.9)	<.0.025 e-bike, >.0.025 NE
	Women	130.9 (21.6)	145.9 (24.8)	131.1 (21.7)	130.9 (21.6)	<.0.025 e-bike, >.0.025 NE
	Relative max power					
	Men	2.0 (0.3)	2.3 (0.4)	2.1 (0.4)	2.0 (0.3)	<.0.025 e-bike, >.0.025 NE
	Women	2.0 (0.4)	2.3 (0.6)	2.0 (0.4)	2.0 (0.4)	<.0.025 e-bike, >.0.025 NE
		E-bike		**CB**		***Between groups***
Hochsmann, 2017(253)	Relative VO_{2peak}	35.7 (5.8)	39.3 (8.3)	36.4 (7.3)	38.6 (6.2)	0.327, 1.4 (-1.4-4.1)$^{+}$
	Relative power output	2.9 (0.6)	3.2 (0.6)	3.0 (0.5)	3.3 (0.5)	0.995, 0.0 (-0.1-0.1)$^{+}$
	Resting Hr	64.7 (6.5)	65.1 (7.6)	68.8 (8.8)	65.5 (10.6)	0.505, 2.0 (-4.2-8.2)$^{+}$
	Hr at 100W max text	113.4 (9.2)	111.5 (7.7)	113.4 (15.9)	109.2 (14.2)	0.219, 2.4 (-1.5-6.2)$^{+}$
	SBP at rest	125.9 (13.8)	124.1 (11.3)	127.3 (10.6)	123.1 (12.4)	0.538, 2.0 (-4.5-8.5)$^{+}$
	DBP at rest	82.4 (8.5)	82.1 (8.2)	87.7 (8.0)	84.5 (8.8)	0.625, 1.2 (-3.9-6.3)$^{+}$
	SBP @ 100W	174.1 (22.9)	160.3 (21.2)	160.8 (20.0)	150.4 (18.5)	0.93, -0.4 (-9.4-8.7)$^{+}$
	DBP @ 100W	86.2 (8.3)	81.9 (6.5)	88.0 (7.1)	84.0 (8.1)	0.709, -1.1 (-7.5-5.2)$^{+}$
		E-bike				***Within groups***
Malnes, 2016(254)	Relative VO_{2peak}	34.1 *(31.6, 36.7)*	36.5 *(34.4, 38.6)*			<.001
	Relative VO_{2peak} , %gain		7.7 *(4.3, 11.1)*			
	High Fitness		1.5 *(-5.6, 8.6)*			0.626
	Low Fitness		9.6 *(5.9, 13.3)*			<.05

	Peak Hr	181 *(175, 187)*	180 *(174, 186)*			0.429
		E-bike commute		**Passive commute**		
Page, 2017(255)	QOL (baseline and week 8)	38.0 (3.9)	39.7 (4.5)	29.6 (6.6)	35.7 (5.6)	>.05 e-bike, passive commute
	OQL (week 4)		38.8 (4.2)		32.6 (6.1)	<.01, ES=0.28
		E-bike				
Peterman, 2016(168)	Absolute VO_{2max}	2.2 (0.5)	2.4 (0.5)			<.05
	MVPA	28.1 (17.5)	29.0 (20.2)			>.05
	MVPA10+	11.7 (14.3)	13.0 (15.2)			>.05
	Absolute max power	165.1 (37.1)	189.3 (38.3)			<.05
	Fasting glucose	5.0 (0.52)	5.0 (0.5)			>.05
	2hr post plasma glucose	5.5 (1.2)	5.0 (0.9)			<.05
	HOMA	2.5 (1.0)	2.6 (0.8)			>.05
	Total cholesterol	3.9 (0.9)	3.9 (0.8)			>.05
	LDL	2.3 (0.8)	2.3 (0.7)			>.05
	HDL	1.2 (0.2)	1.2 (0.2)			>.05
	Triglycerides	1.0 (0.4)	0.9 (0.3)			>.05
	MAP	84.6 (10.5)	83.2 (9.4)			>.05
	SBP	110.0 (12.4)	109.1 (10.9)			>.05
	DBP	67.7 (8.8)	67.0 (8.0)			>.05

[+]difference between groups, 95% CI, CB=conventional bike; DBP=diastolic blood pressure; ES=effect size; HDL=high density lipo-protein; HOMA=homeostatic model assessment; Hr=heart rate; LDL=low density lipo-protein; MAP=mean arterial blood pressure; MVPA=moderate to vigorous physical activity; MVPA10+= moderate to vigorous physical activity of bout of 10-minutes or greater; NE=no activity; QOL=quality of life; SBP=systolic blood pressure; VO_2=oxygen intake value; W=watts

Distance (total and weekly) measured in kilometres; *Duration* (total and weekly) measured in minutes; *Relative* VO_{2max} and VO_{2peak} measured as ml/min/kg; *Absolute* VO_{2max} and VO_{2peak} measured in l/min *Mean EE* measured in kcal/min; *Mean Hr or peak Hr* measured in beats per minute (bpm); *Mean absolute max power* measured in Watts, *Mean relative power* measured in watts/kg*; glucose, cholesterol, LDL, HDL, Triglycerides* measured in mmol/L; *blood pressure* measured in millilitre of mercury (mmHg), *MVPA* and *MVPA10+* measured in minutes per day

Table 3.4 Quality assessment of included studies according to the Effective Public Health Practice Project tool

Study	Component rating						Global rating[a]
	Selection Bias	Design	Confounders	Blinding	Methods	Drop-outs	
Acute studies							
Bernsten(245)	Weak	Strong	Strong	Weak	Strong	Strong	Moderate
Gojanovic(241)	Weak	Moderate	Strong	Weak	Strong	Strong	Moderate
Hansen(244)	Moderate	Strong	Strong	Weak	Strong	Strong	Moderate
Langford(246)	Weak	Moderate	Strong	Weak	Strong	Moderate	Moderate
La Salle(249)	Weak	Strong	Strong	Weak	Strong	Strong	Moderate
Louis(250)	Weak	Strong	Strong	Weak	Strong	Weak	Weak
Meyer(251)	Weak	Weak	Strong	Weak	Strong	Weak	Weak
Simons(243)	Weak	Moderate	Strong	Weak	Strong	Strong	Moderate
Sperlich	Weak	Strong	Strong	Weak	Strong	Weak	Weak
Theurel, 2011(247)	Weak	Weak	Strong	Weak	Strong	Weak	Weak
Theurel, 2012(248)	Weak	Weak	Strong	Weak	Strong	Weak	Weak
Longitudinal studies							
Cooper(171)	Moderate	Moderate	Strong	Weak	Strong	Moderate	Moderate
De Geus(252)	Weak	Moderate	Strong	Weak	Strong	Moderate	Moderate
Hochsmann(253)	Moderate	Strong	Strong	Weak	Strong	Strong	Strong
Malnes(254)	Weak	Moderate	Strong	Weak	Strong	Strong	Moderate
Page(255)	Moderate	Weak	Weak	Weak	Strong	Weak	Weak
Peterman(168)	Weak	Moderate	Strong	Weak	Strong	Moderate	Moderate

[a]Strong=no weak component rating; moderate=one weak component rating; weak=two or more weak component ratings.
Note: blinding was not included in the overall global rating calculation

3.5 Discussion

The aim of the current review was to assess the intensity of PA when riding an e-bike, and to examine the physiological and psychological outcomes associated with e-cycling. Where possible these outcomes were compared to traditional methods of AT (i.e., walking and cycling). Eleven acute and six longitudinal studies were identified. There was moderate evidence that e-cycling provides moderate intensity PA in both physically active and inactive individuals. Furthermore, there was moderate evidence that e-cycling positively impacted cardiorespiratory fitness in physically inactive individuals. The impact of e-cycling on health outcomes beyond physical fitness was inconclusive given the sparsity of current research.

3.5.1 Quality of the evidence

The quality of all studies, except one (253), was weak to moderate. These ratings should be viewed with caution as the purpose of physiological studies, such as the acute experiments reported here, is to explore a specific event in a controlled environment with less focus on obtaining representative samples. As such, many studies did not report how participants were recruited, leading to a weak rating for the selection bias component of the assessment. Study design, control of confounders and methods of assessment are often considered more crucial in these designs, all of which were strong in the acute studies reported here. Furthermore, while blinding is often unachievable in PA interventions, the use of objective methods limits the impact of research bias on the outcomes.

Regarding longitudinal studies, methods of data collection were consistently strong, but with large variation in representativeness, design and reporting of withdrawals and dropouts. Confounders were considered in the context of differences between groups and were therefore rated as strong if studies used a single-group design. One pilot RCT was conducted and was rated as strong (253). Overall, there was a lack of high-quality longitudinal intervention-based research including pre-post measures examining the impact of e-cycling on physiological and psychological health outcomes.

3.5.2 The impact of e-cycling on PA intensity

To accrue health benefits, The American College of Sports Medicine recommend healthy adults engage in 150-minutes of MVPA per week (233). The current review suggests that e-cycling, even while using a high assistance mode, provides PA of at least moderate intensity on a variety of terrain, including downhill. Furthermore, e-cycling can elicit vigorous activity during uphill riding (241, 256) and during rides with highly varied terrain (241, 249). Interestingly, Bernsten and colleagues (256) reported that mean *estimated* METs were lower than mean *measured* METs during e-cycling. Estimated METs have been suggested to overestimate resting energy expenditure, thereby underestimating activity energy expenditure (257). As such, the mean estimated METs reported in this review provide a conservative estimate of exercise intensity.

Relative physiological outcomes further suggest that e-cycling is performed at a moderate intensity with the percent of maximum Hr ranging from 67.1 to 79.1% and the percent of $VO_{2peak/max}$ ranging from 51.0 to 75.0%. These values exceed the hypothesised minimum intensity thresholds required for improvements in cardiorespiratory fitness in healthy adults (233, 258, 259).

3.5.3 E-cycling vs. traditional active transportation

Three studies compared e-cycling to walking (171, 241, 246) of which one compared the two modes on the same route (246). In this study walking led to lower oxygen uptake than e-cycling across all topographies, though significant MET differences were only reported during uphill sections, with e-cycling expending more energy than walking. The few studies conducted suggest e-cycling is performed at a higher intensity than walking, however, more studies are needed to confirm these trends.

In relation to conventional cycling, this review suggests that e-cycling elicits lower physiological markers of intensity than conventional cycling, however the strength of this finding depends on the physiological assessment measure and route topography. Overall, mean percent of $VO_{2max/peak}$ is similar between conventional cycling and e-cycling ranging from 58.0 to 74.0% and 51.0 to 73.0% respectively. Studies examining active commuting on conventional bikes have reported similar mean percent of VO_{2max} in healthy adults ranging from 57.0 to 79.0% (228, 260). However, mean relative oxygen uptake is lower during e-cycling compared to conventional cycling or e-cycling without assistance. Similarly, means and medians of estimated METs are consistently higher during conventional cycling or e-cycling without assistance compared to assisted e-cycling, with values ranging from 6.1 to 8.5 and 4.9 to 8.3 respectively, though the significance of the differences varied across studies.

La Salle and colleagues (249) reported similar MET values between e-cycling and conventional cycling. However, the values reported were substantially higher than those reported in other studies, with mean estimated METs of 8.3 and 8.5 for e-cycling and conventional cycling respectively. Participant demographics may have accounted for these differences, since participants were younger and had previous cycling experience. These participants may have had higher aerobic capacity and therefore self-selected a higher intensity activity level at which to complete the conditions. This is likely given that the relative intensity of activity is similar in studies of e-cycling in physically inactive individuals (168, 171, 241-243, 253). When given the choice to self-select pace and intensity individuals may select a similar physiological intensity across activities regardless of the mechanical assistance, thereby resulting in similar physiological outcomes. In support of this, when individuals were required to maintain a cycling cadence of 60 revolutions per minute throughout a condition, there were significant differences in oxygen uptake and Hr between e-bikes and conventional bikes (241) compared to studies in which individuals were able to self-select their intensity (244, 245, 249). Similarly, when instructed to complete 60-meters of riding in 10-seconds for a total of 30-minutes the reported relative VO_{2max} was 29.0ml/min/kg for e-cycling and 37.0ml/min/kg for conventional cycling (248). This suggests that performing the same amount of work requires more effort on a conventional bike than an e-bike, but that human beings reduce the amount of work conducted on a conventional bike, through choosing a slower speed, to account for the increase in expended effort.

In hilly terrain, where there is less opportunity to adjust effort levels to produce comparable intensity levels, the differences between conventional cycling and e-cycling may become more pronounced, with e-cycling requiring lower intensity activity, as found in studies comprised of routes with hilly features (241, 246). This suggests that e-bikes are less sensitive to environmental factors such as topography. Therefore, physiological measures of intensity are lower on the e-bike than those reported on a conventional bike during uphill riding. The reduced intensity required during uphill riding when using an e-bike is one of the leading arguments for the promotion of e-bikes as an alternative mode of active transportation.

3.5.4 E-cycling and health

In the current review three studies provided weekly e-cycling goals for physically inactive individuals in the context of active commuting (168, 252, 253). Two of these studies reported increases in VO_{2peak} and maximum power output following four weeks of e-cycling (168, 253). In contrast, de Geus and colleagues (174) reported no changes in VO_{2peak} following a six-week intervention, though differences in maximum power output were seen. Differences between studies could be due to distance cycled. Specifically, both Hochsmann and colleagues (253) and Peterman and colleagues (168) reported cycling distances of 70.0km and 69.4km per week respectively, compared to 54.3km per week reported by de Geus (174). The two studies reporting significant increases in fitness also described self-selected riding intensities of between 72.1 and 74.9 percent of maximum Hr (within the moderate intensity zone (168, 253) with an average of 205(SD=43.3)minutes of e-cycling per week (168). This suggests that e-cycling can contribute to meeting weekly PA guidelines.

Without the provision of e-cycling goals, single group studies with physically inactive individuals reported increases in maximal power output of 7.0 to 10,0% over three to eight months, despite lower average distance travelled than other studies (171, 254). Fitness benefits were greatest in individuals classified as having low fitness (254), similar to findings with conventional cycling (228). These results suggest that in the absence of specific goals (i.e., under free living conditions), participants engage in e-cycling and this e-cycling can contribute to improvements in fitness.

Beyond cardiorespiratory fitness, there is a lack of research examining the impact of e-cycling on physiological or psychological health outcomes, limiting our ability to draw conclusions. Peterman and colleagues (168) reported a decrease in two-hour plasma glucose during an oral glucose tolerance test after four weeks of e-cycling. This finding is in line with studies that have examined the impact of exercise on two-hour post exercise glucose concentrations in obese individuals (261, 262) but is novel in the context of e-cycling and conventional cycling. In the same study, no other metabolic changes were reported. Similar null effects on metabolic outcomes were reported in two systematic reviews on conventional cycling (260, 263).

3.5.5 E-cycling for public health?

Overall e-cycling can elicit at least moderate intensity PA. However, total energy expenditure when riding an e-bike is lower than when riding a conventional bike or walking over the same distance, given the reduced amount of time taken to complete a ride on an e-bike. Consequently, if e-cycling were to replace journeys made by walking or conventional cycling, individuals would have to ride for longer for comparable weekly energy expenditure. However, e-cycling is associated with lower ratings of perceived exertion than conventional cycling (246, 249), potentially enabling people to ride more frequently or for a longer duration. This possibility is supported by Hendriksen and colleagues (264), who reported that individuals in the Netherlands commuted 50% further with an e-bike than on a conventional bike.

Findings reported in this study suggest that e-cycling may be suitable for individuals with compromised health. Hansen and colleagues (244) showed that e-cycling elicited MPA in older, obese individuals recovering from surgery due to coronary artery disease, while Cooper and colleagues (171) reported that e-cycling was feasible for middle-aged, overweight individuals with T2DM.

Overall, while there is a trend towards increased fitness following engagement in e-cycling interventions, more intervention research of a longer duration is required before the long-term impact of e-cycling on health can be determined. Fifty percent of the longitudinal studies in this review were approximately one month in length. This may not be enough time to see changes in body composition and some metabolic outcomes. Longer trials with larger samples sizes should be conducted with a focus on including a range of health outcomes in addition to cardiorespiratory fitness. These studies should utilise RCTs and clearly report their target population, recruitment process and dropouts and/or withdrawals. Interventions should also be conducted in clinical populations where PA is compromised. In addition, more research is needed to understand the impact of e-cycling on health based on sex or fitness level.

It is also important to consider the negative outcomes associated with e-cycling when assessing their potential use for health promotion. In the USA, e-bike users reported feeling safer riding their e-bike than a conventional bike, stating that the e-bike helped them to avoid crashes due to their stability, powerful brakes, and the acceleration to avoid incidents and keep up with traffic. However, riders reported cycling faster on an e-bike than a conventional bike and felt that other road users misjudged their speed leading to potentially dangerous situations (175). In the Netherlands, data suggest that, after controlling for age, gender and amount of cycling, use of an e-bike was associated with an increased risk of being involved in a crash compared to conventional cycling (176). The severity of these crashes was not significantly different from conventional cycling (176). More context specific research is required to enable a risk-benefit assessment of engaging specifically in e-cycling. Nevertheless, e-cyclists should be appropriately trained and use safety equipment to minimise risk.

3.5.6 Strengths and limitations

This is the first review to examine the PA intensity, cardiorespiratory, metabolic, and psychological outcomes associated with e-cycling. This review used two pragmatic tools to assess the quality of studies and to give an overall rating of the evidence providing overall representation of the strength of research evidence related to e-cycling and health. However, the EPHPP tool is infrequently used in systematic reviews (265). While use of the tool allows for comparison to a systematic review examining the health benefit of conventional cycling (228) there is no agreement between the EPHPP and the most commonly used Cochrane Collaboration Risk of Bias Tool (Cochrane RoB) when evaluating the quality of RCTs (266). Specifically, the EPHPP produces significantly higher scores for study quality than the Cochrane RoB when assessing the same studies. As such, the current quality assessment may provide a more liberal measure of study quality than would have been found using the Cochrane RoB Tool. However, in addition to RCTs, the current review included non-RCTs for which there is currently no consensus on the most appropriate tool for assessing the risk of bias (267). The most commonly used tools to assess the quality of non-RCTs are the Newcastle-Ottawa Scale and the ROBINS-I tool (265). While common they are not without their limitations (267). As such, future research may wish to select the most appropriate design specific appraisal tools based on the evidence being reviewed, with use of multiple tools being advocated, to provide a comprehensive review of study bias (267).

Additional limitations of this review include the fact that some published studies may not have been identified. However, our systematic and broad search strategy makes this unlikely. It is more likely that we did not identify eligible unpublished studies or those published in an alternative language to English. Sample sizes used in the studies were small and sample size calculations were rarely reported. Therefore, caution should be taken when interpreting the statistical evidence. Given the heterogeneity in outcome measurement we were unable to quantify the effects of e-cycling on outcomes of interest using meta-analyses. In addition, focus on quality of life as a psychological outcome may have meant studies examining psychological outcomes such as depression or anxiety were excluded.

3.6 Conclusion

The composite results of the 17 studies included in this novel systematic review provide moderate evidence that e-cycling elicits activity at an intensity high enough to promote positive health outcomes. E-cycling leads to reduced activity volume and intensity over the same distance compared to conventional cycling. Therefore, e-cycling requires more frequent and longer rides to accrue comparable health benefits. However, given that most individuals travel to work by car (268), e-cycling offers a physically active alternative to the largely sedentary behaviour associated with motorised commuting. Furthermore, longitudinal studies suggest, with moderate confidence, that e-cycling can lead to increases in cardiorespiratory fitness. Longer and higher-quality intervention studies, with transparent reporting, are needed to develop a strong evidence-based understanding of the impact of e-cycling on cardiorespiratory health and to explore the impact of e-cycling on metabolic and psychological outcomes. This will extend the current body of knowledge and provide guidance on public health initiatives to promote e-cycling to improve population health.

3.7 Contribution to this thesis

This review has been instrumental in the development of study three regarding both study design and the selection of outcomes for exploration as discussed in Chapter 5. Specifically, study three will use a longitudinal experimental design and explore a range of physiological, psychological, and metabolic outcomes. Clear reporting guidelines will be followed to ensure transparency in all areas of the research process including recruitment methods, study dropouts and withdrawals.

This review also highlights the need to examine e-cycling in clinical populations, for whom engagement in PA is lower than their non-clinical counterparts (173, 269-272), but who can benefit significantly from engaging in PA (273-275). The two clinical populations included in this review include individuals with coronary artery disease and those with T2DM, for whom e-cycling elicits MPA. Furthermore, in their longitudinal feasibility study of e-cycling in adults with T2DM, Cooper and colleagues (171) reported that engagement in e-cycling led to improvements in fitness, as measured through maximum power output. Given the growing incidence of T2DM, study three will build on the work of Cooper and colleagues to explore the feasibility and acceptability of conducting a randomized controlled e-cycling pilot study in adults with T2DM. As such, study three will directly address current gaps in the literature pertaining to the impact of e-cycling on health in a clinical population.

While the review highlights the potential health benefits of engaging in e-cycling it is important to remember that engaging in a new behaviour will mean a reduction of an alternative behaviour. As such, for the potential health benefits of e-cycling to be fully understood it is important to know the behaviours that are being substituted in favour of e-cycling. Specifically, this review illustrates that the replacement of conventional cycling with an e-bike will lead to a reduction in total energy expenditure, for the same distance travelled, due to the reduced time required to complete the same journey and lower intensity when engaging in e-cycling compared to conventional cycling. As such, the substitution of already active journeys with e-bikes might negatively impact health through a reduction in total PA. However, the substitution of sedentary motorised transportation or sedentary activities, such as watching the television, with e-cycling may increase total PA and positively impact individual health. This observation led to the inception of study two, a review to synthesise the research examining how adults use e-bikes, the reasons for engaging in e-cycling and the impact that e-bike use has on other transportation use.

4 Chapter 4. The impact of e-cycling on travel behaviour: A scoping review

4.1 Overview

This chapter outlines study two, a scoping review of the literature to identify what is known about the frequency and duration of e-bike use, the purposes for which e-bikes are used, factors associated with e-bike use and their impact on travel behaviour. Study two addresses the second objective of this thesis: *explore how and why people use e-bikes and the impact of e-bike use on changing travel behaviour*. The study presented here is a reproduction of the accepted version of the manuscript provided in Appendix 4.1. Where appropriate, expansions have been made to the methods. In addition, an explanation of how this research contributes to the overall thesis is discussed at the end of the chapter.

4.2 Introduction

Travel is an essential part of everyday life for most people. Motorised road travel is a major use of energy, creating air pollution and contributing to global warming (276). Vehicles in congestion emit more pollution than free-flowing traffic (277), which is of concern given that traffic levels, and associated congestion, are expected to rise in many developed countries including the UK (278), Europe (279), Australia (280) and the United States (281).

Adoption of AT, such as walking and cycling, may contribute to reducing congestion, greenhouse gas emissions and air pollution, while also having a positive impact on health through increased PA (132, 282). Consequently, understanding ways to increase AT is important to transport policy makers, urban planners and health care professionals (283). However, engagement in AT, in particular cycling, is low (155, 284, 285). In Europe 12.0% of 27,680 individuals across 28 member states reported cycling every day (286). However, in Europe large variations in reported cycling exist with Spain (4.0%), Luxembourg (4.0%), and England (2.0%) reporting the lowest rates of daily cycling while the Netherlands (43.0%), Denmark (30.0%) and Finland (28.0%) reporting the highest rates of daily cycling (286). Specifically in England in 2019, 26.0% of yearly trips were made on foot and 2.0% on bicycle, accounting for 4.0% of total distance travelled (139). In the United States, in 2018, fewer than 3% and 1% of the population commuted to work on foot or by bike respectively (287). Commonly reported barriers to AT include the distance people must travel, lack of time, hilly terrain, and the undesirability of being out of breath or sweaty when arriving at a destination (146, 288).

E-bikes which require the rider to pedal for electrical assistance to be provided, are a more environmentally friendly and sustainable mode of transportation than motorised vehicles, while providing at least moderate intensity PA (289). Such bikes enable the user to maintain speed with less effort, overcoming some of the barriers to traditional cycling (166) and may encourage individuals to participate in AT in place of motorised travel. For this review only e-bikes that require the user to pedal for assistance to be provided are considered.

E-cycling is increasingly popular, with 40.3 million e-bikes expected to be sold globally in 2023 (290)**.** With this rise in popularity, it is important for authorities to understand where e-cycling fits within current mobility patterns. This will assist in decision-making regarding investment in e-cycling infrastructure and help determine whether strategies to promote e-cycling are appropriate. It is also important to ascertain whether adoption of e-cycling impacts the sedentary behaviour of motorised vehicle use by replacing some car journeys, potentially reducing both motor vehicle congestion and pollution. Or, if in contrast, e-cycling replaces conventional cycling and walking, therefore representing a distraction from the improvement of current cycling and walking infrastructure and initiatives that may increase AT.

An individual's transport mode choice depends on the travel need (e.g., commuting, shopping, escorting children) and specific trip attributes (including distance, location and time requirements (291)). It is therefore important to understand how e-bikes are used (regarding distances travelled and duration of rides) and the purpose of their use to understand the contexts in which e-bikes could be incorporated into current travel systems.

In addition to objective travel choices, the decision to engage in e-cycling is likely to be determined by a series of perceptions regarding the individual and the environment. Studies have begun to explore motivation for e-cycling and experiences of engaging in e-cycling to understand why individuals engage in this activity (166). To date, however, review evidence exploring the factors associated with e-cycling, and how engaging in e-cycling impacts travel behaviour, has not been conducted. Collectively, this information is important to guide future planning initiatives and health promotion campaigns.

A review of the literature will help to map the available evidence to document our current knowledge of how e-bikes are used (i.e., frequency and duration of e-cycling), the purposes for which e-bikes are used, their impact on travel behaviour and to identify potential determinants of e-bike use. In addition, a review will help identify gaps in the literature and highlight future research priorities.

4.3 Methods

Given the early stages of e-bike research (166), and the considerable breadth of the review purpose, a scoping review was deemed the most appropriate method of synthesising the literature (202, 207, 292). The most used framework for conducting and reported scoping reviews was proposed by Arksey and O'Malley in 2005 (205). Since this original publication, the framework has been extended to provide further methodological clarity, as encouraged by the original authors (206, 293). The current scoping review used the five-stage framework proposed by Arksey and O'Malley (205) and expanded by Levac, Colquhoun & O'Brien (206). Reporting of the scoping review followed the PRISMA Extension for Scoping Reviews guidelines to ensure reporting transparency, see Appendix 4.2 for completed checklist (294).

4.3.1 Stage 1: Identifying the research question

The aim of this review was to map the current evidence regarding how and why people use e-bikes, factors associated with e-bike use and their impact on travel behaviour. While wanting to maintain breadth with the research questions, as recommended by Arksey and O'Malley (205), there was a need to clearly define the outcomes of interest. Clearly articulating the scope of the inquiry is essential to ensure the scoping review remains focused (206). Five research questions were formulated to summarise the evidence. From the existing literature this review determined:

- What is known about the frequency and duration of journeys made by e-bike?
- What is known about the purpose of e-bike use?
- What is known about the impact of e-bike use on overall travel behaviour?
- What is known about individual's motivation for e-cycling, experiences of engaging in e-cycling (specifically barriers and benefits to engaging in e-cycling) and general attitudes towards e-bikes and e-cycling?[1]
- What are the current evidence gaps and research priorities?

[1] Examining barriers and benefits to engaging in e-cycling were initially the primary outcomes of interest to provide insight into factors that helped or hindered performance of the behaviour. However, it was acknowledged that prior to engaging in e-cycling an individual's way of thinking (i.e. their attitude) or motivation could impact the decision to initiate the behaviour (or not). As such, examining motivation and general e-cycling attitudes were important contextual factors required to gain deeper insight into e-cycling behaviour.

4.3.2 Stage 2: Identifying relevant studies

In line with recommendations, the search was kept broad both in relation to the search strategy used and sources considered for inclusion in the review (205). This degree of breadth was deemed feasible given the relatively early stage of e-bike research (166). The specific components of study identification are reported below.

4.3.2.1 Identify relevant outcomes

The review included studies that provided data/results relevant to any of the research questions. This included self-report or objective measures of the impact of having access to an e-bike on the use of the e-bike, alternative modes of transport and the purpose of e-bike trips (e.g., recreation, commuting, errands etc.). In addition, outcomes related to the motives for e-cycling, experiences of engaging in e-cycling and general attitudes towards e-bikes and e-cycling were included. Studies that reported future preferences for e-cycling, without having had access to an e-bike were not included as these data would not assess the actual impact of e-cycling.

4.3.2.2 Types of sources

Peer-reviewed primary research including both experimental (i.e., where e-bike access was manipulated by the researcher or other organisation) and non-experimental studies (i.e., no deliberate variable manipulation, participants had prior e-bike access). Cross-sectional and longitudinal quantitative and qualitative designs were considered for inclusion. Theses (PhD, MSc, MPhil or BSc), project reports or presentations and conference proceedings were considered for inclusion. Review articles were screened for appropriate references but not included in the review. Studies published in any language were considered. Editorials, opinion pieces and commentaries were not included as they were deemed very unlikely to contain primary research findings.

4.3.2.3 Types of participants

Studies with adults over 18 years of age, healthy or with long-term health conditions were included. Eligible adult participants were owners of an e-bike or had regular access to an e-bike (e.g., were part of an e-bike sharing scheme, rented an e-bike or were provided with an e-bike as part of an intervention).

4.3.2.4 Context

Only studies of e-bikes that had pedals and were operated in part by the individual (i.e., some amount of energy, above resting metabolic rate, must be expended when cycling) were included. Studies including e-bikes operated solely by a motor, not requiring pedalling, were excluded as they do not represent an opportunity to engage in PA and are likely to lead to different mobility patterns and be influenced by different factors than pedal assisted e-bikes.

4.3.2.5 Search strategy

The following databases were searched from 1989 (the date the first commercial e-bike was produced) to the present day: Elsevier ScienceDirect, ISS Web of Science, ProQuest, EMBASE, MEDLINE (via Ovid) and Scopus. These databases were chosen to cover a range of scientific fields. Search terms pertained to e-bikes only to keep the search as broad as possible. A list of search terms is provided in Appendix 4.3. OpenGrey and Google Scholar (first 20-pages) were searched using the term '*electrically-assisted bicycle*' to increase the chances of identifying unpublished reports or papers. The reference lists from all selected articles were hand-searched for relevant studies. Searches were run up to August 2019.

4.3.3 Stage 3: Study selection

All identified records were uploaded to the online software Covidence (https://www.covidence.org). Duplicate publications were removed, and two reviewers (JEB and ARC) independently conducted title and abstract screening. These reviewers met following completion of 20% and 50% of screening to assess agreement. Full texts were sourced, and when required, translation was conducted by individuals fluent in reading and speaking the required language in addition to English. Full-text screening was conducted independently by two reviewers (JEB and CE) who met at 25% and 50% of full text screening to assess agreement and resolve any conflicts. The use of two reviewers throughout the study selection phase is important to ensure all relevant research is included (206). Where findings from conference proceedings were superseded by a project report or published literature data from the earlier conference proceeding was not reported to ensure that the findings were not duplicated.

Scoping reviews are typically iterative given the increased familiarity of the researchers with the evidence as the review progresses (205). In the current review much of the evidence failed to report on the characteristics of the e-bikes being investigated. This was identified as a concern by both reviewers when conducting full text screening. Previous research has reported that the predominant e-bike design in North America, Australia and Europe includes pedals which the rider must use for power to be provided. However in China, e-bikes are predominantly throttle powered and do not require pedalling (166). As such, unless specifically stating the type of e-bike used, studies conducted in North America, Australia and Europe were included, while those conducted in China were excluded.

4.3.4 Stage 4: Charting the data

A data extraction chart was created and reviewed by all authors prior to data extraction. The chart was designed to be broad in nature to cover the range of different study designs, methods and results reported in the included literature. The following data were extracted from each article: author(s), year and type of publication, location, study aims, study design, study method, sample size and characteristics, outcomes measured and key findings. Data extraction was conducted by two reviewers in a stepwise fashion. Specifically, JEB extracted data from 100% of included studies and FJK then extracted data from 25% of these studies to check for accuracy. Any discrepancies were discussed and resolved.

4.3.5 Stage 5: Collating, summarising, and reporting the results

A descriptive analysis was conducted to provide information on the volume of included studies by year of publication, location of study, study method and outcomes examined. Where behavioural outcomes were examined using qualitative methods these results were incorporated into a descriptive summary. For motivation, experience and attitude outcomes examined using qualitative methods, the findings were characterised by identifying the main themes reported by authors. Common themes across studies are presented. The review of qualitative research to identify the main themes was conducted by two reviewers independently (JEB and FJK). Specifically, each reviewer read the qualitative analysis and extracted the main themes identified by the author. The reviewers met to compare and discuss extracted themes and to resolve any discrepancies that arose. A narrative summary is provided for each outcome reviewed. The meaning of the findings in relation to the overall research question and the broader implications for research, policy and practice is discussed, including identification of relevant evidence gaps and priorities.

4.4 Results

4.4.1 Articles retrieved

In total, 4043 records were identified from database and grey literature searches. After duplicates were removed 2841 records remained and underwent title and abstract screening (see Figure 4.1 for review flow diagram). A total of 181 articles underwent full test screening.

Of these, 61 articles were considered relevant to the aims and were included in the review. Reference lists of eligible studies were searched, and an additional 16 articles were identified for inclusion. Of the 77 articles for inclusion in the review one could not be sourced (295), leaving 76 for inclusion in the analysis.

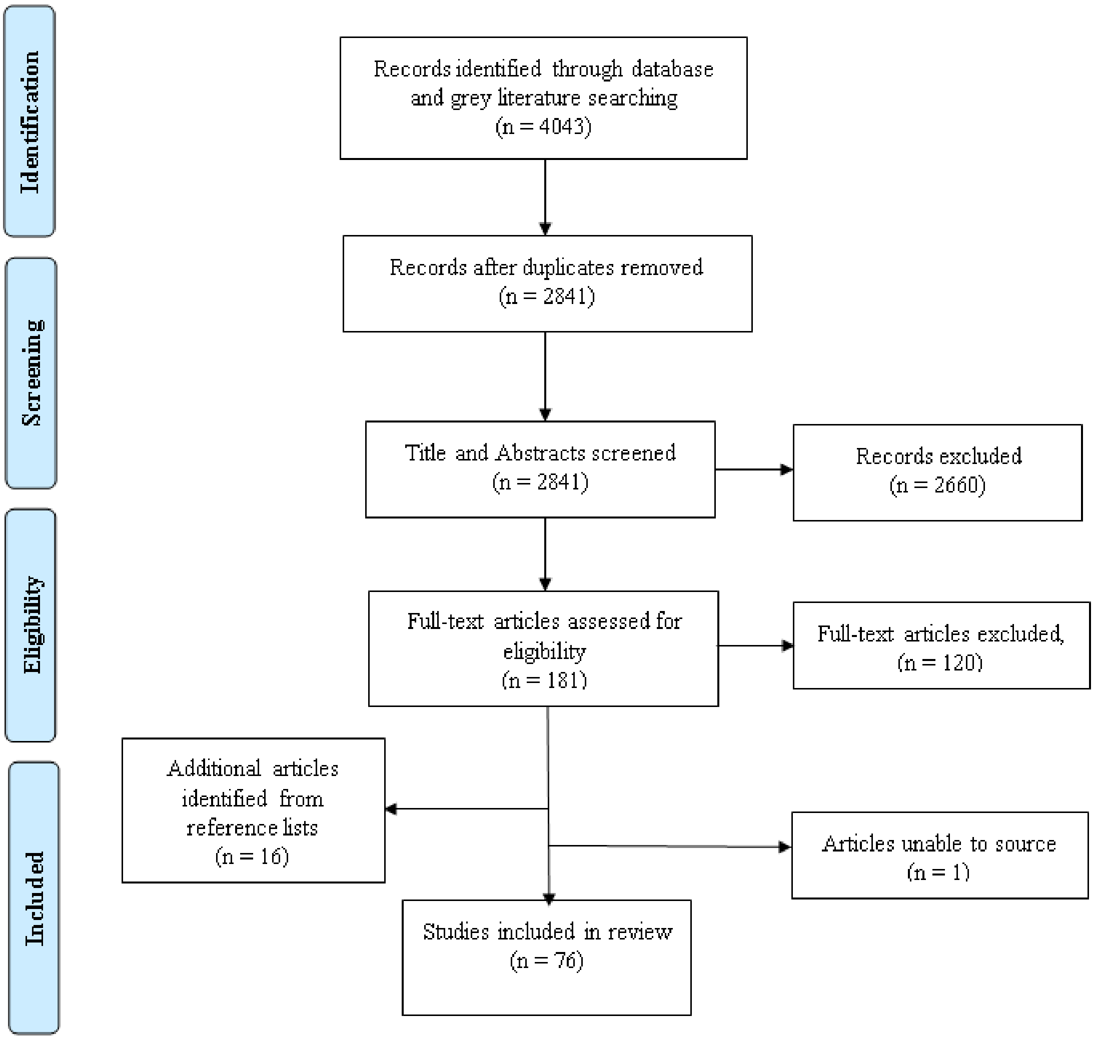

Figure 4.1 Flow diagram of scoping review article identification

4.4.2 Article characteristics

Articles were identified from 17 countries. A total of 80.3% of the articles originated from Europe (n=61), 17.1% from North America (n=13) and 2.6% from Australia and New Zealand (n=2). Five articles (6.6%) were published between 2003 and 2010, all of which originated from Europe, with the remaining articles (93.4%) published from 2011 onwards. Figure 4.2 shows the chronological increase in papers reporting relevant outcomes from 2003 to August 2019.

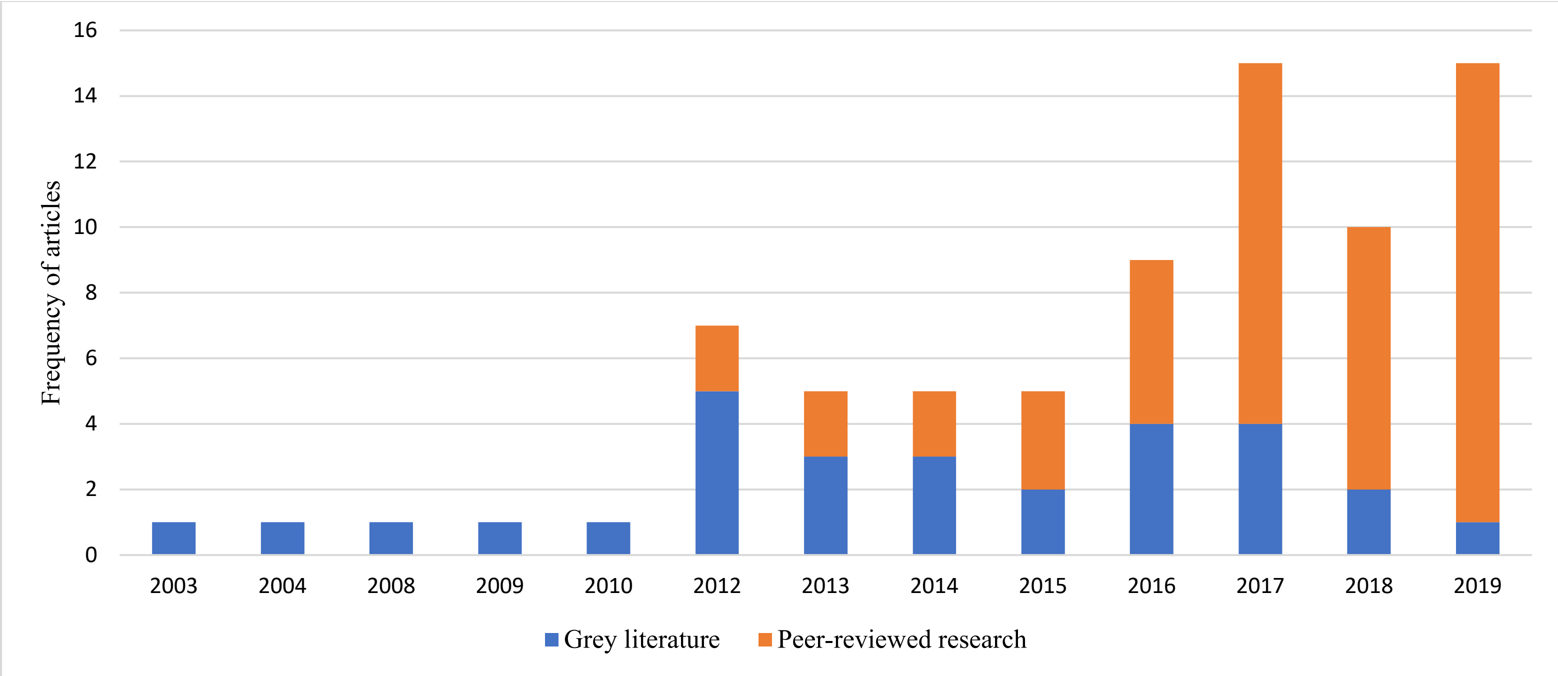

Figure 4.2 Included studies by year of publication and article type

Of the 76 articles, 48 were peer-reviewed research papers drawn from 40 studies, and 28 were from grey literature. Most of the peer-reviewed research has been published in transport related journals (see Table 4.1) and has increased substantially since 2017 (see Figure 4.2). The grey literature comprised five published conference proceedings, four theses, 17 project reports and two project presentations. Of the 68 unique studies identified 40 had a non-experimental design (30 cross-sectional, 10 longitudinal) and 28 were experimental. Most studies (n=65) examined outcomes associated with personal e-bike use. Eight studies examined the impact of e-bike share or rental schemes and three studies examined workplace e-bike initiatives.

Non-experimental studies: Findings from non-experimental studies on personal e-bike use (n=31) are reported in Appendix 4.4. One study examined the experiences of students' use of e-bikes and two explored e-cycling in older adults. The remaining studies did not specify participants' age; however, demographic data showed that most e-bike users were ≥40 years of age. The percentage of female e-bike users in the studies ranged from 15.0 to 56.0%. A 2014 survey of e-bike owners in USA reported 15.0% of the sample were female (232). When the survey was repeated in 2018, 28.0% of the sample were female (296). Samples sizes ranged from 11 to 1796. Nine studies compared e-bike use to conventional bike use. Non-experimental studies from e-bike rental/share schemes (n=8) and workplace e-bike initiatives (n=1) are reported in Appendix 4.5 and 4.6, respectively.

Experimental studies: The populations targeted by experimental studies examining personal e-bike use (n=26) were highly heterogenous (see Appendix 4.7). Populations studied included university staff and students (n=3), university students exclusively (n=1), older adults (n=1), inactive adults (n=4), individuals with T2DM (n=1), stroke survivors (n=1), company employees (n=4), commuters (n=4) and parents (n=1). Two studies provided families with electric vehicles on loan with the inclusion of an e-bike (297, 298). One study required participants to hand over the keys to their motor vehicle in exchange for an e-bike (299). E-bike loan periods varied in length from one day to three years. The percentage of females in experimental studies ranged from 0.0 to 80.0% and sample sizes ranged from three to 1854. Experimental studies from workplace e-bike initiatives (n=2) are reported in Appendix 4.6

Table 4.1 List of journals in which primary literature has been published

Journal	Number of articles published
Acta Kinesiologiae Universitatis Tartuenis	1
British Journal of General Practice Open	1
BMC Public Health	1
Clinical Journal of Sport Medicine	1
Diabetic Medicine	1
Environmental Research Letters	1
European Journal of Applied Physiology	1
European Journal of Sport Science	1
Frontiers in Psychology	1
International Journal of Sustainable Transportation	3
International Transportation	1
Journal of Advanced Transportation	2
Journal of Adventure Education and Outdoor Learning	1
Journal of Cleaner Production	1
Journal of Transport and Health	3
Journal of Transport Geography	2
Medicine and Science in Sport and Exercise	1
Mobilities	1
PLOSone	2
Preventive Medicine Reports	1
Sustainability	2
The Canadian Geographer	1
Transportation Research Record	1
Transportation	1
Transportation Research Interdisciplinary Perspective	1
Transportation Research Part A	3
Transportation Research Part D	3
Transportation Research Part F	1
Transportation Research Procedia	1
Transportation Research Record, Journal of the Transportation Research Board	4
Travel Behaviour and Society	3

4.4.3 What is known about the frequency and duration of e-bike use?

Sixty-one studies (80.3%) reported e-bike use following the acquisition of an e-bike, of which 44.3% were experimental (n=27). E-bike use was primarily measured using self-report online or paper questionnaires. Four non-experimental studies recorded e-bike use using GPS tracking and three with travel logs. Ten experimental studies used GPS tracking or bicycle odometer measurements and eight used travel logs including smartphone applications. The types of e-bike use outcomes reported were highly heterogenous with varying time scales and distance measurements reported.

Reported mean daily distances travelled on the e-bike ranged from 2.7km to 24.0km, with the majority of studies (n=20) reporting mean daily distances between 3.0km and 11.5km. Frequency of e-bike use ranged from 1.9 to 5.1 days per week. Haustein and colleagues (300) reported that recreational riders cycled further distances per trip compared to those that used the e-bike for utilitarian purposes (e.g., commuting, shopping, running errands). While Winslott Hiselius and colleagues (301) reported that e-bikes were used for commuting on 3.6 days per week and for leisure on 1.4 days per week.

Participants cycled longer distances on an e-bike compared to a conventional bike. In an RCT in which adults had access to an e-bike or conventional bike for three months the median distance cycled per week on the e-bike was 20.2km compared to 11.9km on the conventional bike, with individuals spending longer on the e-bike (62.7minutes) compared to the conventional bike (51.1minutes; (302)). Similarly, in a study conducted in seven European countries, Castro and colleagues (303) reported that e-cyclists average daily travel distance was 8.0km compared to 5.3km for conventional bike commuters. In addition, individual trip distances and duration of rides on e-bikes were longer than those on a conventional bike (303, 304). In several studies participants also self-reported increases in cycling frequency and/or duration following the acquisition of an e-bike (181, 264, 296, 298, 305).

The majority of evidence suggested that men ride an e-bike more frequently and further than women (171, 182, 252, 306-308). However, Cappelle (309) found that women ($mean_{age}$ =46 years) cycled more frequently than men, while Castro and colleagues (303) reported that more women were e-bike and conventional bike users than men in a sample of similar age.

Few studies have compared e-cycling between different age groups, of those that have the evidence suggested that younger adults cycled longer distances than older adults (306) and that as age increases there is a decrease in e-bike use (310).

In the workplace, e-bikes were used for work travel by employees in the two studies that provided e-bikes as company transport (298, 311). When e-cargo bikes were introduced as a replacement for conventional bikes or cars/vans in a two-year trial, 147 of 362 messengers rejected the adoption of the bike, with 48.3% reporting a preference to use the car or van (312).

Six of the eight studies examining e-bike rental/share schemes reported e-bike use. Distances covered on the e-bikes ranged from two to 10km. In the two studies that compared e-bike to conventional bike share, the authors reported that individuals travelled further on the e-bike than they did on a conventional bike (313, 314)

4.4.4 What is known about the purpose of e-bike use?

Forty-one studies (53.9%) reported on the purpose of e-bike use using mostly self-reported retrospective measures including questionnaires and travel diaries (41.5% experimental, n=17). E-bikes were used for a wide range of purposes including commuting, shopping, visiting friends and family and recreation. However, e-bikes appear to be used more frequently as a utilitarian mode of transport rather than for a leisure activity. Studies with samples aged ≤ 55years reported the e-bike being used primarily for commuting (169, 232, 296, 301, 305, 309, 315-320) whilst older adults used the e-bike for shopping and visiting friends but rarely for commuting. In addition, older adults used the e-bike for recreational purposes. Whether e-bikes were primarily used for recreation or running errands in older adults varied across studies (182, 264, 321-323). Few studies have examined how the purpose of e-bike use differs between genders. Among older adults Van Cauwenberg and colleagues (182) reported that women used the e-bike for more social visits than men.

In the workplace e-bikes were used for commuting, travelling between offices and to meet customers (298, 311). Of the three studies that examined the purpose of using an e-bike share scheme uses varied and included shopping, running errands, commuting to work or school or for recreation (313, 324, 325).

4.4.5 What is known about the impact of e-bikes on travel behaviour?

Forty-two studies (55.3%) examined the impact of e-bike use on other travel modes, of which 33.3% were experimental (n=14). The degree to which e-bikes replaced alternative transport modes varied across studies. However, the evidence suggests that the car and conventional bicycle were the most substituted modes of transport following acquisition of the e-bike.

The proportion of e-bike trips previously conducted by conventional bicycles ranged from 23 to 72% of total trips. Among older adults Van Cauwenberg and colleagues (182) reported that 72% of conventional bike trips were replaced by the e-bike, with those who were conventional cyclists prior to acquisition of an e-bike reporting greater e-bike substitution than non-cyclists (321).

The proportion of car journeys substituted following acquisition of an e-bike ranged from 20 to 86%, with three studies reporting the substitution of short car journeys with the e-bike[2] (298, 326, 327). E-bikes also substituted for public transport with the proportion of journey substitution ranging from 3 to 45%. Few studies have found e-cycling to impact walking with the exception of one study conducted in the UK in which low levels of driving and high levels of walking were reported prior to the provision of e-bikes compared to the rest of the country (170). In this study 38% of the sample reported a reduction in walking following the acquisition of an e-bike. Castro and colleagues (303) note that the impact of the e-bike on travel behaviour is largely influenced by the primary mode of travel prior to the introduction of the e-bike. Specifically, in Antwerp e-bikes primarily substituted for conventional bike journeys (34%) and private car journeys (38%), while in Zurich, the e-bike primarily substituted for public transport journeys (22%). Across the seven cities the authors reported that the degree of substitution of car, conventional bike or public transport journeys was 2 to 49%, 5 to 60% and 6 to 35% respectively. The mode of transport being substituted was still used extensively in addition to the e-bike. Winslott Hiselius and colleagues (301) reported that the impact of e-bikes on travel behaviour differed between rural and urban areas of Sweden. In rural areas the e-bike substituted 71 to 86% of car trips compared to 42 to 60% of car trips in urban areas. In urban areas the e-bike also substituted for conventional cycling and public transport. No studies have examined the differential impact of e-bike use on travel behaviour based on gender.

In the workplace e-bikes replaced car journeys or conventional cycling (298, 311). Regarding e-bike share or rental schemes on university campus 57% of walking trips were substituted with the e-bike (313), while in Madrid e-bikes substituted similarly for public transport and walking, the primary modes of city travel (324). In the UK 11 bike share projects, Bikeplus (314), reported that e-bike trips primarily substituted for car trips, the primary mode of transport in UK cities (328).

4.4.6 What is known about e-cyclists motivation for e-cycling?

Twenty-eight studies (36.8%) examined participants' motivation for riding or purchasing an e-bike, most of these studies were non-experimental (n=23, 82.1%). Motivation for using or purchasing an e-bike was commonly reported in relation to overcoming barriers to conventional cycling. These included the ability to overcome hilly terrain, to ride with less

[2] These studies do not provide a definition of what constitutes a short car journey

effort and to complete longer and/or faster trips. The ability to reduce travel time was an important motivational factor for younger adults. In addition, younger adults were more motivated to use an e-bike due to environmental concerns, to reduce car use and to save money compared to older adults. Older adults were motivated to e-cycle as it provided them with the ability to continue to ride despite physical limitations and the potential to maintain or increase PA and fitness. Few studies examined differences in motivational factors between genders. However, MacArthur and colleagues (232, 296) reported that females were more likely to buy an e-bike to overcome hilly terrain and to ride with friends and family compared to men.

In the workplace, motivation for e-cycling included sustainability and better mobility around the city (311) and a preference for e-cycling over using the car or conventional bicycle (298). Of the two studies that reported on motivation for using e-bike share schemes, the primary motivation for use was that e-cycling was faster than alternative transport modes, thereby reducing travel time and being more convenient (313, 314).

4.4.7 What is known about the experience of engaging in e-cycling?

4.4.7.1 Benefits of e-cycling

Forty-three studies (56.6%) explored participants reported benefits of e-cycling, the majority were non-experimental (n=25, 58.1%). Table 4.2 provides an overview of the reported individual, social and physical benefits of e-cycling. Participants discussed the benefits of e-cycling in comparison to other transport modes. Specifically, e-cycling required less physical effort than conventional cycling due to the assistance provided and was associated with reduced perspiration. The extra assistance, and reduced effort, enabled participants to travel longer distances and/or decrease their travel time in comparison to conventional cycling. E-bike users were able to ride hilly terrain and take more direct routes to their destination. E-cyclists felt safer and more confident riding an e-bike on busier streets in comparison to a conventional bike due to the ability to keep up with traffic and accelerate faster at traffic lights. E-cycling saved time compared to the car or conventional bike and was perceived as being less restricted by parking or congestion compared to motorised transport.

The e-bike enabled individuals who cannot ride a conventional bicycle to begin riding or who were considering giving up conventional cycling to continue riding. The only reported social benefit of riding an e-bike was the ability to ride with friends and family. Specifically, e-bikes removed differences in riding abilities due to fitness or physical limitations between riders enabling unfit individuals to keep up with fitter individuals riding a conventional bike.

The enjoyment and fun associated with e-cycling was the most consistently reported benefit across all studies.

Few studies examined differences in perceived benefits of e-cycling based on age or gender. Van Cauwenberg and colleagues (182) found no differences in reported benefits of e-cycling between older men and women. Regarding age, in three studies that focused exclusively on older adults (182, 321, 329) the ability to cycle longer distances was a consistently reported benefit. In studies with younger samples (i.e., 40 to 60 years of age) the time savings accrued from e-cycling, in comparison to conventional cycling and a car was a common benefit, with e-cycling providing more predictable journey times.

Similar benefits of e-cycling were reported in workplace initiatives. In addition, participants reported greater autonomy in comparison to travelling by public transport or carpooling and the e-bike enabled easier access around the city, avoiding parking problems (298, 311). In Madrid, the e-bike share scheme provided a faster and more economical mode of transport in comparison to walking or public transport (324). In a rental scheme in the UK, e-bikes provided participants the opportunity to ride with friends and family and those of higher fitness levels than themselves (330).

Table 4.2 Benefits of e-cycling, (the number in brackets represents the number of studies reporting that specific benefit)

Individual	Social	Physical	
Fun/enjoyment (21)	Ability to ride with friends and family (12)	Ability to ride longer distances than conventional cycling (20)	Most commonly reported
Reduced perspiration in comparison to conventional cycling (15)		Faster journeys compared to conventional cycling, walking and sometimes cars (18)	
Reduced overall effort in comparison to conventional cycling (12)		Ability to ride hilly terrain (12)	
Improved health (physical and mental) (9)		Time saving in comparison to conventional bicycle or car (8)	
Ability to continue to cycle despite physical limitations (8)		Ability to ride new routes and to new destinations due to speed and less impact from terrain (9)	
Increased feelings of safety in comparison to conventional cycling (6)		Ability to carry heavier loads (17)	
Increased physical activity (6)		Lower environmental impact (9)	
Increased confidence riding in traffic compared to conventional cycling (5)		Ability to combat weather conditions compared to conventional bicycle; less impact from wind (7)	
Increased feelings of autonomy over travel in comparison to public transport or car (2)		Cost savings (6)	
		Less concern regarding parking or traffic (3)	Least commonly reported
		Ease of use (3)	

4.4.7.2 Barriers to e-cycling

Thirty-seven studies (48.7%) explored participants barriers to e-cycling, with the majority of studies being non-experimental (n=22, 59.5%). Most of the barriers reported related to the e-bike itself or the environment (see Table 4.3). Regarding the environment e-bike users felt unsafe riding with motor vehicles due to risk of accidents. In addition, users were concerned about riding alongside conventional cyclists and pedestrians due to potential conflict. Lack of, or poorly maintained, cycling infrastructure exacerbated these safety concerns. For individuals commuting into the city, lack of charging or parking facilities were barriers to riding. The weather, particularly rain, was a commonly reported barrier to e-cycling.

Regarding the e-bike, users felt anxious about the distance they could travel before the battery ran out of charge. Cycling the e-bike without power was not seen as favourable due to the weight of the bike. In addition, the weight of the bike made it difficult to lift onto cars or public transport and to make repairs. E-bike weight was a greater concern for older adults and women. E-bike users also reported that technical problems were hard to repair themselves or expensive if requiring a mechanic. Maintenance was the most commonly reported barrier to e-cycling for individuals who rode to commute or run errands, while issues with battery life were the greatest concern for recreational cyclists (300). The cost of buying an e-bike and replacing batteries was a barrier to some users, particularly younger adults. Due to the high value of e-bikes users were concerned about theft and therefore carried their e-bike batteries with them when not on the bike.

E-bike users highlighted a general perception of e-bikes being for lazy or overweight individuals and were worried about being judged by others. Younger adults, of working age and who were accustomed to conventional cycling were more likely to report this barrier than older adults. Similarly, the reduced PA when e-cycling, compared to conventional cycling, was a barrier for younger individuals.

Some differences in e-cycling barriers were reported across countries. Specifically, in the Netherlands conflict with other cyclists was a barrier to e-cycling, while in the UK the lack of cycling infrastructure and poor parking facilities were commonly reported barriers (331).

Prill (311) reported similar barriers to e-bike use in their workplace e-bike initiative. In addition, if participants had multiple appointments to attend the e-bike was not seen as appropriate. Participants in Malmo, Sweden reported that e-bikes were not well maintained by the organisation and batteries were left uncharged (298).

Table 4.3 Barriers to e-cycling, (the number in brackets represents the number of studies reporting that specific barrier)

Individual	Social	Physical		
		Environmental	E-bike specific	
Less physical effort and PA than conventional cycling (5)	Theft concerns (15)	**Safety concerns** • riding in car traffic (17) • riding with conventional bicycles and pedestrians (6)	**Battery concerns** • Range anxiety (19) • Charging issues: Remembering to charge, not practical, time (5) • Heavy/awkward to carry (3) • Battery life not as long as proposed by manufacturer (2)	Most commonly reported
Getting too sweaty (2)	Social stigma, e-bikes as cheating (8)	**Cycling infrastructure** • Lack of/poor maintenance of cycle lanes (11) • lack of charging stations (2) • lack of parking facilities (3)	**Cost** • E-bike itself (14) • Replacing battery (3)	
Fear of falling (1)	Regulation over where e-bike can be used (3) – North America specific	Weather (especially rain) (13)	**Weight** • Of e-bike (17) • Riding when battery is dead (5)	
Unable to ride due to health (1)		Hard to integrate with public transport (2)	Hard and expensive to repair and maintain, technical difficulties (14)	
		Hard to integrate multiple destinations, easier and faster by car (2)	**Design of e-bikes** • Limited load capacity (4) • Too few gears (2) • Gear box issues (1) • Not designed to carry children (1)	
		Time constraints, faster by car (2)	Too slow (5)	Least commonly reported
			Uncomfortable (4)	

Regarding e-bike share schemes, barriers were similar to those reported for personal e-bike use. In Madrid, users believed that the geographical coverage of the e-bike share scheme was a barrier to use (324). For some users the cost of the schemes were prohibitive to use (324, 330).

4.4.7.3 What is known about general attitudes towards e-bikes and e-cycling?

Overall participants were satisfied with the experience of e-cycling. de Kruijf and colleagues (332) reported that when e-cycling is perceived as less strenuous it is associated with greater satisfaction, which relates to greater frequency of e-cycling. Dissatisfaction with e-cycling derived from environmental concerns due to poor cycling infrastructure and parking facilities and factors related to the e-bike itself which included poor range and the weight of the e-bike.

Prior to riding an e-bike there was a degree of scepticism associated with e-cycling and a judgement regarding the members of the population for whom e-bikes were designed for. Specifically, e-bikes were perceived as being for older, overweight or lazy adults. However, in one study elderly individuals perceived e-bikes as being for young, active individuals (309). These perceptions are dynamic with experimental studies reporting that attitudes towards e-bikes become more positive with increased use (327, 333, 334). Stromberg and colleagues (335) report that their sample of previous conventional cyclists saw the e-bike as a mode of transportation and not a form of exercise. Similarly, Haustein and colleagues (300) report that utilitarian e-cyclists appreciate the practically of e-cycling for daily transport and picking up children and shopping. Among e-bike share/rental schemes and workplace initiatives similar attitudes to e-bikes were reported.

4.5 Discussion

This review aimed to understand what is known about how e-bikes are used, the purpose of their use and their impact on travel behaviour. In addition, the review aimed to provide insight into the motivation for e-cycling, experiences of engaging in e-cycling and general attitudes towards e-bikes and e-cycling to identify the potential mechanisms that promote or inhibit e-bike use.

4.5.1 E-cycling and travel behaviour

The evidence suggests that e-bikes increase the total frequency and distance travelled by bicycle and promote longer individual cycle trips, compared to a conventional bicycle. E-bikes appear to substitute for 23 to 72% of conventional bike journeys and 20% to 86% of private cars journeys. While previous research has suggested that conventional bicycles can substitute for private car journeys (336, 337), the degree of substitution may not be as high as that seen for e-bikes, with Hatfield and Boufous (338) reporting that recent conventional bicycle trips replaced 33% of car travel in a sample of Australian adults.

The degree to which e-bikes substitute for alternative transport modes largely depends on the primary mode of transport prior to the introduction of the e-bike (170, 303). Findings of the current review suggest that participants in cities with high levels of cycling often report a shift from conventional cycling, as well as car use, to e-cycling (264, 300, 326, 339, 340). While in cities or countries with low levels of cycling the primary transport shift is from car to e-bike (296, 316, 321). As such, interventions should be directed towards areas of high car use to have the most potent impact on population health and road traffic reduction. In many countries, including the UK, the USA, and Australia most journeys are made by car and for relatively short distances (328, 341, 342). In England, for example, 61% of all journeys are completed by car, of which 68% of these are less than five miles in length (328). These short car journeys have a higher impact on air pollution and carbon dioxide emissions per mile than longer journeys (343). Given that most e-bike users travel approximately seven miles per day, longer than the distance individuals report being willing to travel by conventional bicycle (344), e-cycling could positively impact the environment through the replacement of motorised vehicle use to a greater extent than conventional cycling. For individuals substituting private motorised transport or public transport trips for e-bikes there is a significant increase in weekly energy expenditure, which could positively impact health (303).

While e-cycling substitutes for conventional cycling, individuals switching from conventional cycling to e-cycling still accrue enough PA to meet the current guidelines for significant health benefits, due to increased frequency and duration of e-cycling (303). Furthermore, individuals switching from conventional cycling to e-cycling may be prolonging their cycling engagement as physical limitations or health concerns mean these individuals consider replacing conventional cycling with car journeys. This is commonly reported among older adults (321, 329).

In the workplace, the evidence suggest that e-bikes hold potential to substitute for conventional bicycles or cars, however the decision to adopt an e-bike is highly dependent on work requirements and corporate support of maintenance. Research into the impact of e-bike share or rental schemes is increasing as more e-bikes are integrated into bikeshare systems (345). Similar to the findings from conventional bike share schemes (345), e-bikes substitute for a range of transport modes, including walking, public transport and cars, depending on the primary mode of transport in that city. The distance travelled with shared e-bikes is slightly lower than that for private e-bike use. This is not surprising given the bike share systems are introduced in prespecified geographical areas to reduce use of motorised vehicles and enable quick access from one area to another within this location. Therefore, they are bound by the constraints of the prespecified range in which the e-bikes can be used and serve a different purpose to private e-bike use.

4.5.2 What influences e-cycling?

Individuals engage in e-cycling due to a range of benefits that make e-bikes more appealing than conventional bicycles. These benefits also motivate individuals to purchase an e-bike and serve a specific travel demand, such as carrying more cargo, reducing travel times, or travelling further. Younger adults are largely motivated to ride e-bikes due to the environmental benefits and to reduce outgoings through decreased car use, while older adults are motivated to ride e-bikes due to potential health benefits. As such, future e-bike promotion campaigns should aim to target these populations with different messages, specific to these benefits. In countries with both high and low levels of cycling there was a social stigma associated with e-cycling (305, 320, 329, 331, 340, 346). This suggests that even in areas with a positive cycling culture such as Portland (USA) and the Netherlands this positive perception may not currently extend to e-bikes which are perceived as being for lazy and/or overweight individuals. Given that social and cultural norms impact levels of cycling (347), it is important that local authorities engage in initiatives to promote e-cycling as a 'normal' mode of transport. This could be achieved through the provision of e-bikes to individuals on trial periods as this review suggests that the negative perceptions of e-cycling often dissipate following engagement with e-cycling (327, 333, 334, 340). This strategy could help to normalise e-cycling and encourage e-bike sales.

The most frequently reported environmental barrier to e-cycling was concern regarding safety, specifically when riding in motorised traffic or with vulnerable road users (i.e., pedestrians or conventional cyclists). In the current review there are contradictory results of how the speed associated with e-cycling impacts safety perceptions. Specifically, in some studies participants reported feeling safer riding an e-bike than a conventional bike due to an ability to keep up with traffic and avoid potential accidents (305, 327, 348), while in other studies participants reported that the e-bikes speed created dangerous situations, therefore, negatively impacting safety perceptions (183, 316, 331, 349, 350). Interestingly, it is the speed associated with e-cycling that contributes to increased excitement and confidence on an e-bike (183, 296).

The speed, and use of infrastructure designed for motorised vehicles as opposed to shared pedestrian paths or cycles ways, has been reported to lead to more conflict between e-bikes and motorised vehicles than conventional bicycles (183, 351, 352). Interviews with e-bike users in USA showed that e-cyclists were concerned that motor vehicles underestimated the speed of the e-bike due to an inability to distinguish the e-bike from a conventional bike (316). This is supported by video analysis by Dozza and colleagues (352) who suggest that while e-bikes look like conventional bicycles their increased speed means drivers have less time to see them or react to them. However, a recent study suggested that after controlling for the amount of cycling (therefore exposure to potential incidents) and age there is no difference in crash risks between conventional bicycles and e-bikes (178).

Interestingly, regular e-bike users are less likely to report traffic incidents than individuals who use an e-bike for a limited period or have less experience (183). This suggests that experience may reduce likelihood of traffic incidents. In the current review, e-bike owners tended to report fewer safety concerns than non-users (353). Furthermore, countries with low levels of cycling such as Canada, the UK and the USA had more frequent reporting of barriers associated with safety due to poor infrastructure and riding with traffic than countries with high levels of cycling (296, 300, 316, 329, 331, 349). It is therefore important that potential e-bike users are provided with training on how to safely ride and manoeuvre an e-bike in a low traffic environment to help build confidence and to reduce the likelihood of traffic incidents. Furthermore, local authorities should examine how they can best invest in e-cycling infrastructure to help reduce conflict between different road users.

Additional environmental barriers to e-cycling include poor cycling infrastructure, difficultly integrating bicycles with public transport and limited end of trip facilities. These are similar to the environmental barriers reported for conventional cycling (147) and require collaboration between local authorities and organisations to help improve cycling infrastructure. Barriers specific to the e-bike, including the weight and battery life should be addressed through the provision of suitable e-cycling infrastructure such as charging stations and adapting public transport to incorporate e-bikes. E-bike manufacturers have an important role in streamlining e-bike technology and continuing to reduce the weight of e-bikes.

Overall, e-cycling was more common in men than women, a similar pattern to conventional cycling (147). However, in the current review women were more likely to be e-bike owners than men (310). It is possible that women are encouraged to purchase an e-bike due to the anticipated benefits but are more fearful to ride it due to the lack of cycling infrastructure. In countries with high levels of cycling and good cycling infrastructure, such as the Netherlands and Denmark, the mode share of cycling is higher in women than men (143, 347, 354). This was seen in one experimental study conducted in Belgium in which women e-cycled 13% more than men (309). As such, with the provision of appropriate cycling infrastructure more women may be encouraged to ride an e-bike. E-bike use findings suggest that e-bikes are used more frequently for commuting to work compared to leisure use. However, the distance of commuting journeys is less than during leisure rides (300, 301). As such, the total distance ridden across a week maybe similar between leisure riders and commuters, but the pattern of use is different which may vary by life stage. For example, Hendriksen (264) reported that individuals > 65years, mostly leisure riders, rode on average 25.3km per week, while commuters rode 39.4km per week. Interestingly, there were no differences in the purpose of e-bike use between countries with high or low levels of cycling. Understanding the purpose for which e-bikes are used is important for local and/or national policy decisions regarding AT, including e-bike promotion campaigns and for the provision of e-bikes particularly where individuals do not own the e-bikes.

4.5.3 Research gaps and priorities

The study has identified several gaps in the current literature and provided future research priorities. These are outlined in detail in Table 4.4. Specifically, research priorities include a) conduct experimental research to examine the impact of adopting e-cycling on travel behaviour in non-cyclists; b) use objective measures to collect data on e-bike use and travel behaviour; c) conduct longitudinal research to examine the causal impact of individual, social and physical factors on e-bike use and travel behaviour; d) examine the extent to which e-bike availability impacts travel behaviour; e) examine the potential for e-bikes to serve as company vehicles and f) evaluate whether e-bike sharing systems impact alternative travel behaviour.

Table 4.4 Future research priorities for understanding e-bike use and travel behaviour

Research priority	Why required
Objective measures of e-bike use and travel behaviour using GPS or smartphone tracking prior to and during e-bike access to quantify the impact of e-bikes on travel behaviour	Current evidence relies primarily on self-report, retrospective measures of travel behaviour
Longitudinal research to examine the causal impact of individual, social and physical determinants associated with e-bike use and travel behaviour	Current evidence provides a qualitative understanding of potential determinants of e-cycling. No studies have examined the individual, social and physical factors directly associated with e-bike use and travel behaviour through quantitative estimates
Research to examine the effect of e-bike availability on travel behaviour by age, sex and socio-economic status	Few studies have examined the impact of demographic outcomes on e-bike use, travel behaviour or the purpose of use
Experimental research to examine the effects of e-bike availability on travel behaviour in individuals less familiar with e-cycling	Most of the research to date has been conducted with e-bike owners or those familiar with cycling. Individuals unaccustomed to e-cycling will likely display different patterns of use and possess different attitudes and experiences of e-cycling
Research to examine the potential of e-bikes to serve as company vehicles and replace cars or light goods vehicles for deliveries	Limited research in this area. This is an important area of research as 36% of all car journeys made in England in 2017 were for commuting or business purposes and light commercial vehicles were the fastest growing motor vehicle in the UK in the last 25 years
Evaluation of the addition of e-bikes to bike share systems and their impact on alternative transport	Limited research in this area. It is important to ascertain whether the provision of these, more expensive products, is a valuable strategy to increase bike use

4.5.4 Implications for policy

The evidence presented suggests that e-cycling has the potential to positively impact the environment, through reduced motorised vehicle use, and individual health, through increased or prolonged cycling. However, without the inclusion of e-cycling as a standalone category in NTSs it is hard to fully comprehend the extent to which e-cycling substitutes for other transport modes. As such, discussion is required among local and national authorities and researchers to discuss whether the current evidence is strong enough to encourage the promotion of e-cycling as an alternative to motorised transport and to identify what further evidence maybe required to direct and inform policy. Experts should review the psychological factors associated with e-cycling reported here to prioritise schemes that can help to promote e-cycling and reduce motorised vehicle use in areas where motorised vehicle use is currently high.

4.5.5 Study strengths and limitations

This is the first review to comprehensively explore how e-bikes are used, their purpose of use and impact on travel behaviour and to identify the volume of this evidence. In addition, the review has documented the factors associated with e-cycling and identified key future research priorities. A key strength is the appropriateness of the method used to address the research aims, allowing a broad and informative scope of a wide field of literature. In addition, rigorous methods to searching, screening and data extractions were applied and followed the established PRIMSA scoping review extension checklist.

There are, however, some limitations to consider. Scoping reviews are broad in nature and while they provide an overview of existing literature formal assessment of study quality is not conducted (205, 206).While the purpose of a scoping review is to identify all available literature, regardless of quality, determining what gaps lie in the evidence base can be difficult if the quality of the current evidence is not defined. This has led some researchers to suggest that some form of quality assessment should be completed as part of the review process (293). However, this will present challenges when decided how to assess study quality due to the broad range of study designs and methods included (206).

Another proposed method of increasing the rigour of a scoping review is to conduct a consultation with key stakeholders, following preliminary collation of findings, to provide additional perspectives to the results and identify the applicability of the review. While this consultation process (Stage six in the Arksey and O'Malley framework) is considered optional, others suggest that it is a key element of the scoping review process (206, 293). However, there is limited guidance on how or why to consult stakeholders and how to analyse or incorporate the results into the review (206). In the current review, consultation could have involved identifying a cohort of e-bike users and sharing the findings with them to gather their expertise and perspectives on the findings. However, given the lack of guidance available regarding how to integrate this information and the limited time available this was not conducted as part of the current review.

In addition, while the search terms were broad it is possible that some relevant articles were missed. Studies conducted in China were excluded as most e-bikes in China do not require pedalling for assistance to be provided. This exclusion could have meant that some relevant studies were omitted.

Given the heterogeneity of outcomes reported it was not possible to quantitatively synthesise the literature, making comparisons between studies difficult. The authors have attempted to report the results in an objective way and provide sufficient detail for readers to draw conclusions regarding the evidence. Furthermore, when reviewing qualitative research, extraction of common themes was guided by the authors' interpretation of the findings and their identified themes. The themes may have been different to those identified by other qualitative researchers.

4.6 Conclusion

This scoping review identified 76 studies that examined the role of e-cycling on a variety of behavioural and psychological outcomes. The research consistently demonstrated that e-bikes serve to increase cycling frequency and duration and can substitute for motorised transportation particularly short car journeys. With half of all car journeys in the UK being between one and five miles in length (355) e-bikes represent a viable sustainable alternative means of transport for a large proportion of car journeys.

4.7 Contribution to this thesis

This review identified a series of gaps in the current evidence that will be addressed in study three. Firstly, the review shows that research collected to date has relied on self-reported measures of travel behaviour and mode substitution following e-bike acquisition. While reliably providing contextual information, such as travel mode and purpose (356), self-reported measures are less reliable when assessing trip frequency and duration (99, 356, 357). Objective measures of e-cycling and travel behaviour are needed to develop a greater understanding of how the provision of an e-bike influences mobility behaviour. This finding led to the decision to measure travel behaviour using both GPS and travel diaries in study three to assess a) whether individuals are willing and able to adhere to these data collection methods and b) examine e-cycling behaviour and its impact on other transport use.

Secondly, the review highlighted the scarcity of research examining prospective longitudinal changes in travel patterns following acquisition of an e-bike. To address this gap, study three will use a pre-post experimental design to objectively measure e-cycling and travel behaviour before and while having access to an e-bike. This will provide a quantitative measure of modal shift associated with e-cycling.

Thirdly, in the current review over 50% of the research included explored the behaviour and beliefs of e-bike owners or regular users. Referred to as early adopters of e-bikes due to their exposure to a growing range of e-bike products and specialist e-bike stores (305, 358), this population is likely to have different motivations, beliefs, and experiences of e-cycling to those unfamiliar with cycling. To have a significant impact on public health, individuals who are less familiar with cycling need to be encouraged to engage in e-cycling. Study three will address this gap with the provision of e-bikes to adults with T2DM and objectively measure travel behaviour. In addition, qualitative research will be conducted to examine how this population experience e-cycling, with a particular focus on identifying the barriers and facilitators to engagement. This qualitative component will provide insight into the potential determinants of e-cycling in this population. Combining this qualitative examination of e-cycling and using objective measures of travel behaviour will enable the development of a deeper understanding of how e-cycling experiences directly impact behaviour in this specific population. This information will help guide future e-cycling initiatives and identify the appropriate individual, social and environmental factors that should be addressed to promote e-cycling.

Fourthly, the review highlights a limited amount of research examining differences in e-bike use based on gender. Therefore, study three will aim to recruit an equal number of males and females to gain insight in differences in e-bike use and e-cycling experience.

Overall, study three will begin to address some of the research gaps identified in study two, helping to expand the body of evidence examining how e-bikes are used, their potential for modal shift and identifying potential determinants of use, specifically in a clinical population who engage in low levels of PA and AT (226).

5 Chapter 5: Background and methods for a randomized controlled pilot study exploring e-cycling among adults with T2DM

5.1 Overview

Chapter 5 explores the impact of lifestyle interventions, with a focus on community-based interventions, on increasing PA behaviour in adults with T2DM through a review of the literature. The chapter presents the rationale for conducting a community-based e-cycling intervention in this population, reports on patient and public involvement (PPI) work conducted to inform intervention design, and outlines the methods used to examine the potential of the intervention to increase a range of health and behavioural outcomes. In depth information on the methods and associated results are provided in Chapters 6, 7 and 8. The published protocol for the study is available in Appendix 5.1. Aspects of the methods and discussion presented here are a reproduction from the protocol paper. Deviations from the original protocol are detailed and justified.

5.2 Literature review

5.2.1 T2DM: Incidence, diagnosis, and pathology

T2DM is a metabolic disease characterised by the progressive worsening of insulin sensitivity (primarily in the skeletal muscle, adipose tissue, and liver) and of pancreatic beta (β) –cell functioning, resulting in fasting and postprandial hyperglycaemia. T2DM accounts for 90 to 95% of all cases of diabetes around the world (359, 360). The WHO (361) most recent diagnostic criteria for diabetes include glycated haemoglobin (HbA1c, which represents glucose control over the previous three months) of ≥ 48mmol/mol (6.5%), a fasting blood glucose value of ≥7.0 mmol/L and/or a two-hour post oral glucose tolerance test (OGTT) blood glucose of ≥11.1 mmol/L.

Despite a diagnosis of T2DM based on discrete thresholds of glucose regulation progression towards T2DM can be viewed on a continuum of glycaemic dysregulation that can begin up to 10-years before diagnosis (362). The WHO recognises two categories of abnormal blood glucose regulation that exist between normal glucose homeostasis and diabetes, known as intermediate hyperglycaemia or prediabetes. These categories include impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) in which individuals have higher than normal blood glucose, but values below the diagnostic cut-off point for

T2DM. Individuals with intermediate hyperglycaemia are at increased risk of CVD and developing T2DM (363).

By 2040, approximately 642 million individuals worldwide will be diagnosed with diabetes, of which 90% will be T2DM (364). In 2019, the prevalence of diagnosed T2DM in the UK was approximately 4.2 million, with an expected rise to in excess of five million by 2030 (365). However, given the often lack of symptoms, many incidences of T2DM remain undiagnosed for several years (361). T2DM is progressive in many people and as the disease progresses after diagnosis, hyperglycaemia becomes increasingly hard to treat, requiring intensification of glucose-lowering medications. It is this chronic hyperglycaemia that is associated with many of the complications discussed below. As such, the primary aim of T2DM treatment is to tighten glycaemic control by reducing hyperglycaemia. Using computer simulation modelling, (IMS Core Diabetes Model of Type 2 Diabetes; (366)) of the 2014 UK T2DM population, Baxter and colleagues (367) reported that improvements in glycaemic control could generate savings of £299 million over five years due to reductions in diabetes associated complications.

5.2.2 Complications of T2DM

Chronic hyperglycaemia, characteristic of T2DM, is associated with negative micro- and macrovascular complications. Microvascular complications affect small blood vessels including the capillaries, arterioles and venules and include nephropathy (kidney disease or damage), neuropathy (nerve damage) and retinopathy (damage to the eyes) (368-370). The development of hypertension is also associated with nephropathy (371). Macrovascular complications affect the larger blood vessels, including arteries and veins and include atherosclerosis (i.e., the build-up of plaque on the walls of the arteries, causing them to narrow) of the arteries in the brain (cerebrovascular disease), heart (coronary heart disease) and limbs (peripheral vascular disease), impairing blood supply to these tissues (372-374). The risk of coronary heart disease or major stroke is at least double in individuals with T2DM compared to those without (375) and is a leading cause of death in this population.

In addition, T2DM can lead to significant reductions in quality of life and the onset of depressive symptoms (376, 377), which can have a negative impact on the lives of both diagnosed individuals and their families (378). T2DM puts considerable strain on the health care system with an estimated 10% of the NHS yearly budget being spent on the treatment of diabetes. Eighty percent of this budget is attributed to treating the potentially avoidable complications associated with the disease (379).

5.2.3 Risk factors for the development of T2DM

The development of T2DM represents an interaction between genetic and environmental factors (380). Many risk factors are unmodifiable, including sex, age (361), ethnicity (381), family history of diabetes (382, 383), history of gestational diabetes (384), low birth weight (385), preterm birth (386) and depression (387). However, there are several risk factors that are modifiable as outlined in Table 5.1.

Table 5.1 Modifiable risk factors for the development of T2DM

Modifiable risk factor	Evidence
Unhealthy diet	Esposito et al (388) conducted a meta-analysis of 18 prospective studies and found that the risk of T2DM was 20% lower amongst individuals who displayed healthful dietary patterns, i.e., the cumulative effects of overall diet (RR[95%CI], 0.80[0.74, 0.86]).
Sedentary time	Biswas et al (389) conducted a meta-analysis of five prospective studies and found that individuals with the highest amount of sedentary time were nearly twice as likely to develop T2DM as those with the lowest amount of sedentary time (HR[95%CI], 1.91[1.66, 2.19]).
Physical inactivity	Aune et al (35) conducted a meta-analysis of 14 prospective cohort studies and found that the risk of T2DM was 35% lower among adults with high versus low total PA (RR[95%CI], 0.65[0.59, 0.71]). Similarly, Jeon et al (390) found that the risk of T2DM was 31% lower amongst adults in the highest compared with the lowest category of MPA (RR[95% CI], 0.69[0.58, 0.83]) in their meta-analysis of 10 prospective cohort studies.
Obesity	Abdullah et al (647) conducted a meta-analysis of 18 prospective cohort studies and found that the RR of T2DM was 2.99 (95%CI, 2.42, 3.71) in overweight adults compared to normal weight controls and 7.19 (95%CI, 5.74, 9.00) in obese adults, compared to normal weight controls. Kodama et al (391) found that for every one standard deviation increase in BMI there was a 55% increased risk of T2DM (RR[95%CI], 1.55[1.43, 1.69]).
Waist circumference	In a meta-analysis of 25 prospective cohort studies, Kodama et al (391) found that waist circumference, a measure of central adiposity, was more strongly associated with risk of T2DM than BMI (reported above). Specifically, there was a 63% increased risk of T2DM for every one standard deviation increase in waist circumference (RR[95%CI], 1.63[1.49, 1.79]).
Smoking status	Pan et al (392) conducted a meta-analysis of 88 prospective cohort studies in adults and found that the risk of T2DM was 37% higher in current smokers compared with non-smokers (RR[95%CI], 1.37[1.33, 1.42]).

BMI=body mass index; CI=confidence interval; HR=hazard ratio; MPA=moderate intensity physical activity; PA=physical activity; RR=relative risk; T2DM=type 2 diabetes mellitus

5.2.4 Glucose control and variability

As previously stated, the primary goal of T2DM treatment is to ensure tight glycaemic control. The degree of glycaemic control is traditionally determined by assessment of HbA1c, a measure of the amount of glycosylation of haemoglobin that occurs in red blood cells as a response to circulating glucose. HbA1c represents glucose control over a two-to-three-month period. High levels of HbA1c are associated with ACM and CVD incidence and mortality in both individuals with and without diabetes (393). There is consistent evidence from large scale RCTs that poor glycaemic control (i.e., sustained hyperglycaemia) is a significant risk factor for microvascular diseases. Specifically, the United Kingdom Prospective Diabetes Study (UKPDS) showed that intensive therapy, designed to control glucose levels, led to a significant reduction in microvascular complications over 10-years compared to a control group (394).

Regarding macrovascular outcomes, extended follow-up studies of the UKPDS (394), the Veterans Affairs Diabetes Trial (395) and the Steno-2 study (396) demonstrated a relationship between hyperglycaemia and macrovascular disease. A meta-analysis of five RCTs showed that a 0.9% reduction in HbA1c over an average of five years follow-up led to a 15% reduction in coronary heart disease and a 17% reduction in non-fatal myocardial infarction. However, there was no significant effect on stroke or ACM (397). It has also been reported that managing blood pressure and reducing LDL-cholesterol are essential to lessen the risk of CVD in individuals with T2DM (398, 399) and subsequently multi-factorial interventions to manage diabetes should be used.

Recently, attention has turned to the impact of glycaemic variability as a risk factor for the development of diabetic complications. Glycaemic variability represents the fluctuations from peaks to nadirs in plasma glucose concentration (400) and has been associated with micro- and macro-vascular diabetic complications (401, 402). Among individuals with T2DM, postprandial hyperglycaemia (the increase in plasma glucose concentrations after consuming a meal) significantly contributes to individual glucose variability (403). Postprandial hyperglycaemia and glucose variability are reported to be strongly correlated in individuals with T2DM (404) and in individuals with normal glucose control (405). Monnier and colleagues (406) reported that postprandial hyperglycaemia made a significant contribution to the overall hyperglycaemia seen in individuals with T2DM. In a 14-year follow-up of 505 patients with T2DM, Cavalot and colleagues (407) reported that, after adjusting for potential non-glycaemic risk factors, two-hour postprandial hyperglycaemia was strongly associated with CVD incidence and ACM. It is now widely accepted that postprandial hyperglycaemia is an independent risk factor for CVD and mortality in individuals with T2DM (408, 409). This position is supported by RCTs that have examined the utility of acarbose therapy (designed to reduce postprandial glycaemia) on reducing cardiovascular events in individuals with T2DM (410).

5.2.5 The role of PA in the prevention of T2DM

As previously highlighted physical inactivity is a major risk factor for the development of T2DM. Global health-care costs of physical inactivity are estimated to be INT$37.6 billion due to the development of T2DM, the largest amount spent of one of five non-communicable diseases assessed (73). Results from prospective cohort studies show that even after adjusting for factors such as BMI or obesity the risk of developing T2DM is higher in physically inactive individuals (35, 390, 411). Therefore, engaging in PA is an important component in the prevention of T2DM.

In line with these observational findings, lifestyle interventions, which include a PA component, report reducing the incidence of T2DM by 28.5% to 58.0% in individuals with IGT (412-416). Specifically, in the United States Diabetes Prevention Programme, Knowler and colleagues (412) reported that lifestyle intervention, including 150-minutes of MVPA per week was more effective than the hypoglycaemic drug metformin (850mg twice daily) at reducing incidence of T2DM in adults with IGT. In the exercise arm of the Da Qing study a 46.0% reduction in T2DM incidence was achieved without weight loss in Chinese adults with IGT. This suggests that PA is an effective component of lifestyle interventions at preventing or delaying the progression from IGT to T2DM, even in the absence of weight loss.

5.2.6 The role of PA in the management of T2DM

PA is critical in the management of T2DM due to its potential to improve glucose control and other cardiovascular risk factors including blood pressure, lipid profiles (i.e., lower LDL-cholesterol and triglycerides) and weight loss and maintenance (417, 418). Meta-analyses demonstrate the long-term beneficial role of exercise in reducing HbA_{1c} in individuals with T2DM (419-421). Grace and colleagues (422) conducted a meta-analysis of 27 RCTs to examine the impact of aerobic exercise on markers of glycaemic control in individuals with T2DM. Their pooled data (i.e., irrespective of exercise modality or duration) demonstrated that exercise led to reductions in HbA_{1c}, fasted blood glucose, fasted insulin, and homeostatic model assessment of insulin resistance (HOMA-IR) compared to non-exercise controls. In addition to the long term improvements in glycaemic control, just one bout of exercise can reduce hyperglycaemia by 39% over a 24 hour period in individuals with T2DM (423).

However, individuals with T2DM are less physically active than their healthy counterparts and many fail to meet the current recommendations of 150-minutes of MVPA per week (164, 269, 424). Cross-sectional data from the National Health and Nutrition

Examination Survey 2003-2006 found that adults with diabetes had significantly lower total activity counts (Median[IQR], 125,645[106,883, 146,407]) as assessed through accelerometery compared to individuals with normal glucose control (Median[IQR], 189,498 [173,036, 205,960]) (269).

5.2.7 Interventions to increase PA in individuals with T2DM

Due to the beneficial outcomes of engaging in PA researchers have investigated a variety of strategies to encourage individuals with T2DM to become more active. One such strategy is the use of structured exercise. Engaging in structured exercise has been found to significantly reduce HbA1c (425, 426). Findings from two meta-analyses demonstrated that structured exercise had a greater impact on HbA1c than PA advice alone both immediately post and six months after programme completion (419, 427).

The impact of structured exercise programmes on glucose control is largely dependent on the intensity and volume of the exercise performed. Specifically, Umpierre and colleagues (419) found that structured exercise of ≥150 minutes per week was associated with absolute HbA1c reduction of 0.89% (9.7mmol/mol) compared to 0.36% (3.9mmol/mol) for those engaging in <150-minutes of exercise per week. In addition, higher intensity exercise is associated with greater reductions in HbA1c than lower intensity exercise (422). However, the beneficial clinical effects of engaging in higher intensity exercise must be considered alongside factors that promote adherence, such as affective response (428), to encourage long term PA behaviour. Furthermore, supervised, structured exercise interventions require a significant amount of contact time and expertise, making them potentially unfeasible for large scale implementation. As such, there has been increased interest on developing interventions that can be delivered in everyday settings. A meta-analysis of 17 behavioural interventions aimed at increasing PA in individuals with T2DM, and delivered primarily in clinical and community based settings reported significant improvements in HbA1c (weighted mean difference[95%CI], -0.32%[-0.44, -0.21%] and an increase in objectively measured PA minutes (standardised mean difference[95%CI], 0.45[0.21, 0.68]) compared to controls (429). Increases in PA have also been reported following interventions delivered in practice settings for those with T2DM (430). These reviews revealed that interventions of longer duration (>3months) and with more face-to-face contact had a greater impact of PA behaviour and metabolic outcomes than those of shorter duration and less frequent contact (429, 430). Similarly, a meta-analysis of the longer-term impact of behavioural interventions (i.e. >6-

months), including those delivered in clinical and community settings revealed that the total number of contacts, with more face to face contacts, were associated with greater PA (427).

While promising, current reviews collectively examine the impact of clinical and community-based PA interventions, making it difficult to tease apart the differential impact of these interventions on behaviour and health outcomes. However, interventions delivered in clinical care and offered by health care professionals (e.g., dietitians or GPs) are likely to be costly due to the use of highly trained staff and resources. Furthermore, clinical based interventions may be off putting for individuals of low education or income due to cultural and linguistic barriers or these individuals may lack access to such care. Utilising community-based exercise programmes for individuals with similar characteristics such as age-groups or chronic conditions is recommended by the WHO and may help engage individuals of low income and ethnic minorities who are at greater risk of developing T2DM and therefore have a greater need for effective strategies to address these inequalities (431, 432). Community-based interventions have been found to be effective at leading to long-term PA behaviour change in adults (433)

A meta-analysis of 11 community-based, PA interventions for individuals with T2DM revealed increases in self-reported PA and a reduction of HbA1c levels of 0.32%, (95%CI, -0.65, 0.01; 3.5mmol/mol) compared to controls (434). These findings are similar to those reported by Avery and colleagues (429) but considerably lower than reported from engagement in structured exercise (419, 422). More recently Mendes and colleagues (435) reported a 0.32% (3.5mmol/mol) reduction in HbA1c following a nine-month community-based exercise programme compared to a standard care group. While Galle and colleagues (436) reported that community based exercise and PA counselling led to a 0.30% (3.3mmol/mol) reduction in HbA1c compared to controls who received information on PA guidelines.

While there appears to be a positive impact of community-based interventions on PA behaviour and glucose control among individuals with T2DM these effects appear to be driven by the incorporation of structured exercise either alone or in combination with counselling. Furthermore, few studies have examined the long-term impact of such interventions on behaviour and outcomes (430) and what is reported shows that positive effects generally dissipate over time (427, 437, 438). Community-based interventions also face unique challenges regarding intervention implementation and issues of staff turnover and funding which can impact delivery (439-441), as well as high participant attrition (436, 442-444). Despite these challenges, community-based PA interventions are cost-effective for the general population and individuals with T2DM (445-447). What is needed is to develop novel interventions in community settings that promote high engagement and encourage long term independent PA behaviour while minimising impact on resources.

5.2.8 Promotion of PA through AT

As reported in section 1.3, AT has been identified as a means through which to integrate PA into everyday life with positive health benefits. Among individuals with T2DM, active commuting is associated with increased PA and lower BMI (226). While both walking and cycle commuting serve to increase PA, research suggests that cycling may provide greater health benefits than walking (118), potentially due to the higher intensity of activity associated with cycling in comparison to walking (263).

However, rates of AT in the UK, especially cycling, are low among individuals with T2DM (226). While community-based initiatives can serve to increase cycling behaviour (160, 161, 448, 449) it is rarely maintained over time (450, 451). Furthermore, there are a number of barriers to regular cycling that could discourage engagement including physical constraints associated with hilly terrain and poor physical fitness, as well as a lack of time and the distance people have to travel (174). These barriers may be accentuated in individuals with T2DM given their overall lower levels of PA.

5.2.9 T2DM and E-bikes

E-bikes help to overcome some of the barriers to regular cycling by providing electrical assistance when the rider is pedalling leading to reduced physical exertion compared to conventional cycling. Among individuals with T2DM a community-based feasibility study (PEDAL1), which included e-bike training and the provision of an e-bike for five months, led to a 10% increase in power output, a sign of increased fitness (171), likely to be the result of increased PA. Furthermore, e-cycling was perceived as enjoyable with 14 of the 18 participants purchasing an e-bike at the end of the study. Building on this work, an adequately powered RCT, comparing an e-cycling intervention to a control group is needed to assess the effectiveness of e-cycling on health and behavioural outcomes among adults with T2DM. However, there is currently insufficient evidence to support a full-scale RCT, nor are there data to allow estimation of appropriate sample size. Therefore, a pilot RCT is needed to determine the feasibility of conducting such a trial and to provide information needed for the design of a full-scale RCT trial, if warranted.

5.3 Aims and Research Questions

5.3.1 Primary aim and research questions

The primary aim of this pilot study was to assess the feasibility of conducting a randomized controlled e-cycling trial among individuals with T2DM. The primary aim was addressed by answering the following research questions:

1. What are the most effective methods of recruiting individuals with T2DM?
2. Are participants' willing to be randomized, remain in the study, adhere to the intervention and data collection methods, and what are the rates of harmful events?
3. Can the intervention be implemented as intended?
4. Are the intervention and study procedures acceptable to participants and instructors?
5. What are participants' experiences of e-cycling?

5.3.2 Secondary aim and research questions

While pilot RCTs are insufficiently powered to statistically examine the effectiveness of an intervention on outcomes (452), they provide an opportunity to investigate the potential promise of the intervention. As such, the secondary aim was to examine the association between the intervention and outcomes measured to determine intervention promise. To address this aim the following research question was developed:

6. What is the potential effect of the intervention on a range of individual clinical, physiological, and behavioural outcomes?

5.4 Methods

The reporting of this study is in accordance with the Consolidated Standard of Reporting Trials (CONSORT) extension for randomized pilot and feasibility trials (453) and the Standards for Reporting Qualitative Research (SRQR; (454). Completed checklists are provided in Appendices 5.2 and 5.3, respectively.

5.4.1 Patient and public involvement

In February 2018, JEB conducted two face-to-face PPI events with seven adults with T2DM. Attendees provided feedback on the study design, data collection methods and intervention content. Appendix 5.4 provides an overview of the questions asked and the collated responses across the two groups. In addition, attendees reviewed and provided feedback on study information letters and consent forms.

5.4.2 Ethics approval and data protection

The study was approved by the NHS Health Research Authority South West/Central Bristol Research Ethics Committee (Ref: 18/SW/0164, see Appendix 5.5 for approval letter) and was sponsored by the University of Bristol. Amendments to the protocol were authorised by the sponsor and submitted to the REC and HRA for approval. All data collected in the study were maintained and stored in accordance with the data protection regulations. All patient identifiable information was stored in a database separate from the database that held anthropometric measures, results of blood tests, physiological measures and travel and PA data. Personal data stored on NHS or University computers were password protected and only JEB and the supervisory team had access to the passwords. Personal data on paper files were stored in a locked filing cabinet in the Biomedical Research Centre at the University of Bristol. The study was registered on the International Standard Randomized Controlled Trial Number (ISRCTN) registry (ISRCTN67421464).

5.4.3 Study design and setting

The study was named PEDAL2 as it built on the feasibility study, named PEDAL1, conducted by Cooper and colleagues (171). PEDAL2 was a parallel-group, two-arm, randomized waitlist-controlled pilot study comparing an e-cycling intervention against a standard-care waitlist control in adults with T2DM. The single centre study was conducted in the city of Bristol, England. Eligible individuals were randomized to one of the two study arms. Most measures were collected at baseline (time 0 [T0]) and immediately following the intervention period (T1). Additional data were collected in the final week of the e-cycling intervention (PA and travel behaviour) and throughout the intervention (e-cycling frequency, duration and distance). Qualitative interviews were conducted with both participants and instructors at the end of the intervention.

5.4.4 Recruitment

Recruitment occurred in three settings; 1) primary care practices, 2) Bristol based diabetes education days run by the Bristol Diabetes and Nutrition service and 3) Bristol Diabetes Support Network groups. All primary care practices (n=52) in the Bristol, North Somerset and South Gloucester (BNSSG) Clinical Commissioning Group (CCG) were invited to act as participant identification centres (PIC) for the study. Practices that expressed an interest in being a PIC were asked to conduct database searches and send study information to all potentially eligible individuals (see Appendices 5.6 and 5.7 for invitation letter and study information sheet respectively).

Information about the study was shared at local diabetes education days run by the Bristol Diabetes and Nutrition service. This free half day education course, run once a month, is offered to all individuals newly diagnosed with T2DM. At the end of the course attendees were shown a video demonstrating the impact of e-bike use for two individuals living with T2DM highlighting work from PEDAL1 (171) (https://www.youtube.com/watch?v=-rAp15If1Uk&feature=emb_title; this video was designed and managed by JEB). Individuals who were interested in participating were provided with a study information sheet and left their name and contact details if they wished to discuss the study with the researcher.

Study information, and the above video, were shared at the Bristol Diabetes Support Network groups. These groups are open to individuals with T1DM and T2DM living in Bristol and the surrounding areas. The groups meet monthly to provide support and education and are endorsed by Diabetes UK. Interested individuals were invited to leave their contact details or contact the study team directly by telephone, in writing or by email.

Individuals who contacted the research team were asked how they heard about the study. Eligibility for the study was determined over the telephone. Individuals deemed eligible were asked to get clearance from their GP to engage in PA, including a maximal fitness assessment, and to have their blood pressure taken (see Appendix 5.8). All participants deemed eligible for the study at this point were invited for baseline testing. Recruitment for the study began in November 2018, telephone screening began in March 2019 and ended in May 2019.

5.4.5 Eligibility

Individuals were eligible to participate in the study if they met the following inclusion criteria:

- Clinical diagnosis of T2DM
- Aged 30 to 70 years

Individuals were ineligible to participate if they met any of the following criteria at the time of recruitment:

- Engaged in ≥150-minutes of MVPA per week (assessed by the Get Active Questionnaire; (455)),
- Taking exogenous insulin,
- Had a myocardial infarction or stroke in the past six months or had evidence of end-stage renal failure or liver disease,
- Had any other contraindications to exercise,
- Had uncontrolled hypertension (systolic blood pressure >160mmHg and/or diastolic blood pressure >90mmHg), for which they were not taking medication, as reported by their GP,
- Were not cleared to engage in PA by their GP,
- Were unable to read and communicate in English.

5.4.6 Consent and withdrawal

Eligible individuals were booked in for baseline data collection (T0; see Figure 5.1 for study design flow). At this first face to face contact a member of the research team outlined the study procedures, as per the information sheet. Individuals were advised that the study was voluntary and that they had the right to withdraw at any time, without the need for explanation. Individuals who wanted to participate were asked to read, complete, and sign a consent form (Appendix 5.9), which was countersigned by the member of the research team obtaining consent. Approximately three weeks after the end of the intervention all instructors that delivered the intervention were invited to take part in a telephone interview and were given an information sheet regarding the purpose of the interview (Appendix 5.10). Prior to completion of interviews instructors were asked to read, complete, and sign a consent form which was countersigned by the researcher (Appendix 5.11).

5.4.7 Sample size

The target sample size was 40 individuals, 20 in each study arm. This sample size was based on recommendations for pilot studies which aim to provide an estimation of a standard deviation for use in the sample size calculation to inform a larger RCT (456, 457). There were no explicit targets regarding the number of individuals to be recruited or screened as the feasibility of different recruitment strategies was being explored. The recruitment rate in a similar population and region for a combined diet and exercise intervention was approximately 30% (458). A lower recruitment rate was anticipated for a cycling intervention with PEDAL1 reporting a recruitment rate of around 20% in the same population (171). Recruitment and screening closed when 20 participants had been randomized to each of the two study arms. The number of individuals invited to participate in the study and the numbers recruited were recorded. Based on PEDAL1 a retention rate of approximately 80% was anticipated (171).

5.4.8 Allocation and randomization

Randomization occurred after consent was obtained and baseline data had been collected. Forty individuals were stratified based on sex and randomly assigned to either the e-cycling intervention or waitlist control in a 1:1 allocation ratio. Permuted blocks of random size were used. The data manager for the Nutrition Theme of the Biomedical Research Centre generated the random allocation sequences which were accessible through a password protected web page. Participant ID and sex were entered into the Web page and a random allocation was issued. Blinding to intervention allocation was not possible for any participant involved in the trial and all participants were informed of their group allocation via telephone.

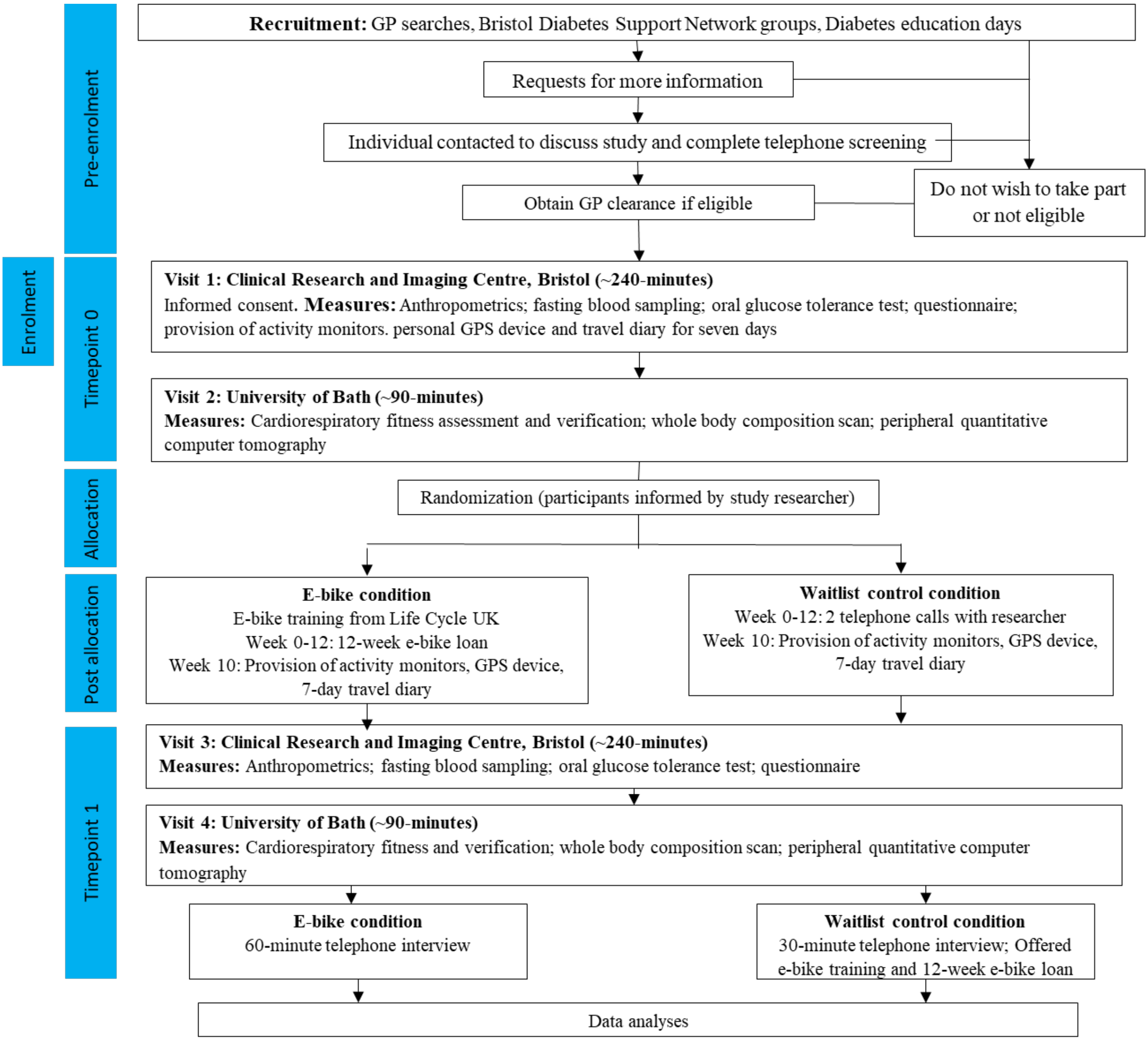

Figure 5.1 PEDAL2 study flow

5.4.9 E-cycling intervention

5.4.9.1 Intervention content

Individuals randomized to the e-cycling condition received a one-to-one e-cycling intervention that was developed for the study. Appendix 5.12 outlines the process through which the intervention was designed and details the intervention content and delivery format. In summary, the intervention content was designed using qualitative data from one-to-one interviews with individuals who took part in PEDAL1 (171). Interviews were conducted by the research team immediately after and six months after a 20-week e-bike loan. For the purpose of the current intervention development, JEB categorised these interviews using the TDF (208) to identify barriers and enablers to e-cycling engagement. The identified barriers and enablers were mapped onto intervention functions and associated BCTs, that would be appropriate for use in the current intervention, were identified (203). In addition, BCTs identified in the literature as positively impacting PA behaviour in individuals with T2DM were incorporated into the intervention design (429, 459). A total of 16 BCTs were incorporated into the intervention. The intervention delivery mode, including the length of the e-bike training and loan period were determined by the research team and Life Cycle UK (LCUK). The final intervention content and method of delivery is detailed in Appendix 5.13 and discussed in brief below.

5.4.9.2 E-bike training phase

Following baseline testing, participants completed e-bike training at LCUK, a Bristol based cycling charity who specialise in bicycle training (Figure 5.2 outlines the intervention timeline). The training consisted of two one-to-one sessions. Training session one was mandatory and followed the National Standard for Cycle Training guidelines levels one and two (known as Bikeablity; https://bikeability.org.uk/). Example activities included starting, stopping and being able to signal intentions to other road users. Individuals' previous cycling experience was considered when conducting the training. Training session two was optional and based on need and desire as determined between the instructor and participant. Session two was designed to facilitate e-cycling practice with the instructor. In addition, the advanced skills of National Skills Level three were covered including riding on busier roads and navigating complex junctions if appropriate. Training sessions one and two were designed to be between 90 to 120 minutes. Throughout the sessions, the instructors provided participants with feedback on their e-cycling and gave verbal encouragement. The practical e-cycle training was followed by brief behavioural counselling in which instructors encouraged participants to set e-cycling goals, plan where and when they wanted to ride, identify potential barriers to e-cycling and brainstorm strategies to overcome these barriers.

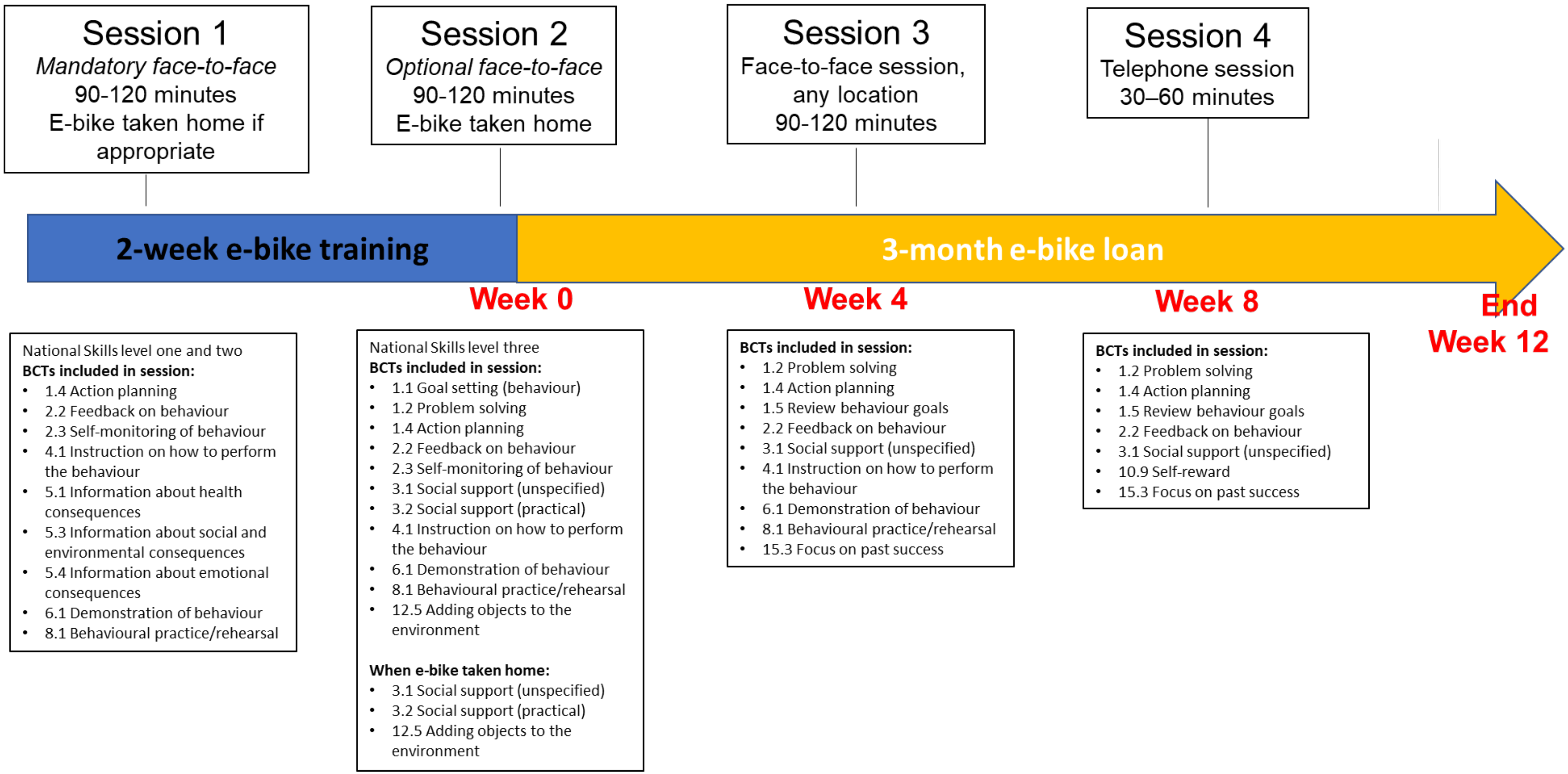

Figure 5.2 Outline of the PEDAL2 intervention

Instructors shared information on the potential health, social and environmental benefits of e-cycling. Participants were encouraged to monitor their e-cycling behaviour and were given a paper logbook to record their activity. Each participant also had the option to track their activity using a GPS device (Garmin Edge 130 GPS) which was paired with the participants mobile phone (Garmin connect mobile; https://connect.garmin.com/). Participants were invited to join a private, PEDAL2 social media group (Whatsapp) to share their experiences and ride ideas with other participants.

Following the training phase participants were provided with an e-bike to take home to use as they desired. E-bikes were either ridden home by the participant or loaded into the participants motor vehicle and taken home. Upon taking the e-bike home, participants were provided with a helmet, pannier, bike lock and maps of cycle routes in the area. Participants were provided with the details of the LCUK maintenance service in case of breakdown.

5.4.9.3 E-bike loan phase

Participants were loaned the e-bike for 12-weeks and were instructed to use the e-bike themselves and not to lend it to friends or family. No specific e-cycling frequency, duration or distance targets were imposed by the researchers. Four weeks after taking the e-bike home participants attended a face-to-face refresher session with their instructor (session three). This session took place at a location of the participant's choice (i.e., at their home or in the local community) and lasted approximately 120-minutes. It consisted of a practical riding component and brief behavioural counselling. The practical riding component was based on the participants' needs. The instructor provided feedback on the participant's e-cycling during the session and reviewed and discussed the participants' e-cycling activity over the past four weeks. The instructor provided positive encouragement for any e-cycling engagement. The instructor discussed e-cycling behaviour in relation to previous e-cycling goals specified and encouraged the participant to make plans for future rides. At week eight, the instructor contacted the participants by telephone to discuss their e-cycling activity, barriers that had arisen, potential strategies to overcome these barriers, and e-cycling goals for the final four weeks. At the end of week 12, participants were asked to return the e-bike to LCUK, or an instructor collected the e-bike. Throughout the e-bike loan phase, LCUK provided a call out maintenance service.

5.4.9.4 Instructor training

Four instructors from LCUK delivered the intervention. Each participant was assigned an instructor and worked with them throughout the intervention. All instructors were disclosure and barring service checked, first aid qualified, and held full National Standard cycle instruction qualifications. Therefore, instructor training focused on the behavioural aspects of the intervention content and comprised of two sessions. Session one (three hours) taught instructors how to communicate with participants in a way to promote and encourage behaviour change. This session was developed and delivered by Karan Thomas, an independent consultant in Health Improvement and Public Health practice (https://bctonline.co.uk/team/karan-thomas/). Training session two (two hours) focused on intervention content. The importance of completing intervention activities was discussed. Instructors were provided with checklists to record intervention activities and report adaptations to intervention content (see Appendix 5.14). Training session two was developed and delivered by JEB.

5.4.10 Control group

Participants randomly assigned to the waitlist control received two telephone calls at weeks six and 10 after baseline testing, to maintain engagement in the study. During these telephone calls participants were asked about their general health and were directed to diabetes support groups and diabetes services offered in the local community, in line with standard care procedures. During the telephone calls participants were asked if they had had contact with any other individuals in the study to ensure no contamination between conditions had occurred. After post-intervention data collection participants in the control group were offered e-bike training session one and loaned an e-bike for three months. Sessions two, three and four were not conducted.

5.4.11 Study outcomes

The outcomes that were selected to address the aims of the study are described in detail in Chapters 6 to 8. Table 5.2 provides an overview the outcomes used to address each of the research questions, the data collection method and the time point of measurement.

Table 5.2 PEDAL2 research questions, associated outcomes, data collection methods, time point measurements and analysis plan

Research question	Outcome	Data collection method/tool	Time points of measurement			Analysis plan
			Baseline testing (T0)	During intervention	Post testing (T1)	
1. What are the most effective methods of recruiting individuals with T2DM?	• # GP practices approached; # that agree to act as PIC site • # individuals identified through GP database searches response rate to information letters • Reasons for not wanting to participate in the study • # of participants that attended additional recruitment settings • # participants recruited from each recruitment setting • # individuals that consent to be part of the study	Study records	X			Frequencies and percentages
2. Are participants' willing to be randomized, remain in the study, adhere in the intervention and data collection methods and what are the rates of harmful events?	• # participants retained in study following randomization • # Individuals that complete post-testing • # of participants that attend each of the intervention sessions and data collection sessions • # of harmful events	Study records		X		Frequencies and percentages
3. Can the intervention be implemented as intended?	• # of training sessions attended by participants and additional contact with instructors • Extent to which intervention content is completed as planned • # and extent of adaptations	Intervention checklists		X		Frequencies and Percentages
4. Are the intervention and study procedures acceptable to participants and instructors?	• Acceptability of intervention to participants • Acceptability of study procedures to participants • Acceptability of intervention delivery to instructors	Semi-structured interviews			X	Thematic analysis based on research question
5. What are participants experiences of e-cycling?	• Experiences of e-cycling • Participant's barriers and facilitators to e-cycling	Semi-structured interviews			X	Thematic analysis based on research question
6. What is the potential effect of the intervention on a range of individual clinical, physiological, and behavioural outcomes?	• Weight, height, BMI	Tanita digital scales, SECA 700	X		X	Comparison of change scores between conditions
	• Waist circumference	Non-stretch tape measure	X		X	
	• Fasting glucose, insulin, lipids, C-reactive protein, HOMA-IR, HOMA-B	8mL blood sample	X		X	

Research question	Outcome	Data collection method/tool	Time points of measurement			Analysis plan
			Baseline testing (T0)	During intervention	Post testing (T1)	
	• OGTT outcomes: iAUC for glucose and insulin, Matsuda index, original insulinogenic index, total insulinogenic index, and insulin secretion-sensitivity index-2	2mL blood samples at 15, 30, 45, 60, 90, 120 minutes post 75g of anhydrous glucose	X		X	
	• HRQoL: physical and mental summary	Short Form 36 Health Survey (39)	X		X	Comparison of change scores between conditions
	• Cardiorespiratory fitness	Maximum oxygen uptake using cycle ergometer	X		X	
	• Body composition: whole body fat mass and lean mass, trunk fat mass and leg fat and lean mass	Dual-energy x-ray absorptiometry	X		X	
	• Femur intermuscular adipose tissue, subcutaneous fat area, muscle density and muscle cross-sectional area	Peripheral quantitative computer tomography				
	• Travel behaviour • # of trips, # of trip chains • Transport mode (walking, cycling, e-cycling, car, bus, train) • Trip purpose	QStarz GPS and travel diary	X		X	Mean (SD) or median (IQR)
	• Estimated CO_{2e} emissions	QStarz GPS, travel diary	X		X	Mean (SD) or median (IQR)
	• Total PA (time spent in MVPA)	Actigraph (GT3X)	X		X	Comparison of change scores between conditions
	• MVPA due to e-cycling	Actiheart & QStarz GPS	X		X	Mean (SD) or median (IQR)
	• E-cycling behaviour: # journeys, distance travelled, pattern of e-bike use	Bike odometer & Garmin 500 GPS		X		Mean (SD) or median (IQR)

BMI=body mass index; CO_{2e}=carbon dioxide equivalent; GP=General practitioner; GPS=global positioning system; HOMA-B=Homeostatic model assessment for assessing β-cell function; HOMA-IR=Homeostasis Model Assessment for assessing insulin resistance; HRQoL=health related quality of life; iAUC=incremental area under the curve; IQR=interquartile range; MVPA=moderate to vigorous physical activity; OGTT=oral glucose tolerance test; PA=physical activity; PIC=participant identification sites; SD=standard deviation; T2DM=type 2 diabetes mellitus

5.4.12 Analysis plan

5.4.12.1 Quantitative analyses

The primary outcomes included recruitment and consent rates, retention and adherence to study procedures and data provision as recommended by the extension of CONSORT 2010 to pilot trials (453). Analysis of these data were descriptive, expressed as frequencies and percentages. Any adverse events were described appropriately. Characteristics of the study sample were summarised by condition using descriptive statistics (means and standard deviations, medians and interquartile ranges, or frequencies and percentages as appropriate). Descriptive comparisons of these data were made between the intervention and waitlist control group. Evidence of promise of the intervention (i.e., whether the intervention can lead to changes in outcome measures) were examined using comparison of change scores between conditions for all secondary outcome measures (except e-cycling during the intervention) as proposed by the CONSORT extension for pilot studies (453).

5.4.12.2 Qualitative analyses

The interview data were analysed using the framework method (460). The framework method sits within the family of analyses methods known as 'thematic analysis' (461, 462). The framework method has been used to examine the feasibility and acceptability of interventions and research methods (463, 464). It is suited to research that has specific questions and a pre-defined sample (465). In addition, framework analysis has two main advantages over other qualitative methods: 1) it does not require adherence to either inductive or deductive analysis approaches and can therefore be applied to a variety of research questions. This is important in the current research given the specific study objectives which require both inductive and deductive analysis, and 2) it does not prescribe to a single epistemological or ontological framework thereby providing a degree of flexibility regarding how data analyses is approached (462). Framework analyses leads to the development of a data matrix which includes rows of participants and columns of themes and cells which summarise the data. This enables the researcher to move easily through the data to identify patterns and themes (462).

In the current study an enhanced seven-stage process developed by Gale and colleagues (461) was used to guide data analyses using the framework method (see Figure 5.3) This staged process provides researchers with a clear recipe for conducting and reporting data analyses, thereby increasing transparency (461). How each of these stages was applied to the specific research questions of interest are reported in Chapter 6, section 6.3.5 and Chapter 8, section 8.3.1.

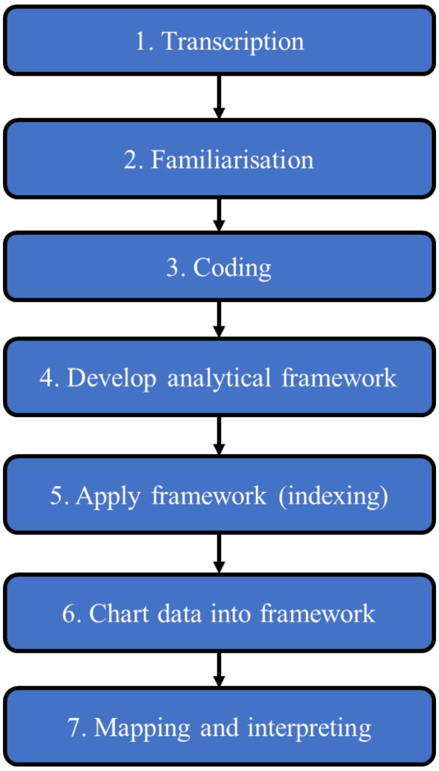

Figure 5.3 Seven-stage process used in the analysis of qualitative data (461)

5.4.12.2.1 Qualitative Rigour

The concepts of validity and reliability are difficult to address in qualitative research, leading some to question the trustworthiness of qualitative research (466). However, there is debate within the literature regarding the appropriateness of these terms in qualitative research, largely influenced by the epistemological and ontological position of the researcher. In the current study reality is believed to exist beyond the context of the interview and generalisability and reliability are important factors to consider. This is a common position in health research in which the researcher wants organisations and governments to make judgements about their research and to whom the issues of generalisability, validity and reliability of findings are important.

Lincoln and Guba (467), while rejecting the positivist terms reliability and validity, proposed the constructs of dependability, credibility, transferability, and confirmability to address the trustworthiness of qualitative research. Nowell and colleagues (468) provide guidelines on how to ensure each criteria are addressed in qualitative research. What each of these constructs mean and how they relate to the current research is discussed in Appendix 5.15.

5.4.12.2.2 Reflexivity

Reflexivity is the process of examining one's personal characteristics, beliefs, emotions, and motivations during the course of the research to critically evaluate how these factors may influence the research process and outcomes (469). In the current context the interview represents a process through which data, outside of the immediate context, can be elicited. However, the interview is also an interaction between the researcher and participant which will impact the data that is generated. While the researcher aimed to avoid bias in all aspects of the research process, the nature of being human means that total objectivity is unattainable. Therefore, it is important to be reflexive about the impact the researcher may have on the research through identification of preconceived thoughts and beliefs about the phenomenon that could influence how they interact with the participant and subsequently introduce bias. A reflexivity statement for this study is provided in Appendix 5.16.

5.4.13 Progression criteria

The progression criteria for this trial included the following:

1. At least 20% of potentially eligible individuals express an interest in being part of the study. This criterion was based on previous e-cycling feasibility work conducted with individuals with T2DM (171). The proportion of individuals that express an interest in the study from each recruitment strategy was calculated to identify the most effective recruitment method.
2. At least 80% of eligible individuals (identified through telephone screening and GP study clearance) are successfully randomized. This is based on findings from other PA RCTs for individuals with, or at risk of, T2DM (458, 470).
3. Attrition of the pilot trial is low, with a study retention rate of ≥80%. This criterion is based on findings from a previous feasibility study conducted in a similar population (171) and a criterion applied in Cochrane reviews of face-to-face and remote PA interventions in adults (471-473).
4. At least 70% of participants in the intervention group attend at least 60% of the intervention sessions. This criterion is based on previous PA interventions conducted in individuals with T2DM (474).

5. Process evaluation findings suggest that > 80% of participants report the study methods to be comprehensible and acceptable. This figure is based on a process evaluation of a lifestyle intervention for individuals with T2DM (475).

5.5 Discussion

PA is a key component of managing T2DM. However, this population are less physically active than individuals without diabetes and community-based lifestyle interventions have largely been unsuccessful at leading to sustained changes in PA behaviour. E-cycling has been found to be an acceptable and enjoyable PA among individuals with T2DM. As such, more research is needed to examine the feasibility of conducting a RCT and to determine if engagement in e-cycling has the potential to positively impact both health and behavioural outcomes. This chapter describes the methods used in PEDAL2, a pilot randomized waitlist-controlled trial designed to evaluate the feasibility of conducting an e-cycling intervention in individuals with T2DM. The e-cycling intervention developed was guided by previous literature and analysis of semi-structured interviews with the target population to identify barriers and enablers to e-cycling engagement. The process of intervention development has been comprehensively documented, and the final intervention was characterised using the widely recognised and validated BCT taxonomy (476, 477). Comprehensive reporting of intervention content, particularly in the walking and cycling domains, is often overlooked making evaluation of the impact of intervention content on study outcomes difficult (160, 478). Future process evaluations conducted as part of an effectiveness trial can explore the efficacy of these BCTs in relation to changes in outcomes measured and the mechanisms of action through which this behaviour change is mediated (198). These results can inform the selection of BCTs for inclusion in similar interventions and contribute to the evidence base investigating how and why health behaviour change interventions are successful or not (209, 219).

It is important to acknowledge potential limitations of this proposed study design and methods. Firstly, the lack of blinding may create challenges with study retention particularly in the control group, potentially creating bias. This is common in exercise trials, and we have addressed this by offering all control participants the e-bike loan at the end of the trial. Secondly this single-centre pilot trial limits the ability to generalise to other cities across the UK or rural areas in which the feasibility and associated outcomes could be different. Thirdly, the intervention and specific BCTs selected to target identified causal mechanisms was identified using the original Behaviour Change Wheel guidance (479), before becoming aware of the Theory and Techniques tool (209, 480, 481). The Theory and Techniques project represents substantial progress in identifying hypothesised links between BCTs and causal mechanisms. Fourthly, it is recognised that 16 individual BCTs maybe challenging to implement in practice. However, while there is evidence to include certain BCTs, there is lack of evidence to omit others (459, 478), so the decision was made to include all 16 identified BCTs. The ability to deliver the BCTs will be evaluated as part of the feasibility testing. Despite the limitations, the data collected in this study can be used to inform the development of future e-cycling interventions and identify appropriate outcomes measures for examination in a definitive trial if deemed appropriate.

5.6 Contribution to this thesis

The study outlined in this chapter builds on the feasibility work conducted by Cooper and colleagues (171). Studies one and two highlight the need for longitudinal randomized studies to explore changes in health and travel behaviour following the provision of an e-bike, specifically among clinical populations. Prior to conducting a full-scale evaluation, it is important to ascertain whether such a trial can feasibly be conducted and identify which outcome measures are sensitive to change. Many of the outcome measures selected and data collection methods used in the current pilot RCT are based on the findings of studies one and two and therefore address the research gaps identified. Specifically, study one identified a lack of longitudinal research examining the impact of e-cycling on health. The current study explores the potential promise of an e-cycling intervention to positively impact a range of metabolic, psychological, and physiological outcomes. Study two identified a need for longitudinal research, using objective measures, to assessed changes in travel behaviour following e-bike acquisition. PEDAL2 uses GPS and accelerometery to objectively measure and quantify changes in PA and travel behaviour over time following the acquisition of an e-bike. In addition, the experiences of e-cycling are examined to identify key barriers and facilitators to engagement in e-cycling. This information can be used to inform future e-cycling initiatives in clinical populations.

6 Chapter 6: The feasibility of conducting a pilot randomized controlled e-cycling trial in individuals with T2DM

6.1 Overview

Building on the PEDAL2 study design and methods outlined in Chapter 5, the current chapter examines the feasibility and acceptability of conducting the PEDAL2 study. As such, Chapter 6 addresses, in part, the third objective of this thesis: *Utilise e-bikes in an intervention aimed at increasing PA in adults with T2DM to explore the feasibility of conducting a randomized trial.* An introduction, detailed methods and results are presented, the findings are discussed and their implications for future research considered.

6.2 Introduction

RCTs are considered the most rigorous study design for examining the causal relationship between a treatment and outcome, due to randomization which provides a robust method of preventing selection bias and minimising confounding (193). Coupled with a comprehensive process evaluation, RCTs examining the impact of health behaviour change interventions can provide high-quality impactful evidence that is essential for evidence-based practice (191, 482, 483).

However, conducting RCTs of PA interventions presents a unique set of challenges. These include the ability to recruit the target population, the inability of blinding to group allocation and subsequent retention of the control group, the acceptance of the study measurements, which are often physiological, and factors associated with intervention delivery and acceptability (484). Failure to recruit and retain participants makes it nearly impossible to determine the effectiveness of an intervention. Furthermore, recruitment of individuals with chronic disease into a PA trial can be challenging due to additional safety and medical concerns associated with engaging in PA (484-486). Therefore, having a good understanding of effective recruitment pathways and retention strategies is essential.

In addition, knowledge of how an intervention is implemented is crucial to be able to make accurate judgements of effectiveness (487). This can be especially challenging in PA interventions in which the participant is required to perform specific exercises and instructors may require expertise to teach these exercises (484). Understanding how an intervention is implemented allows for changes to be made, to increase intervention effectiveness.

Given the high financial and resource costs associated with conducting a RCT, addressing these uncertainties prior to a fully powered evaluation is advantageous. As discussed in section 2.3.3 pilot studies evaluate the feasibility of recruitment, retention, adherence, intervention delivery and outcome assessment and their use can increase the chances of successfully conducting a high-quality RCT. However, pilot RCTs are underutilised in the context of PA interventions (484). In the context of e-cycling one pilot RCT examined the impact of e-cycling on health in comparison to conventional cycling in overweight adults (253). Specifically, Höchsmann and colleagues reported a primary outcome of maximum exercise capacity, but no feasibility outcomes (253). The term pilot was likely used due to the small sample size (n=32). This is a common misuse of the term 'pilot' within the PA intervention pilot and feasibility study literature (488). To date, no research has examined the feasibility of conducting an e-cycling RCT. This is particularly important when conducting PA interventions in individuals with chronic conditions such as T2DM, where recruitment and retention is often low, and slow, due to strict eligibility criteria (458, 489, 490). As reported in Chapter 5, section 5.2.9, PEDAL1 demonstrated that individuals with T2DM are highly receptive to e-bikes (171, 491). As such, the use of e-bikes as a means of increasing PA in this population warrants further investigation. However, there are several uncertainties that need to be addressed prior to conducting a full-scale RCT. Furthermore, there is insufficient data to allow estimation of appropriate sample size for a fully powered trial. Therefore, a pilot RCT is needed to determine the feasibility of conducting such a trial and to provide key information needed for the design of a full-scale RCT study, if warranted.

This chapter addresses the primary aim of study three: **to assess the feasibility of conducting a randomized controlled e-cycling trial among individuals with T2DM** by answering the following four research questions:

1. What are the most effective methods of recruiting individuals with T2DM?
2. Are participants' willing to be randomized, remain in the study, adhere to the intervention and data collection methods, and what are the rates of harmful events?
3. Can the intervention be implemented as intended?
4. Are the intervention and study procedures acceptable to participants and instructors?

6.3 Methods

Chapter 5, Table 5.2 provides an overview of the methods used in PEDAL2. Below detailed methods used to answer the four primary research questions above are reported.

6.3.1 What are the most effective methods of recruiting individuals with T2DM?

The following information was recorded to answer research question one; the number of primary care practices approached; the number of practices that agreed to act as PICs; the number of potentially eligible individuals identified through database searches; and response rates. Reasons for not wanting to participate in the study were recorded. The number of individuals that attended Bristol diabetes education days and the Bristol Diabetes Support Network groups, and the number that expressed an interest in the study was recorded. Recruitment rates from the three settings and the number of individuals that consented to participate in the study were recorded. Demographic information from individuals that consented to be in the study was collected.

6.3.2 Are participants' willing to be randomized, remain in the study, adhere to the intervention and data collection methods, and what are the rates of harmful events?

The number of individuals retained in the study following randomization was recorded. Retention rates were determined based on the number of individuals that completed the intervention and the post-testing measures. The number of individuals that attended each of the intervention sessions and data collection sessions was recorded.

Participants were asked to report adverse events resulting from e-cycling (e.g., musculoskeletal problems, falls or road traffic incidents) by calling the study phone line. The number and types of adverse events were documented.

6.3.3 Can the intervention be implemented as intended?

There is currently no consensus on the key components to examine when assessing implementation (198). Therefore, intervention *dose*, *fidelity* and *adaptations* were reported as suggested by Moore and colleagues (198). Intervention dose was determined through recording the number of intervention sessions attended by participants as well as the volume of additional contact between instructors and participants. The average length of time that each participant spent in face-to-face and telephone contact with the instructor was reported for the training phase and loan period separately. Intervention delivery fidelity (492) was determined by the degree to which the intervention content was delivered by the instructor (reported as a percentage). This information was obtained through completion of checklists by instructors. Information on adaptations made to the intervention was recorded by instructors and reported descriptively.

6.3.4 Are the intervention and study procedures acceptable to participants and instructors?

The acceptability of the intervention and data collection methods were explored through semi-structured interviews approximately two weeks after post-testing (for participants) and after all intervention participants had returned the e-bikes (for instructors). Interview questions for participants focused on perceptions and experiences regarding participation in the intervention and data collection processes and were driven by the research questions (see Appendix 6.1 for participant interview guide). Interview questions for instructors focused on factors that impacted intervention delivery including intervention content, facilities, time, and burden as well as the adaptability of the programme and how it compared to other programmes they delivered at the organisation (see Appendix 6.2 for the instructor interview guide).

For both instructors and participants, the interview consisted of open-ended questions and prompts. Open ended questions encourage the interviewee to engage with the interviewer on a specific topic, in contrast to more dichotomous questions that usually require a yes/no or single word answer (462). All interviews were one-to-one telephone interviews to suit the needs to the interviewee and to reduce travel. While telephone interviews have been suggested to be inferior to face-to-face interviews due to a lack of visual cues, there is limited evidence that this is the case (493). Rather, telephone interviews may enable participants to share information more openly than face-to-face interviews, and participants may be more relaxed when talking from the comfort of their own home (493). All interviews were conducted by JEB and were audio recorded using encrypted recording devices. The recordings were transcribed verbatim by Transcription UK and stored using NVivo data management software (NVivo10, QSR International, 2012). The transcripts were checked against the original recordings to ensure reliability.

6.3.5 Analysis

6.3.5.1 Quantitative analyses

Characteristics of the study sample were summarised by condition using descriptive statistics (means and standard deviations, medians and interquartile ranges, or frequencies and percentages as appropriate). In addition, baseline characteristics by those who completed post intervention assessments and those that dropped out of the study were summarised using descriptive statistics. Primary outcomes were analysed descriptively and expressed as frequencies and percentages, with confidence intervals provided when reporting outcomes pertaining to the progression criteria. Any adverse events were described.

6.3.5.2 Qualitative analyses

As reported in section 5.4.12.2, interview data were analysed using the framework method (460) and guided by Gale and colleagues seven-stage analysis process (461). Data analyses were conducted by JEB with close discussions with a senior research associate and expert in qualitative research (AS). This process is outlined in detail in Appendix 6.3 and summarised below.

2. **Familiarisation**

Interviews with 34 study participants and three instructors were conducted and analysed. JEB listened to all audio recordings and read each transcript. AS read four participant interview transcripts and two instructor interview transcripts. JEB selected specific transcripts to represent diverse experiences and opinions of participating in the study.

3. **Coding**

JEB and AS independently, and inductively, assigned codes to each segment of the data deemed to be relevant to the research questions from the selected transcripts.

4. **Develop an analytical framework**

The researchers met to discuss coding and an analytical framework was developed. The two researchers independently coded two more participants transcripts and one instructor transcript, noting any new codes. The researchers met again to discuss the coding and to revise the initial framework as required. The conceptual relationship between codes was considered and similar codes were grouped together into categories. The researchers did not look beyond what was explicitly said by participants, adopting a semantic approach to identifying categories. In this sense, the categories were a method of organising the data, acting to display common patterns within the dataset.

5. **Applying the analytical framework**

JEB coding the remaining transcripts. If a new code was required, this was discussed with AS before adding to the analytical framework. If a new code or category was added, previously coded transcripts were checked for data relevant to the new code.

6. Charting the data into a matrix

A framework matrix was developed consisting of participants in rows with summaries of categories in columns. The matrix contained summaries of the data for each participant with references to specific examples but not the actual raw data. AS checked the summaries of the first four transcripts to ensure the summaries captured the essence of the data.

Four participants and one instructor were sent a copy of their interview transcript and an interpretation of the data. They were asked to review their transcribed data and comment if they felt the interpretations represented or misrepresented their views.

7. Mapping and interpreting the data

The significance and implications of the categories, and how they relate to one another was examined to generate broader themes, while considering the research objectives. This was done by JEB and AS collaboratively. The findings are reported narratively in the results and illustrative quotes presented.

6.4 Results

6.4.1 What are the most effective methods of recruiting individuals with T2DM?

Recruitment for the study commenced in November 2018 and ended in May 2019. Data collection ended in March 2020. As outlined in Chapter 5 section 5.4.4, three recruitment strategies were explored: 1) primary care practices, 2) Bristol diabetes education days and 3) Bristol Diabetes Support Network groups.

6.4.1.1 Primary care practices

The study was adopted as a National Institute of Health Research portfolio study. This classification meant the research team were provided with financial and administrative support to engage with primary care practices by the local clinical research network, the West of England (WoE) NIHR Primary Care Team. The team sent out a research information sheet (RISP) to all primary care practices in the BNSSG CCG (n=52). The RISP explained the study design and outlined the requirements of the practice should they wish to be a PIC. Primary care practices sent expressions of interest (EOIs) to the WoE NIHR Primary Care Team who passed this information to the researchers. EOI from primary care practices were received from November 2018 until December 2018. Figure 6.1 outlines the three recruitment methods used for this study.

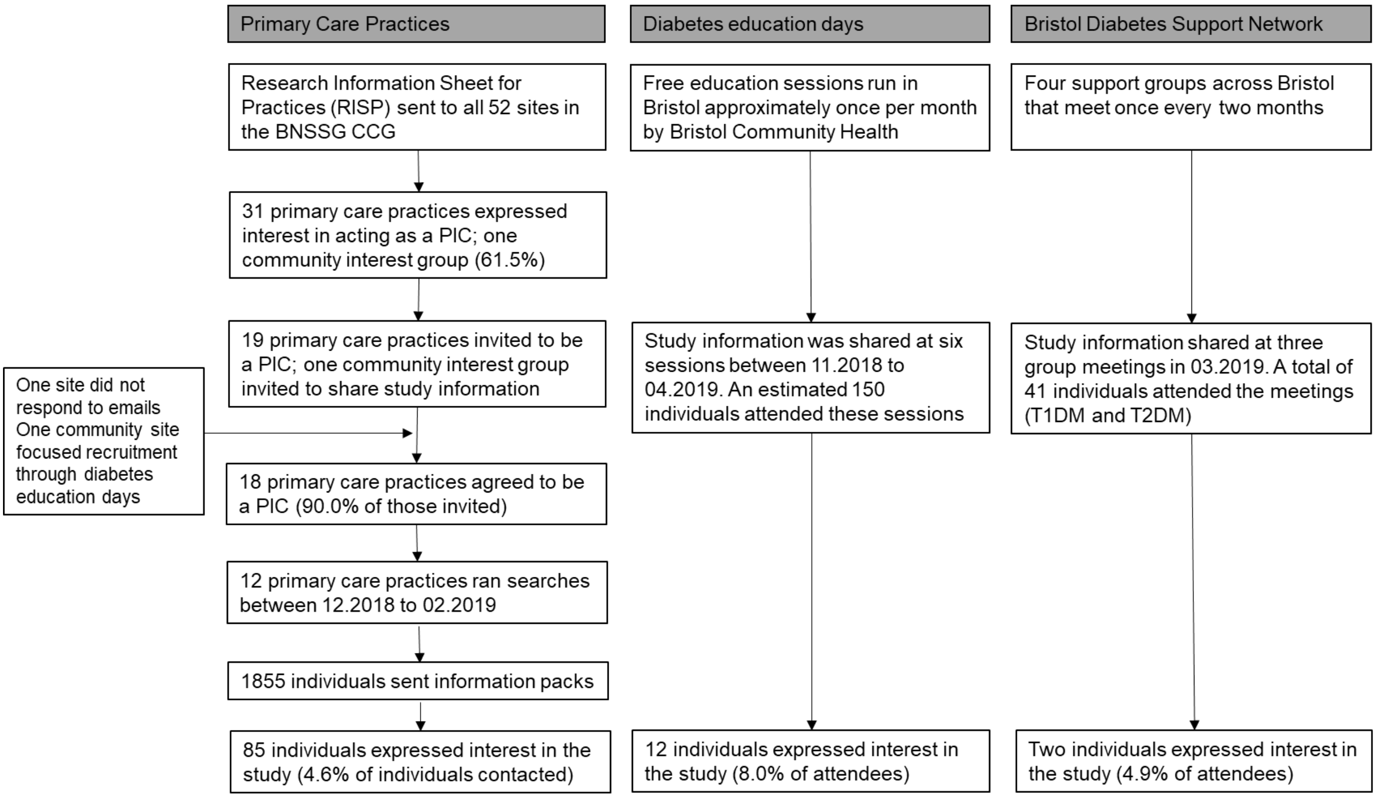

Figure 6.1 Number of individuals recruited from different recruitment methods

A total of 31 primary care practices and one community interest group expressed an interest in being a PIC (61.5% of practices in the BNSSG CCG). Of these, 20 were selected as PICs (including Bristol Community Health). The indices of multiple deprivation (IMD) were used to identify the area-level social-economic status served by the practices. Using the IMD, JEB and the supervisory team selected practices to cover a range of levels of deprivation. These sites were emailed directly with more study information. Of the 20 sites contacted 18 agreed to act as a PIC. These practices were sent the study eligibility criteria from which to create and conduct database searches. Practices were asked to screen individuals on the inclusion criteria (age and diagnoses of T2DM) and on five of the seven exclusion criteria reported in section 5.4.5 (excluding GP clearance and the ability to read and communicate in English).

Of the 18 practices, 12 ran database searches. Database searches were conducted between December 2018 and February 2019. A total of 1855 individuals were identified as potentially eligible and were sent study information packs in the post. Six practices were unable to screen individuals based on all five exclusion criteria, resulting in some individuals being sent information packs who may not have been eligible for the study. Appendix 6.4 provides details of the searches conducted by each primary care practice and the number of individuals from each site who were sent study information. A total of 85 individuals (4.6% of those contacted) expressed an interest in participating in the study.

6.4.1.2 Diabetes education days

Information about the study was shared at six sessions between November 2018 and April 2019. The exact number of individuals at each session was unknown. However, an estimate of 30 individuals at each session was provided by the Diabetes and Nutrition service team. As such, an estimated 150 individuals received information about the study. Twelve individuals left their contact information and were contacted by the researchers (8.0% of attendees). One of these individuals also received information for the study from their primary care practice and expressed an interest in participating.

6.4.1.3 Bristol Diabetes Support Network

Information about the study was shared at three of the four support meetings in March 2019 (one group was exclusively for individuals with T1DM and therefore information was not shared at this group). A total of 41 individuals attended the three sessions. These included both individuals with T1DM and T2DM of various ages. The proportion of individuals with T2DM in the groups was unknown. Two individuals from these sessions requested further information about the study (4.9% of attendees).

6.4.1.4 Recruitment reach

The National Diabetes Association estimated that in 2019 there were approximately 50,255 individuals, of all ages, living with T2DM, in the BNSSG CCG. The three recruitment strategies used in this study reached 2,046 individuals living with T2DM. Therefore, approximately 4.1% of individuals in the area living with T2DM received information about the e-bike study (95%CI: 3.9, 5.9%).

6.4.1.5 Recruitment

A total of 111 individuals expressed an interest in participating in the study. Table 6.1 outlines the specific channels through which individuals heard about the study. Of these 111, 98 were identified through the three specified recruitment strategies (6.0% of those that received study information). An additional 13 individuals heard about the study from other sources. Figure 6.2 provides an overview of the flow of participants through the study, included pre-enrolment numbers.

Table 6.1 Methods through which individuals expressed an interest in participating

Location	Number
Primary care practices	85 (1 also heard from Diabetes education day)
Bristol Diabetes Support Network	2
Bristol diabetes education days	12 (1 also heard through primary care practice)
Other sources	
Dietitian	2
GP suggested contact	2
Nurse provided study information	2
NIHR website	1
West of England Academic Health Science Network newsletter	1
Sent information by a friend	1
Diabetes research day	1
Bristol community health	1
Unclear	1 (emailed researcher email) 1 (contacted researcher by telephone)

Of these 111, 107 were invited to take part in a telephone screening, while four were informed that the study was full at the time of expressing interest. Seventy-six individuals completed telephone screening. Fifty-three individuals were deemed eligible based on telephone screening and GP clearance was sought. Twenty individuals were deemed ineligible and three did not want to participate. GP clearance was received for 46 individuals. For six individuals the clearance forms were never returned, and one individual was deemed ineligible by the GP due to poor overall health. Forty-two individuals were booked in for baseline testing.

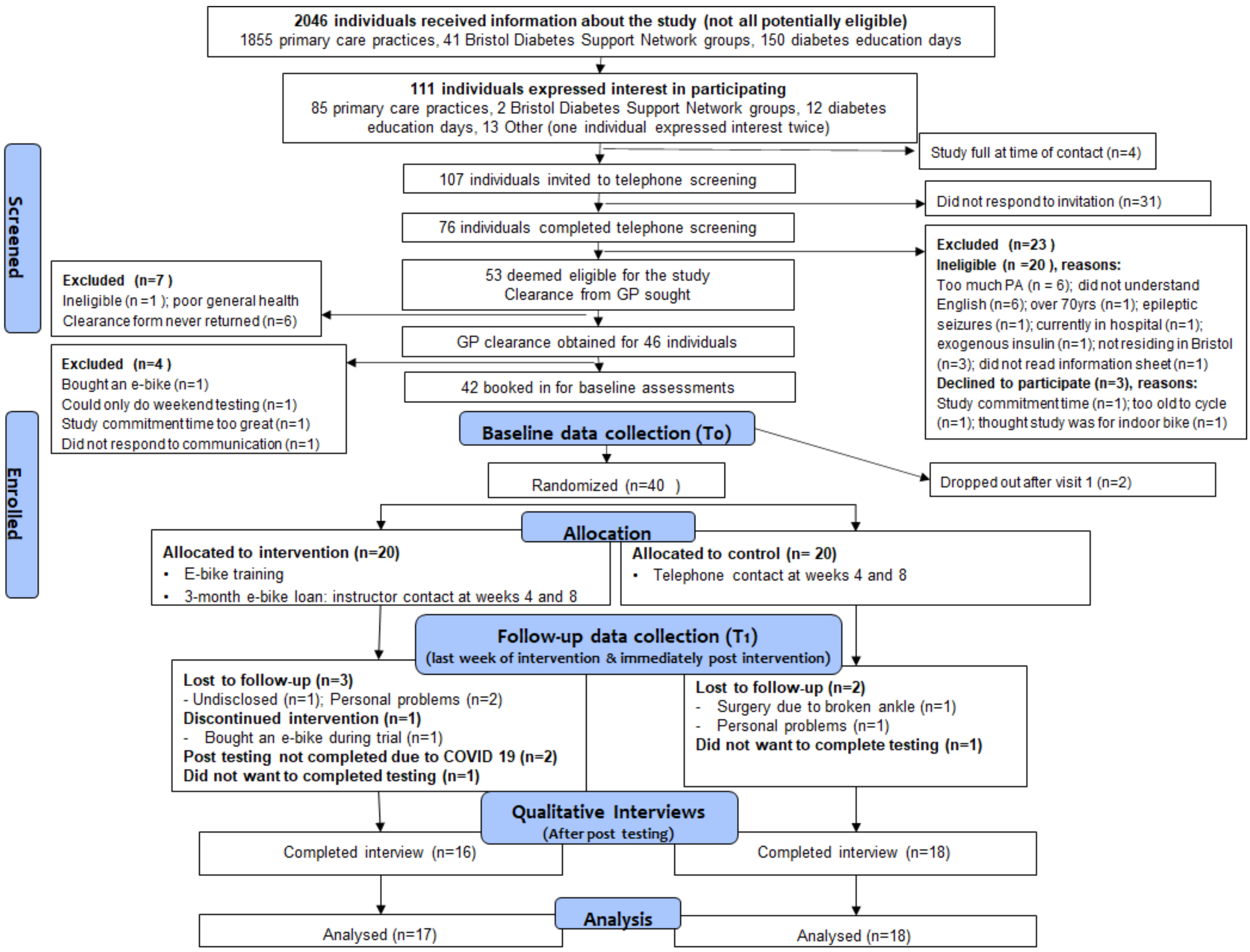

Figure 6.2 Flow of participants through the study

6.4.1.6 Final sample

Forty-two individuals were consented to participate in the study but two dropped out after visit one, stating lack of time to participate. As such, 40 individuals (95.2%) completed baseline assessments and were randomized, representing 87.0% of participants identified as eligible for the study being randomized (95%CI: 73.7, 95.1%) Table 6.2 reports the avenues through which the final sample were recruited.

Table 6.2 Location of recruitment

Location	Number	Percentage
Primary care practices	34	85.0
Bristol Diabetes Support Network	0	0.0
Bristol diabetes education days	1	2.5
Dietician sharing study information	2	5.0
Nurse sharing study information	1	2.5
Diabetes research day	1	2.5
Bristol community health	1	2.5

Note: one participant received information about the study from the Diabetes education day but subsequently received information about the study from their GP. This individual is identified as being initially recruited through the Diabetes education day.

Twenty individuals were randomized to the e-bike intervention condition and 20 into the waitlist control. The baseline characteristics of the participants in each group are displayed in Table 6.3.

Table 6.3 Baseline demographic characteristics of all participants, by condition

Variable	Intervention (n=20)	Control (n=20)
Age (y), mean (SD)	57.9 (8.9)	56.2 (8.4)
Gender (n, % female)	8 (40.0)	7 (35.0)
Ethnicity (n, % white)	18 (90.0)	12 (60.0)
Education (n, %)		
≤ High school	2 (10.0)	1 (5.0)
High school	2 (20.0)	2 (10.0)
Apprenticeship or trade certificate	3 (15.0)	4 (20.0)
College or diploma	5 (25.0)	4 (20.0)
Bachelor's degree	5 (25.0)	7 (35.0)
Post-graduate degree	1 (5.0)	2 (10.0)
Employment status (n, %)		
Working full-time	9 (45.0)	6 (30.0)
Working part-time/occasionally	3 (15.0)	5 (25.0)
Unworking	2 (10.0)	0 (0.0)
Retired	3 (15.0)	7 (35.0)
Voluntary	1 (5.0)	0 (0.0)
Self-working	1 (5.0)	2 (10.0)
Homemaker	1 (5.0)	0 (0.0)
Household income (n, %)[a]		
< £24,999	8 (40.0)	6 (31.6)
£25-£49,999	9 (45.0)	6 (31.6)
£50-£74,999	2 (10.0)	5 (26.3)
£75-£99,999	0 (0.0)	2 (10.5)
£100,000 +	1 (5.0)	0 (0.0)

[a] One individual did not report household income in the control condition, SD=standard deviation

6.4.1.7 Individuals not interested in participating

Seventy-six individuals returned the reply slip stating they were not interested in participating in the study. Table 6.4 outlines the reasons given for not wanting to participate.

Table 6.4 Reasons for not wanting to participate in PEDAL2

Reasons	Individuals who stated this reason
Limited mobility (e.g., knee replacements, join pains, osteoarthritis)	19
Lack of time	16
Fear of cycling on roads with cars	10
Cardiac problems	5
Aged over 70	5
Engaging in ≥150-minutes of PA per week	5
Lack of confidence riding a bike	4
No storage for a bike	3
Unable to ride a bike	2
Diabetes already well managed	2
Theft concerns	1
On border with prediabetes & T2DM	1
Owns an e-bike	1
Deceased	1
Additional health concerns	1 chemotherapy; 1 asthma; 1 rectal cancer; 1 registered blind
Study procedures	1 (fear of cannulation); 1 (unable to fast for blood samples)
No reasons provided	11

Note: Individuals could report more than one reason

Based on the reasons provided 41 individuals (53.5%) would have been ineligible for the study based on the specified exclusion criteria.

6.4.2 Are participants' willing to be randomized, remain in the study, adhere to the intervention and data collection methods, and what are the rates of harmful events?

6.4.2.1 Randomization and Retention

Forty individuals completed baseline assessments and were randomized, representing 95.2% of those who consented. Retention of participants in the study was 87.5% (95%CI: 73.2, 95.8%; n=35). Five participants dropped out of the study completely and no end-point data were collected (lost to follow-up Figure 6.2). Specifically, in the intervention condition, one participant could not be contacted prior to any e-bike training and two discontinued during the intervention with no further contact.

Reasons for discontinuing the intervention were either a close family member being diagnosed with a serious health condition or due to undisclosed personal reasons. In the control condition two participants discontinued with no further contact. Reasons for discontinuing were either a broken ankle requiring surgery or personal problems. See Appendix 6.5 for baseline demographics for individuals that completed the study and those that were lost of follow-up. All participants that dropped out of the study were men, no other differences were apparent.

6.4.2.2 Attendance at data collection sessions

All 40 participants attended baseline testing. Table 6.5 outlines participants attendance at data collection sessions. Two participants (one from each condition) did not want to participate in face-to-face post-testing but completed the telephone interview. Another participant did not want to complete face-to-face post-testing as they discontinued the intervention due to purchasing an e-bike. This participant completed a telephone interview. Two participants did not complete face-to-face post-testing due to COVID-19 but completed the telephone interview.

Table 6.5 Number of data collection sessions attended by 40 randomized participants

	Baseline Testing, n (%)		Post-Testing, n (%)		
	Visit One (Bristol)	Visit Two (Bath)	Visit Three (Bristol)	Visit Four (Bath)	Telephone interview
Control	20 (100.0%)	20 (100.0%)	18 (90.0%)	17 (85.0%)	18 (90.0%)
Intervention	20 (100.0%)	20 (100.0%)	13 (65.0%)[a]	13 (65.0%)[a]	16 (80.0%)

[a]Two participants face-to-face post-testing was cancelled due to COVID-19 concerns

6.4.2.3 Collection of outcome measures

Table 6.6 provides information on the rates of collection of outcome data and valid measurement for assessment of the secondary research question presented in section 5.3.2. An overview of the secondary outcome measures collected is provided in table 5.2 and in detail in section 7.3. Information regarding the rate of completion of these measures is reported here for completeness in assessing the feasibility of collecting selected outcomes. An in-depth report of each outcome measure completion rate is provided in Appendix 6.6. To summarise, completion rates of fasting blood sampling was high (97.5% and 70.0% for baseline and post-testing respectively). A total of 92.5% of participants completed the OGTT and frequent blood sampling at baseline and 62.5% at post-testing. The primary reason for not collecting blood was a failure to bleed the participant by the research staff. One participant declined blood sampling at post-testing.

Overall, 87.5% and 60.0% of participants completed the incremental fitness assessment and provided valid data at baseline and post-testing, respectively. Four participants were unable to participate in the fitness assessments due to the GP not providing clearance and one participant did not bring appropriate clothing. Additionally, at post-testing one participant did not complete the fitness assessment due to an ankle injury and one participant did not want to complete the assessment. Of those that completed the incremental fitness assessment a further three, at baseline and post-testing, did not complete the supramaximal verification assessment. Reasons for lack of completion included: a) feeling unwell, b) having health conditions that led the researcher to not conduct the assessment, c) not wanting to complete the assessment. High rates of completion, with valid data, were obtained for the body composition scans, leg scans, GPS and Actigraph accelerometer monitoring and the travel diary. Fewer participants wore the Actiheart accelerometer at post-testing due to having reactions to the electrode pads. Eighty-five percent of participants completed the interviews at post-testing.

As outlined in Table 5.2 (detailed information provided in section 7.3.3.1) travel behaviour was determined through identification of trips using GPS and travel diaries. In total, 71.2% and 57.5% of trips identified at baseline and post-testing respectively, were identified using GPS data and verified by travel diaries. At baseline and post-testing respectively, 13.8% and 27.2% of trips were identified solely on GPS data while 15.1% and 15.3% of trips at baseline and post-testing respectively were identified solely based on travel diaries. This shows the decrease in travel diary completion at post-testing.

Of the 16 participants that completed the e-cycling intervention odometer data were available for 14. Due to sizing concerns three additional e-bikes were loaned from a company called Batribike (https://batribike.com/). These models of e-bike were not equipped with inbuilt odometers. These bikes were fitted with cateye velo wireless odometers (CC-VT230W) by the instructors. However, two of the wireless odometers failed to record data. All inbuilt odometers on the remaining e-bikes (Raleigh motus) successfully recorded the total distance travelled. Participants were also provided with a GPS and/or paper logbook to track their e-cycling during the loan period. Two participants explicitly stated that they did not want to use the GPS device at the start of the intervention. Of the 14 individuals that were provided with a GPS device, nine used it to track their e-cycling, while eight participants completed the paper logbook. Four of these participants completed both the logbook and used the GPS device. Therefore, trip data are available for 13 of the 16 participants that completed the intervention (81.3%).

Table 6.6 Rates of outcome measurement completion and valid measurements

Measure	Baseline, n(%)				Post-Testing, n(%)			
	Intervention		Control		Intervention		Control	
	Completed	Valid	Completed	Valid	Completed	Valid	Completed	Valid
Anthropometrics	20 (100)	20 (100)	20 (100)	20 (100)	13 (65)	13 (65)	18 (90)	18 (90)
Fasting bloods	20 (100)	20 (100)	19 (95)	19 (95)	13 (65)	13 (65)	15 (75)	15 (75)
OGTT blood sampling	19 (95)	19 (95)	18 (90)	18 (90)	12 (60)	12 (60)	13 (65)	13 (65)
Incremental fitness	18 (90)	18 (90)	17 (85)	17 (85)	10 (50)	10 (50)	14 (70)	14 (70)
Supramaximal fitness	17 (85)	17 (85)	15 (75)	15 (75)	9 (45)	9 (45)	12 (60)	12 (60)
DEXA scan	20 (100)	20 (100)	20 (100)	20 (100)	13 (65)	13 (65)	17 (85)	17 (85)
pQCT scan	19 (95)	19 (95)	19 (95)	19 (95)	12 (60)	12 (60)	16 (80)	13 (65)
Physical HRQOL	20 (100)	20 (100)	20 (100)	20 (100)	13 (65)	13 (65)	17 (85)	17 (85)
Mental HRQOL	20 (100)	20 (100)	19 (95)	19 (95)	13 (65)	13 (65)	17 (85)	17 (85)
Vehicle data	20 (100)	20 (100)	20 (100)	20 (100)	13 (65)	13 (65)	18 (90)	18 (90)
Actigraph worn	20 (100)	18 (90)	20 (100)	18 (90)	13 (65)	12 (60)	17 (85)	15 (75)
Actiheart worn	20 (100)	19 (95)	19 (95)	18 (90)	11 (55)	9 (45)	14 (70)	13 (65)
QStarz worn	20 (100)	20 (100)	19 (95)	19 (95)	13 (65)	13 (65)	17 (85)	17 (85)
Travel diary	20 (100)	20 (100)	19 (95)	19 (95)	12 (60)	12 (60)	16 (80)	16 (80)
E-cycling during intervention								
Odometer					14 (70)			
GPS unit					9 (45)			
Logbook					8 (40)			
Post interviews					16 (80)		18 (90)	

DEXA=dual energy X-ray absorptiometry; GPS=global positioning system; HRQOL=health related quality of life; OGTT=oral glucose tolerance test; pQCT=peripheral quantitative computer tomography

6.4.2.4 Attendance at intervention sessions

Table 6.7. shows the number of individuals that attended the intervention sessions. Of the whole sample, including those that had withdrawn at the time of measurement, 62.5% (95%CI: 50.9, 73.1%) of intervention sessions were attended by the 20 participants.

Table 6.7 Number of intervention sessions attended

	Sessions				
	Session One	Session Two	Session Three	Session Four	Total
Active participants (n)	19	19	17	16	
% that attended training session (n)	100.0% (19)	79.0% (15)	59.0% (10)	37.5% (6)	68.9%
Inactive participants	1	1	3	4	
Overall % that attended the training session	95.0%	75.0%	50.0%	30.0%	62.5%

Active participants=individuals that were participating in the study at the time of measurement. Inactive participants=individuals that had withdrawn from the study at the time of measurement.

6.4.2.5 Harmful events

Three harmful events were reported and documented by LCUK. These events occurred with the instructors during the training phase. Two of these adverse events required hospitalisation, one of which was directly related to e-cycling. Specific details of these incident are outlined in Table 6.8. An additional three incidents were reported by participants in the post intervention interviews and are reported in the table for completeness. Two of the participants had two or more falls.

Table 6.8 Harmful events reported during the study

Individuals	Date	Description
During e-bike training		
PS011	07.05.2019	After a 45-minute e-bike lesson outside the participant returned to the training centre. The participant reported feeling unwell and subsequently fainted. An ambulance was called, and the participant was taken to hospital. The paramedics found no injuries and could not pinpoint the cause of the episode. The participant was discharged from hospital with no concern. The participant reported that they had been fasting for Ramadan, against the advice of their GP.
PS027	21.05.2019	The participant had a low-speed fall caused by checking for traffic at the last minute when pulling out from a junction. The participant was not yet familiar with the hydraulic brakes so came to a quick stop rather than slowing down. As a result, the participant lost their balance and fell onto the tarmac. The participant bumped their nose and mouth on the handlebars. Had sore mouth and one to two cm scratches on nose that bled slightly. Graze on forearm and wrist. No joint pain when asked to flex wrist. Participant continued with cycling.
PS011	04.07.2019	Participant had a low-speed fall at the entrance to the park. The participant was trying to turn around, lost balance and the bike tipped over. The participant attended Accident and Emergency after the session and was informed they had a fracture in their left elbow. After three weeks recovery the participant received clearance from their GP to continue with the cycle training.
During e-bike loan		
PS011	20.10.2019	During a ride on a shared cycle path, the e-bike ran out of battery charge. The participant continued to cycle without the battery. On an uphill section the participant went to put their feet down, lost balance and fell over onto the tarmac. No damage was reported.
PS043	Unknown	After finishing the lesson, the participant went to ride home and fell off the e-bike. Participant did not report any injuries associated with the fall.
PS027	Unknown	Participant was cycling on a segregated cycleway. A toddler ran out in front of them, and they put the brakes on. The brakes led the participant to an abrupt stop causing them to fall sideways and bruising their arm and knee.

6.4.3 Can the intervention be implemented as intended?

6.4.3.1 Intervention dose

Twenty participants were randomized to receive the intervention. Table 6.9 shows the number of participants active in the intervention who attended each session and received additional training. Prior to beginning the intervention one participant withdrew for reasons unrelated to the study.

6.4.3.1.1 E-bike training period

All active participants (n=19) attended session one. Session two was optional based on the perceived e-cycling ability of the participant, by instructors, and whether the participant requested a second lesson. Four participants (21.0%) were deemed to have sufficient skill and confidence to take the e-bike home after session one and did not request a second session. As such, 15 participants (79.0%) completed session two. Twelve (63.0%) took the e-bike home after these two sessions and three participants (16.0%) required additional training prior to taking the e-bike home. The average number of sessions prior to taking the e-bike home was 2.1 (median: 2). The median duration of each session was 120 (IQR: 120,120) minutes.

The median time between the first lesson and taking the e-bike home was 11 (range: 1 to 106) days. Specifically, 11 participants took the e-bike home within two weeks of having the first lesson and five took the e-bike home within one month. One participant required additional e-bike training and had to wait for specialised equipment (a mirror and seat post) before taking the e-bike home. One participant had an accident during training resulting in training being paused. One participant went on holiday during the training phase and as such there was a delay between training sessions.

6.4.3.1.2 E-bike loan period

The median time between taking the e-bike home and session three was 35 (IQR: 29, 62) days. Prior to session three, two participants withdrew from the study, leaving 17 active participants. Of these 17, 10 (59.0%) attended session three. The median duration of session three was 120 (IQR: 97.5, 120) minutes. For one participant this session was completed as a telephone call. Two participants had one additional face-to-face training session after session three due to lack of confidence riding the e-bike.

One participant returned their e-bike prior to session four due to purchasing their own e-bike, leaving 16 active participants in the intervention. Of the 16 individuals in the intervention, six (37.5%) completed session four. The median time between session three and four was 49 (IQR: 37, 58) days. For one participant session four was conducted as a face-to-face session, for the other five this was a telephone conversation. The median duration of session four was 30 (IQR: 30, 52.5) minutes. The median e-bike loan period for the 16 participants that remained in the intervention was 14 (IQR: 13, 17) weeks.

Table 6.9 Number of e-bike sessions attended and average duration

	E-bike training phase			E-bike loan phase		
Session	Session One (n=19)[a]	Session Two (n = 19)[a]	Additional sessions	Session Three (n=17)[a]	Additional sessions	Session Four (n=16)[a]
N	19	15[b]	3[c]	10	2[c]	6
%	100.0	79.0	16.0	59.0	12.0	37.5
Median duration (IQR), minutes	120 (120,120)	120 (105,120)	150 (135,275)	120 (97.5,120)	135 (127.5, 142.5)	30 (30,52.5)
Notes			one session: n=2 four sessions: n=1		one session : n=1	

[a] n represents the number of participants enrolled in the intervention at that time, [b] Four participants took the e-bike home after session one and therefore did not complete session two, [c] The number of individuals that had additional e-cycling sessions, IQR=interquartile range

6.4.3.1.3 Total instructor contact time

The median time spent in contact with the instructor was 240 (IQR: 172.5, 367.5) minutes. The median number of sessions, both face-to-face and telephone was 2 (IQR: 2, 4).

6.4.3.2 Dose response

Examination of the relationship between the amount of contact time with the instructor and total distance ridden during the intervention revealed no correlation between the two (R=0.002). This is not surprising given that confident riders were unlikely to attend session two, and unconfident riders engaged in significantly more lessons but may not have had the confidence to ride frequently. Attending at least one session during the e-bike loan period appeared to be associated with greater distance travelled over the course of the intervention, with a median of 153.1 (IQR: 139.7, 318.8)km for those that attended a session with the instructor during the loan period and a median of 49 (IQR: 20, 120)km for those that did not attend a session with the instructor during the loan period.

6.4.3.3 Intervention fidelity

Appendix 6.7 displays the proportion of participants who received each of the components of the four intervention sessions as reported by checklists completed by the instructors. In summary, all participants completed the National Skills training level one and 90.0% completed at least eight of the 14 skills from level two. However, these skills were not all completed during session one with ten (50.0%) participants completing these practical skills in session two. Of the 15 participants who attended session two, seven (47.0%) completed some aspect of National Skills training level three. Four participants took the e-bike home after session one and therefore did not complete session two.

Regarding the behavioural counselling during e-bike training, fidelity was high with over 80.0% of participants receiving all specified content. The one exception was in session one in which 37.0% of participants did not engage in *action planning.* Instructors reported that this activity was not completed as participants would not be riding the e-bike between sessions one and two and felt this discussion was better suited for immediately prior to taking the e-bike home. Eighty percentage of participants who attended session two engaged in *action planning.* In session two, 87.0% of participants were encouraged to set *e-cycling goals* and 93.0% discussed potential barriers to e-cycling and brainstormed potential strategies to overcome them (*problem solving).*

Overall, sessions conducted during the e-bike loan phase had high fidelity with attendees receiving 90.0 to 100.0% of the intended intervention content. However, sessions three and four were infrequently conducted (see Table 6.9). For session three, three participants were unable to attend due to work commitments and four participants provided no reason. No reasons were provided for the 11 session four telephone calls that were not conducted.

In total, 13 participants monitored their e-cycling either using the logbook, GPS device or both.

6.4.3.4 Intervention adaptations

Adaptations to intervention dose and fidelity are largely reported in section 6.4.3.3 and were in response to the needs of the participant. Appendix 6.8 reports each specific adaptation to the intervention as intended. Additional adaptations include one participant completing e-bike training at home due to work commitments. This individual had three face-to-face training sessions and a further three face-to-face sessions during the loan phase. For six participants the e-bike loan phase extended beyond three months. Reasons for extended loan periods included illness which prevented e-cycling (n=2), lack of riding confidence (n=1), difficulties scheduling post-testing (n=2), post-testing appointment was changed and later cancelled due to COVID-19 (n=2). Some reasons for adaptations to the intervention were unknown. These adaptations largely relate to the omission of behavioural counselling components in a small number of participants (A total of 29 adaptations across seven participants).

6.4.3.5 Instructor administration time

Instructors' total administration time for the study was 19 hours for the 19 participants. Specifically, six participants administration required 30-minutes of administration, seven required one hour and six required 1.5-hours.

6.4.4 Are the intervention and study procedures acceptable to participants and instructors?

6.4.4.1 Participant process evaluation

A total of 34 participants took part in telephone interviews at the end of the study. Appendix 6.9 provides details of the codebook development. The analysis resulted in the development of four overarching themes which align with the research objectives: *Study participation; Acceptability of assessments and monitoring devices; Experience of e-bike training and intervention; Experience of research visits.* These themes incorporate 16 sub-themes reported below with illustrative quotations. Each quote is followed by a participant ID code and participant characteristics for context.

Theme 1: Study participation

Participants reported factors that influenced their decision to participate in the study and physical conditions that impacted participation in the study procedures. This information is captured in four sub-themes: *benefit the community, personal interest, response to randomization* and *participant co-morbidities.*

Benefit the community

Participants expressed that participating in the study enabled them to 'help' the researchers as well as others living with T2DM:

'Well, I think I just had a letter through the post regarding the study. Decided I'll go with it. If I can help, I'll see if I can help'

(PS024, Control, Male, 56years)

'The reason why I joined the study is because obviously it's something that would benefit people with my condition'

(PS034, Control, Male, 51years)

Personal interest

Participants believed that participating in the study would give them insight into their health, through completion of unusual assessments. Having access to personal results was important for diabetes management and identification of unknown health conditions:

'*Something I'm interested in, is to see how my body has reacted to that sort of sugary drink, and things like that, and the scans…. because it's all people with diabetes, you know, I would think people would be very interested in that because it's tests that you don't normally get when you go to your doctors, isn't it?'*

(PS016, Control, Male, 69years)

Participants were also interested in seeing how their results changed over the study period:

'I wouldn't mind looking through the results so you could compare, because I'd be interested in that to use it to push myself on to do more'

(PS013, Int, Female, 64years)

Having the opportunity to trial an e-bike was a major reason for signing up to the study and participants were optimistic that signing up for the study and having access to an e-bike would positively impact their PA and health, including their diabetes:

'That whole excitement and getting on a bike is one of the driving things for signing up in the first place, but also I think I would have done more, or would have been hoping for fitness to improve more, if I'd been on the bike side of things, because it makes you do more.

(PS003, Control, Female, 46years)

Response to randomization

Participants in the control group were disappointed about their group allocation, due to their desire to try an e-bike immediately and because they would not get to see the impact of e-cycling on the assessment outcomes:

'*I was a little bit disappointed. I would've liked to have seen what the difference would've been after they've done the bike for the three months'*

(PS006, Control, Female, 65years)

Knowing they would access the e-bike at the end of the study reduced the disappointment:

'You know what, it didn't matter because it was going to be something that would eventually happen. In one way I was looking forward to trialling the bike but it's something that's going to happen in the future. I'm a patient man'

(PS051, Control, Male, 56years)

Individuals who were more aware of the randomization process were less disappointed about their allocation to the control group than those who were less aware of the process:

'I was fine about that as I knew to expect it. I think I'd been briefed very well to expect that was a possibility, so it wasn't a surprise, and I wasn't upset by that'

(PS033, Control, Female, 51years)

'I was ready to go. That's the thing. I felt if someone is ready to go and they can do it there and then, well why not?'

(PS028, Control, Male, 53years)

Participant co-morbidities

Participants reported a variety of physical conditions that impacted their ability to complete study assessments:

'*I didn't do the fitness test. Oh, that's what it was. I fell and hurt my ankle, I had to go to hospital that's why I couldn't do the fitness test'*

(PS012, Int, Female, 42years)

Older participants reported more chronic conditions such as recovering from cancer or arthritis, while younger participants reported more acute conditions such as chest infections or knee injuries.

Theme 2: Acceptability of assessments and monitoring devices

Participants expressed their perceptions of the various study assessments and monitoring devices. These experiences were captured in three sub-themes: *compatibility with lifestyle, reaction to electrodes, physiology assessment experience*.

Compatibility with lifestyle

Operating the Garmin GPS, for those in the e-bike condition, was manageable for some and unattainable by others:

'The only thing I couldn't do, what do you call it. The GPS, I couldn't get my head around that. I just couldn't get my head around it'

(PS015, Int, Male, 59years)

For those that did use the GPS, self-monitoring their e-cycling was enjoyable:

'*The Garmin, I was using that as well and I was downloading it onto my phone and things like that, it was really good'*

(PS011, Int, Female, 57years)

Participants who were working reported a high degree of burden in relation to overall monitoring due to their busy daily activities:

'It was a case of, "Oh, I've got to remember to do all this and record it all and write it down and take it off in the shower" and all of those sort of things, so they're pretty inconvenient'

(PS027, Int, Male, 63years, working full time [FT])

Completing the travel diary was challenging due to lack of clarity about what to include and/or the nature of participants' journeys. In addition, some participants struggled to recall their journeys and/or remembering to complete the diary:

'I think for the charts, there were some days where I did multiple journeys, and was really sort of mad, here, there and everywhere. There wasn't enough space'

(PS003, Control, Female, 46years, working FT)

' *'it was a bit annoying to try and – if I did it straight away, it would have been okay, but putting it down and going back to it, not for me'*

(PS020, Control, Female, 61years, working part time [PT])

Remembering to wear the waist monitors and/or turn the GPS device on was challenging for participants. Several participants used prompts to remind themselves to put the devices on:

'I think I probably forget to turn the tracker on one day, I charged it but I think I may have forgotten to turn it on, but I didn't really have any problem with that because I just left it where my phone was and picked it up when I got up and put it on'

(PS002, Int, Male, 62years, retired)

Despite memory concerns, physically wearing the waist monitors was not a burden:

'*It worked like a belt really doesn't it? I would say it was fine, not intrusive at all'*

(PS032, Control, Male, 53 years, working FT)

However, the chest worn monitor was found to be uncomfortable and prone to movement or falling off due to adherence issues with the electrodes:

'And there were times that they fell, so you were trying, and if you were out, you know. I didn't have the replacements with me, so you were trying to reattach them and hold the in place at times'

(PS034, Control, Male, 51years)

Reaction to electrodes

Most participants reported having a reaction to the electrodes. This included red skin, a rash, itching or blistering. The reactions were worse at post-testing and took time to heal. This led some participants to not wanting to wear the monitor at post-testing:

'The first time round, it was sort of mid-point to the end and I was a bit rashy and just itchy. The second time round the intolerance to it happened really quickly, so within the first day, and it was really irritating, and I had to have periods off of it because actually I blistered'

(PS003, Control, Female, 46years)

Physiology assessment experience

Participants found completing the maximal exertion test difficult but understood that this was the purpose of the assessment.

'The exercise tolerance one, I took trying to get to the maximum seriously. So that was, on both occasions, quite an effort'

(PS001, Control, Male, 61years)

In addition, the mouthpiece and nose clip worn during the assessment caused discomfort:

'Oh, well the mouth monitor, I think, was the worst thing. That made doing the bike bit hard'

(PS009, Int, Female, 62years, retired)

The body composition scans did not concern participants, due to the minimal effort required:

'Well I didn't mind the scans; you were laid down, just thinking about it'

(PS051, Control, Male, 56years)

However, a small number of participants reported difficulty getting in the leg scanner:

For me, being my age, getting my leg in the scanner at Bath, you know, the table's straightforward enough, but that was again, it was just a bit awkward, as you know'

(PS016, Control, Male, 69years)

There were mixed feelings regarding blood sampling. Some participants reported a general dislike of having blood taken and found cannulation uncomfortable, while others had no concerns about having blood taken:

'I have to say, as I'm getting older I'm getting a bit queasy and I don't know why….. The second time, the nurses really struggled to get the cannula in. I'm always a little bit, not as blasé as I used to be'

(PS007, Int, Male, 58years)

'I've never been bothered by giving blood, so having all the blood samples taken wasn't a problem'

(PS041, Int, Male, 55years)

Theme 3: Experience of research visits

Participants discussed the logistical aspects of attending research appointments and their perception of these visits. These experiences were captured in the sub-themes: *engagement with staff, time requirements to participate* and *travel requirements, perception of participation.*

Engagement with staff

Participants enjoyed engaging with the research staff. These positive interactions impacted participants' perception of the research visits and assessments:

'I never thought I would enjoy bloodwork so much as I did with your staff. They were great'

(PS025, Control, Female, 65years)

Staff were perceived as knowledgeable of the study purpose and procedures and they made participants feel at ease:

'The staff were absolutely brilliant, you know, explained everything, I felt really relaxed. We just engaged in conversation, and it was really, just really good. I enjoyed that'

(PS051, Control, Male, 56years)

Time required to participate

Participants felt the study involved a considerable time commitment. Retired individuals were not concerned about this commitment as they felt they had the time available, whereas individuals who were working appreciated being able to book appointments outside of regular work hours including evenings and weekends:

'That's alright, because I don't work or anything, so that was no hassle'

(PS008, Int, Female, 59years, retired)

'The daytime ones for the bloods and stuff, because I could do them early and then go on into work afterwards, that was absolutely fine. I don't think that I could have done the activity bit in a weekday, certainly not in the morning, just because getting into work to do things'

(PS003, Control, Female, 46 years, working FT)

Despite flexibility fitting all appointments around work schedules was still challenging:

'I mean, the last visit, that was a bit of a challenge because it was during the week, so the meant I just sort of took some time off work'

(PS034, Control, Male, 51 years, working FT)

Participants felt that having more appointments available outside regular work hours would make the study more appealing to those working full time.

Travel requirements

Most participants were unfamiliar with the location of research visits two and four at the University of Bath. Being unfamiliar with the appointment destination or how to get there caused some anxiety.

' How was getting to Bath?'

'Stressful. But only because I hardly ever go to Bath and we normally avoid Bath'

(PS013, Int, Female, 64years, working PT)

The distance and density of traffic when travelling to Bath was a considerable burden and some participants felt the journey was only possible by car:

'The last time it was horrendous. I'd left absolutely extra early and it's a good thing I left really early because I ended up being late because of the traffic'

(PS051, Control, Male, 56years, working FT)

'I think I would have struggled if I didn't have a car, because that's quite a distance'

(PS033, Control, Female, 51years, working PT)

Perception of appointment location and distance did not vary based on employment status. All participants would have preferred appointments to be in the same location:

'*If all of the visits were in the same place, that would slightly simplify it for the participants'*

(PS001, Control, Male, 61years, retired)

Parking was a challenge in Bristol due to limited space and the distance of the parking facilities from the appointment location. Parking in Bath was easier due to the large university car park and provision of parking permits. Several participants commented on the cost incurred of attending appointments:

'*It was only a couple of pounds a time, but when you do it a couple of times all those things add up to sort of £25. You don't give away £25 for no reason, do you?'*

(PS028, Control, Male, 53years)

Perception of participation

Participating in the study was perceived as a positive experience:

'*This* [the study] *was exposure to different kinds of equipment that is available to try out and tests in equipment that I've never seen before. That was quite an experience'*

(PS034, Control, Male, 51years)

Some participants felt that the study procedures were clearly explained, and appointments ran smoothly:

'The information sheet before told me exactly what to expect. Before you go in, you know exactly what you're going to be doing'

(PS034, Control, Male, 51years)

However, others would have liked more explicit information about the time commitment and specific study procedures:

'I think first and foremost it would be help by using a short sheet to express what you're doing, and explain a bit more about that'

(PS021, Control, Male, 59years, working FT)

Theme 4: Experience of e-bike training and intervention

Individuals in the e-bike group shared their experience of the e-bike intervention and the equipment provided. These experiences are captured in the sub-themes: *appropriateness of equipment; access to e-bikes; perceived efficacy of instructor and instruction;* and *theft concerns.*

Appropriateness of equipment

Several participants felt that the e-bike they were loaned was too large, leading to feelings of discomfort:

'*I never felt comfortable with the bike that I was given because I found the frame too high. I did use it and I got more used to it but I never felt particularly comfortable'*

(PS007, Int, Male, 58years, Instructor 01)

As such, two participants changed e-bikes during the loan period due to the size concerns:

'*The second one was okay with me, I enjoyed the second one. I could get on and the seat went down to the level I wanted it to'*

(PS011, Int, Female, 57years, Instructor 01)

The weight of the e-bikes made it difficult to manoeuvre for some participants:

'*I think the electronic bike was so heavy and not manageable'*

(PS023, Int, Female, 56years, working FT, Instructor 01)

These concerns were reported by men and women and echoed by instructors.

The extra equipment provided by LCUK (panniers, lock and mirror if required) was appropriate. Some participants purchased additional equipment including padded seats, shorts or waterproof clothing:

'*Clothes wise I bought a jacket and a pair of shorts and that was it. It was only the light and a jacket, yes'*

(PS041, Int, Male, 55years, Instructor 01)

Access to e-bike

Due to a limited range of e-bike sizes available some participants had to wait for a suitable bike size to become available before having a lesson or had to wait for seat posts to arrive that could lower the bike height. These delays meant some participants did not get the e-bike when expected:

'*Initially I was really excited, and I loved that I got it in the summer. Although there was a delay of three months getting the bike. So, I got it just as I was going to go on holiday'*

(PS044, Int, Female, 67years, Instructor 04)

Several participants felt the length of the e-bike loan should have been longer to account for health conditions, weather, and/or time constraints that impacted riding:

'*If I could have done for the full three months that I had it, every day when I wasn't ill, and then I had it for another three months, I think I would have been out and about on the bike, I think, because a few times I was going to go up to my dad's on it'*

(PS012, Int, Female, 42years, Instructor 01)

E-bike community

Participants were invited to join pre-existing group rides. One participant attended group rides. Some participants intended to join group rides, but it never materialised, while others preferred to ride alone:

'*No. I kept meaning to ring up. There was somewhere I could have rung up, but I just didn't get round to it in the end'*

(PS008, Int, Female, 59years, Instructor 02)

'*I'm more than happy* [to cycle alone] *I can stop as and when it suits me'*

(PS049, Int, Male, 68years, Instructor 04)

One participant tried to connect with participants via the PEDAL2 WhatsApp group but no other participants engaged:

'*I didn't go on any organised rides. I thought about it, but on the WhatsApp group there were no responses. I put a comment on there if people wanted to go out and there was no response'*

(PS041, Int, Male, 55years, Instructor 01)

Perceived efficacy of instructor and instruction

Despite an initial belief that the e-bike training would be unnecessary, participants with lots of cycling experience reported learning new skills, particularly concerning how to ride in traffic:

'*That was really useful actually because I was a bit, you know, "I don't need to do this," kind of, thing "I've always cycled, I don't need to be shown what to do." But it was actually quite useful just to do some basics'*

(PS007, Int, Male, 58years, lots of cycling experience, Instructor 01)

For participants with limited cycling experience, who completed all, or more allocated sessions, the training was perceived as appropriate, in relation to both time and content, to enable participants to ride the e-bike:

'Yes, it was pretty good, it reinforced the road awareness that I think is quite important, particularly if you haven't ridden a bike for a while. I feel that was very good at pointing out what you should do at junctions and double checking you're aware of everything and making sure you were looking both ways. I think, is very important and they definitely reinforced that'

(PS027, Int, Male, 63years, little cycling experience, Instructor 02)

However, for participants with no previous cycling experience the training was good but they did not feel ready to ride on the road:

'*I think it was just one. I only had one* [lesson] *because I wasn't going on the road, I think he just let me take it. If I would have been going on the road, there would have been a few more lessons. I would have needed quite a few'*

(PS012, Int, Female, 42years, no cycling experience, Instructor 01)

Differences in the perception of the training were dependent on the instructor. Some instructors were perceived as engaged and adapted the lesson to meet the participants' needs while others felt instructors rushed the training:

'[the instructor] *was excellent. They did it in stages. You progressed out into the little space they've got round the Centre. Once you were fully competent you went out and ventured more to where the bus route is. Then in the end we went round XX and I don't think I would have ever cycled around XX without* [the instructor]. *It just opens your eyes to what you can do'*

(PS013, Int, Female, 64years, lots of cycling experience, Instructor 03)

'Tell me about the training you received?

'Which I didn't get….. I jumped on the bike, rode up and down 50 yards each way "Right, that's fine, thank you very much" I mean, I wasn't there much more than about 40 minutes, then I took the bike home, which took me by surprise'

(PS049, Int, Male, 68years, lots of cycling experience, Instructor 04)

For participants with lots of cycling experience minimal training did not impact their confidence, but for those with minimal experience more training was required to increase confidence:

'*And maybe cycling for an hour would have boosted my confidence and got me a better technique, you know'*

(PS047, Int, Male, 69years, little cycling experience, Instructor 03)

Participants who found instructors to be disengaged had no follow-up contact. Several participants, with varying experience, felt the follow-up sessions were unnecessary and as such several participants did not complete these sessions:

'He suggested it [doing a follow-up session] *but we spoke on the phone, I think and I told him I'd been going out quite a lot. And I think he felt everything was fine and there was no real need to do another session. I was happy cycling on my own and I didn't really think it was necessarily going to be a benefit'*

(PS007, Int, Male, 58years, lots of cycling experience, Instructor 01)

However, those that did complete the session found it enjoyable and felt they learnt something new:

'We did the 45 minutes around XX, sort of road and cycle paths. Yes, it was good. Not really necessary, but it was good to do. It was silly little things. When I was following him, we went down a one-way system the wrong way, but it was perfectly fine because the roads are actually saying "bikes allowed" on it. It was just little technicalities, you're thinking, "Well, is that right or not?" but obviously it was. It's just to reassure yourself and I asked a few little questions, so it was just putting my mind at rest really.

(PS041, Int, Male, 55years, little cycling experience, Instructor 01)

Theft concerns

Many participants were worried about the e-bike being stolen and felt they had to plan their journeys around having a safe place to lock the e-bike at the destination:

> '*I know there's a problem with cycle theft so I'd need to plan ahead and know that I was going to be able to leave it somewhere secure'*
>
> (PS007, Int, Male, 58years)

The fear of theft was exacerbated as the e-bike was loaned and participants were unsure of the implications for themselves if the e-bike was stolen:

> *'I'd lock it up, I'd be less worried about if it got stolen, because it's, like, mine, so I could do something about it, you know? I haven't got to explain to someone else how I managed to lose a bike'*
>
> (PS002, Int, Male, 62years)

Due to this concern participants avoided certain journeys on the e-bike, with a few participants reporting using the e-bike purely for leisure rides where they would begin and end the journeys at home:

> *'I was more worried about this one getting stolen or something. There have been bike thefts at the hospital, and I was thinking, "Hang on, I don't want to get this pinched." I was a bit dubious about riding it to work'*
>
> (PS015, Int, Male, 59years)

6.4.4.2 Instructor process evaluation

Three of the four instructors took part in telephone interviews at the end of the study. Appendix 6.9 provides codebook development details. Nine sub-themes were formed, overarched by two themes of *perception and delivery of intervention content* and *logistics of intervention delivery.* Due to the small number of instructors demographic information is not provided with quotes, rather an ID number that links participants to the instructors are provided.

Theme 1: Perception and delivery of intervention content

Within this theme, instructors discussed their thoughts regarding the appropriateness of the intervention and their ability to adapt to the needs of the participants. These experiences are captured in four sub-themes: *e-bike skills training; delivery of behaviour counselling; intervention adaptability* and *compatibility with values as an instructor.*

E-bike skills training

Delivery of the skills training was straightforward as it followed the National Skills bicycle training, which instructors regularly delivered:

'*So, in terms of what we're delivering, the actual standard makes sense, because it ties in with what cycling instructors know how to deliver and feel comfortable delivering, so there's not a learning curve there. And it covers all of the basics, in terms of what the participants will need, to ride safely and ride competently'*

(Instructor 03)

The location of training was not ideal due to limited car free space:

'*In an ideal world being somewhere like the XXX would be better because it's a completely off-road environment and there's lots of space there. Whereas doing it at XX there's always a minimal risk of a car or a van coming through. I was keeping an eye out for that when we did stuff in those areas. In an ideal world somewhere with a bigger traffic-free area would be great'*

(Instructor 02)

Delivery of behaviour counselling

The behavioural counselling took place both formally sitting down before or after the first session and/or informally during rides. All instructors believed that working with participants to identify barriers to e-cycling and helping participants plan where to cycle was an important component of the programme, which made the participants feel supported:

'*I think it was good to vocalise them* [barriers to e-cycling] *and discuss them. I felt people felt that having that discussion was useful. It made them think about the barriers. It made them feel that their concerns were being listened to. So we weren't just going, "Here's a bike, get on with it."*

(Instructor 02)

The level of comfort initiating and engaging in these conversations depended on instructors' perception of their expertise to speak to the intervention content and their ability to encourage positive behaviour change. Instructors who felt confident in their knowledge and ability to have these discussions found them enjoyable:

'Yes, it is fine [delivering the behavioural counselling] *because I had some training in that as well, in how to gee people up and how to listen to them. I found that quite pleasurable, actually, talking to them and trying to encourage them to overcome the little hang-ups they'd*

made for themselves or their thinking had caused. That was fun for me, actually. The psychology was quite fun and the nudging'

(Instructor 03)

Personal beliefs about the impact of cycling on certain health outcomes influenced how one instructor felt delivering the programme:

'*For other people there was less awareness of the physical benefits* [of cycling]. *Particularly* [Participant X] *talked about weight loss. Even if I were to go and ride an e-bike loads, I wouldn't necessarily lose weight because there's much more linked to it, there's your sleep and your diet and what other exercise you do. I was able to have the discussion to some level, but sometimes it felt a bit formulaic because I'm not a nutritionist.*

(Instructor 01)

Intervention adaptability

Instructors' felt that the wide range of skills among participants necessitated adapting the programme which they were able to do:

'*I felt fine adapting the programme because people didn't necessarily fit into the exact structure that was prescribed. That wasn't an issue, I was able to adapt it'*

(Instructor 01)

However, perception of the appropriateness of adaptions, from a programme perspective varied. Some instructors reported that the programme was flexible, while others felt the programme was prescriptive by design:

'*Obviously there is a wide range of skills and confidence levels of the people participating, but it felt like it was set up in such a way that you can quickly breeze through all the skills stuff for people who are relatively component'*

(Instructor 03)

'I'd say that not everything was applicable to everyone. It seemed like there were some redundant sections that still needed to be filled in even though it wasn't relevant for that person'

(Instructor 01)

Instructors would have liked more training on the programme content and how adaptations could be made prior to delivery, particularly regarding the number of training sessions they could offer participants and how to complete the programme content*:*

'I think what could be improved is the initial talk. It wasn't until I really looked at it again [the programme] *that I realised there was a lot more to it than I thought. For me, I think I needed another session saying, "This is why we do this, this is why we do this, this is why we do this. This is what you do on the second, this is what you do on the third week." It just didn't go in the first time, and that might be just me'*

(Instructor 03)

Compatibility with values as an instructor

The programme design, including the amount of paid time, enabled instructors to develop a relationship with the participants:

'*I really enjoyed getting to know people a bit better and finding out what they were hoping to do'* (Instructor 01)

Instructors found it satisfying to work with individuals who may not have previously considered cycling and for whom, engaging in cycling, could have a significant impact on their health. Helping these individuals learn, and watching them progress was rewarding:

'*What I liked was teaching people who obviously needed a lot of exercise and needed some help with it. Teaching people to ride electric bikes, it's always a pleasure'*

(Instructor 03)

One instructor felt that working on this programme provided them with knowledge that could be used to promote cycling at the individual or local level:

'*From my own perspective, it was good to hear what are barriers for other people, because obviously, as someone who is trying to advocate people using bicycles more often, it's a little snapshot of what some people feel are the barriers. And that's good to kind of feed into other cycling advocacy stuff. So if the local council or the national government is going, "Hey, we're making cycling really accessible," or, "Bristol is a cycling city," you can go, "Well, these people, who are just getting into cycling, see these things as barriers, so there is still work to do."'*

(Instructor 02)

Theme 2: Logistics of intervention delivery

Instructors discussed various factors that impacted their ability to deliver the intervention. These factors are organised into five sub-themes: *communicating with participants; participant characteristics; communicating with peers; equipment; administration.*

Communicating with participants

Instructors discussed difficulties getting in touch with participants to organise initial training and during the e-bike loan period:

> *'She definitely took the bike away on her second session. After that it was really difficult to get in touch with her to get the lesson set up near her home. We did eventually, but it took quite a long time to get done'*
>
> (Instructor 01)

While this was largely due to lack of participant engagement, one instructor reflected that they did not stay in touch with participants:

> *'I could see that I'd missed a lot out with my initial people. I hadn't rung them enough and I hadn't kept in touch'*
>
> (Instructor 03)

Participant characteristics

Instructors reflected that while having positive intentions and motivation to improve their health, PEDAL2 participants were less motivated to engage in cycling than their normal clients:

> '*Yes, I guess the people who kind of self-refer are doing it because they really want to learn how to cycle, or improve their confidence so they can cycle more and in trickier situations. The participants here were doing it for different motivations, so they weren't quite as motivated and keen to kind of do it* [cycle]. *But you know, everyone was up for it. On a scale of one to ten, ten being super keen, they were all seven or eight, rather than nine or ten'*
>
> (Instructor 02)

This was provided as a potential explanation for why it was sometimes difficult to get in contact with participants.

Instructors felt that, overall, PEDAL2 participants had lower level of cycling proficiency, lower fitness levels and higher weight than regular clients and this impacted their ability to ride and/or manoeuvre the bikes:

'*for* [Participant Y and X] *their weight is higher than my average client. There was a bit more work on balance, getting on and off and just fitness as well. They weren't fit enough to do as much in an hour or an hour and a half as I would normally get through'* (Instructor 01)

Having more information about participants health status, beyond having T2DM, would have been beneficial prior to conducting the programme.

Communication with peers

Instructors perceived a lack of communication between themselves and LCUK regarding programme implementation logistics included how many lessons could be conducted and billing time. Instructors did not discuss programme implementation with other PEDAL2 instructors:

'*We kind of all just were like ships in the night, passing each other at different times. Or, if we did see each other, we were working, so we didn't get much chance to sit and discuss stuff'* (Instructor 02)

Instructors expressed that limited communication with other instructors was normal within the organisation. All instructors felt that communicating with peers would have been useful early on in implementation to share experiences:

'*I think if you were doing it again, with the same number of participants, with a bigger study, or rolling out, it would be good to have a pool of instructors and get them together at the beginning, to have a little chat, and then get them together. So, after the first batch of people has gone through the programme, get them to discuss stuff, as well'* (Instructor 02)

Equipment

The size of the e-bikes was a concern. Instructors had to either order extra equipment to make the e-bike fit the participant, wait for an appropriate size bike before conducting a lesson, or organise a smaller bike during the loan period:

'*I think that was a real challenge* [size of the bikes available]. *That resulted in quite long delays for people waiting to get bikes. With the one in one out situation where Life Cycle had to get a bike back before they could give it out to someone else, that wasn't ideal'*

(Instructor 01)

Prescribing bikes that were perceived as large by participants was perceived as a potential reason why some participants required more lessons or engaged in minimal riding:

'To some extent the first couple of lessons were a write-off because the smallest available bike at that time was still too big for her and she just didn't feel confident getting on it, which is completely fair'

(Instructor 01)

Due to the weight of the bike, and participants handling ability, more e-bikes of smaller sizes and step through bars would have been appropriate. Instructors felt that this was an important learning point for future programmes:

'From a credibility point of view, if you're coming into that study as a participant I'd expect as a minimum to get the correct sized bike on my first lesson'

(Instructor 01)

Perceptions of the ease of use of the Garmin varied. Some instructors felt it was easy to operate and instruct participants while others felt it was too much for themselves and participants to learn:

'The Garmin I think that was a step too far for some of them because they are mostly older people. I think it depended whether they had a son or daughter to work it for them. I'm fairly technical and I think these Garmins are a bit too much. Someone 10 years older than me, 20 years older than me, I think it's asking a bit much, actually'

(Instructor 03)

Administration

Instructors spent a considerable amount of time organising sessions or rearranging missed sessions. However, being able to bill for this time reduced the burden of administration:

'*There was quite a lot of background admin, just to arrange the sessions'*

(Instructor 02)

'For me, I would have dedicated a lot less time to it and a lot less detail. With communications with people I'm doing one to ones with, I try to just stick to the minimum logistics necessary. Then if they've got questions and stuff, I answer those during the lesson because that's time I'm getting paid for. Even if that means they spend less time cycling, then I'm okay with that because that's the time I'm getting paid for. Whereas with Pedal-2 because I knew I was getting paid for it I made a much greater effort to send feedback on people, to check in with people and see how people were doing and stuff'

(Instructor 01)

The paperwork associated with PEDAL2 was more than for a regular one-to-one lesson. While instructors recognised the need for the paperwork, they highlighted the importance of balancing the amount of paperwork against instructor burden:

'There's a balancing of getting the information you need to get and not making the paperwork too onerous. That's not something that Life Cycle's instructors have to do very much'

(Instructor 01)

Instructors found the checklists helpful as a reminder of what to complete but felt it could be restructured for clarity and to reduce repetition:

'*I didn't fill in every line, for instance, because it wasn't quite clear to me whether they had got that or not. I know I taught it to them. Whether they got hold of it or not was another matter, so I didn't know whether I could tick it or not. Sometimes when I saw them again I could tick it because they demonstrated. Teaching it to someone doesn't mean they get it'*

(Instructor 03)

6.5 Discussion

The current chapter examined the feasibility and acceptability of conducting a pilot randomized controlled e-cycling trial among adults with T2DM. Participants were successfully recruited, randomized, and retained in the study. The study procedures and intervention were deemed to be acceptable by this clinical population and cycle instructors. Based on the results, and the progression criteria reported in Chapter 5, a fully powered RCT is warranted subject to procedural amendments and intervention refinement based on the study findings discussed below.

6.5.1 Recruitment

Overall, coordinators from Bristol Diabetes Support Network and Diabetes education days and GPs were willing to assist with the identification of potentially eligible individuals. Furthermore, over 60% of primary care practices in the local CCG expressed6 an interest in acting as a PIC. The involvement of the local clinical research network (an initiative set up by NIHR to coordinate and support the delivery of research across the NHS) was key in engaging primary care practices by acting as a liaison between researchers and primary care practices. Previous research has found that direct contact from researchers is ineffective at engaging primary care clinicians (494).

The three recruitment strategies used reached 2,046 individuals, equating to 4.1% of individuals living with T2DM living in the area. Of those that received study information 5.8% provided EOIs. While the rate of EOI was similar across all recruitment strategies, due to their extensive reach (90.7% of those reached) targeted mail-outs from primary care practices was the most effective recruitment strategy from which 85.0% of participants were recruited. The rate of EOI was considerably lower in the current study than the 28.3% reported by Cooper and colleagues in PEDAL1 (171), from which progression criteria for this study was based. There are two possible reasons for these differences. Firstly, the two studies used different recruitment strategies. Cooper and colleagues (171) recruited from an existing pool of 99 individuals who had previously participated in an observational research study. In the current study individuals were recruited from real world settings to identify effective and sustainable recruitment pathways. As such, it is possible that the targeted sample had different characteristics and levels of motivation for engagement. Secondly, it is probable that a significant number of individuals provided with study information were ineligible. Specifically, 50% of GP practices were unable to screen on the five exclusion criteria and the Bristol Diabetes Support Network meetings including both individuals with both T1DM and T2DM of all ages. Of the individuals that returned the invitation slip and declined to participate (n=76), 53.5% were identified as ineligible based on their responses. As such, the EOI of 5.8% from those reached is a conservative estimate of those that received information and were eligible. Following EOI in the study (n=111), 41.4% of individuals were deemed eligible for the study. This is a higher ‘success rate’ than other lifestyle intervention trials for T2DM (489, 490), potentially due to the stricter criteria used by other studies based on outcomes of interest (i.e., CVD events, reduced body weight). This suggests that the current eligibility criteria are appropriate for a future RCT, though they should be reviewed based on the selected primary outcome measure under investigation.

Given the current findings, a future trial should use targeted recruitment through GP practices as the primary recruitment strategy. This targeted mail-out method of recruitment has been effective for recruitment in other PA interventions (485, 490) and has been found to produce a more representative sample than flyers or untargeted methods (485). Where possible more restrictive database searches that closely reflect the eligibility criteria should be conducted to reduce the number of ineligible individuals contacted.

6.5.2 Randomization and retention

It was possible to recruit and randomize the full sample with a retention rate of 87.5% at post-testing. This is similar to the retention rates of a randomized e-cycling trial among overweight adults (253) and a walking trial for individuals with T2DM (495). Cooper and colleagues (2018) reported a 90.0% retention rate in PEDAL1, though all participants received an e-bike.

Qualitative findings revealed that the ability to try out an e-bike was one of the primary motivations for participating in the study. As such participants were disappointed with a control group allocation. The opportunity to access an e-bike at the end of the study alleviated some of this disappointment. At the end of the study, 13 of the 18 control group participants completed e-bike training and loaned an e-bike. Therefore, use of a waitlist control likely increased control group retention following randomization. The use of waitlist controls in trials has been debated. Some researchers believe that their use leads to an overestimate of the intervention effects due to participants engaging in minimal healthy behaviours in anticipation of a future intervention (496). Others argue that the expectation of a future intervention motivates participants to change their behaviour to get a ‘head start’, therefore underestimating the intervention effect (497). Given the inability of blinding participants in PA interventions and the positive impact on study retention, a waitlist control is imperative for future e-bike trials. Process evaluations should explore the extent to which individuals in the waitlist control changed their health behaviours following randomization.

6.5.3 Collection of data

There was high attendance at data collection sessions and a high rate of study measure completion. This is potentially due to participants desire to undergo assessments that are not part of routine care and to gain insight into the impact of e-cycling on their health. Based on this finding all participants were provided with personal reports at the end of the study which were positively received by participants as shown through email responses to the reports. The provision of individual reports should be used to encourage adherence to data collection methods in future trials. Participants willingness to complete measures and return for testing was also influenced by interactions with study staff, who were perceived as knowledgeable and created a relaxed atmosphere. Providing a welcoming and relaxed environment has been found to be an effective strategy for maintaining participants in clinical research, but one that is often overlooked (498, 499).

Regarding specific outcome measurements, the least frequently completed measures were regular blood sampling (due to difficulties bleeding participants), the fitness assessments (due to lack of GP clearance, inappropriate clothing, injury or not wanting to complete the assessment) and activity monitoring using the Actiheart (due to major skin irritations). In general, the incremental fitness assessment was perceived as hard work. Despite this most participants were willing to complete the additional supramaximal assessment. Completion of a supramaximal test is beneficial for making accurate estimates of VO_{2max} while removing the need to conduct a second fitness assessment on a different day prior to intervention delivery. Completion of two fitness assessments prior to intervention delivery is encouraged to reduce error in initial measurement due to unfamiliarity with the assessment (500). In the current trial, 28.8% of VO_{2max} scores were higher following the supramaximal assessment and were taken as the final VO_{2max}. Given participants willingness to complete this measure use of a supramaximal assessment should be considered in a future trial to increase the degree of confidence in VO_{2max} results.

Participants were compliant with wearing the Actigraph accelerometer and GPS device, similar to previous research (501). However, the Actiheart caused major skin irritation and adhesion was poor. These issues have been reported in other studies using the same device (502-504). While the Actiheart has been found to be a reliable and valid measure of PA energy expenditure through integration of Hr and accelerometery (505), its use was of high burden to participants. In comparison, the Actigraph accelerometer, while providing a general measure of PA behaviour poorly identifies cycling (506). If researchers wish to examine the intensity of activity associated with e-cycling then Hr devices should be used, ideally coupled with accelerometery, in watch format to increase compliance and reduce burden.

In addition to the wearable devices, participants were asked to complete a paper travel diary. The degree of completion decreased from pre to post intervention. The diary was found to be confusing and trip recall was difficult. However, during data processing the travel dairy was frequently used to classify trips, identify trips not recording via GPS and provide trip context. Researchers wishing to measure travel behaviour should consider offering an online tool for recording trips to ensure that contextual trip information is recorded. This will enable participants to record journeys in real time using smartphones.

6.5.4 Intervention implementation

The intervention was feasible to deliver by a community-based organisation and their certified instructors. However, tailoring of the intervention was required based on the wide range of cycling skill level in the sample. Given the costs associated with the provision of instruction (£5556 on instruction and staff administration in the current trial, approximately £78 per session delivered) it is important to consider the base level of cycling ability of participants. During recruitment, all participants stated they had some degree of cycling experience. However, during training two participants disclosed having no cycling experience. While it is important to provide an intervention that is accessible to all, individuals should have basic knowledge of how to ride a bike prior to entered a cycling trial, to maximise the chances of intervention success. Individuals that do not know how to ride a bike could be directed to free community 'learn to cycle' initiatives such as is offered by LCUK. Potential participants could also be invited to an e-bike taster session as part of recruitment to determine whether they feel e-cycling is appropriate for them.

During the loan period sessions were infrequently conducted. Participants felt that these sessions were unnecessary, and in some cases, instructors failed to reach out to participants. For those that attended the refresher sessions they were reported to be enjoyable and increased feelings of support. Furthermore, attendance at one of these sessions was associated with greater e-cycling during the trial. Incorporating refresher sessions after initial training appears to keep participants engaged through developing rapport with the instructor and their use is encouraged in future e-cycling trials. Specifically, instructors should be advised on the importance of these sessions as a key component of the intervention and should strive to encourage attendance. Sersli and colleagues (160) recommend the use of refresher sessions following their review of conventional bicycle training as a means of increasing cycling behaviour.

Overall, the degree of adherence to delivering each component of each session was high (i.e., intervention delivery fidelity). The high adherence to both the skills training and behavioural counselling maybe reflective of the comprehensive resources developed for use by the instructors, which were reported to be useful, and the instructors previous experience delivering bicycle skills training and engaging with individuals in this manner. However, the study relied on self-report measures, which produce higher ratings of fidelity than observer reports (507, 508). A future trial should incorporate independent assessments of fidelity such as observation of sessions (492, 509). In addition different domains of fidelity, as proposed by the NIH Behaviour Change consortium, should be examined including assessments of instructor training on the intervention, receipt of the intervention and engagement by the participants (492). These domains are infrequently examined in the evaluation of PA interventions but are important for intervention scale-up and sustainability (507).

In the current trial 13 participants tracked their e-cycling using logbooks and/or a GPS device. Though not identified as a formal evaluation of engagement with the intervention, this suggests that the participants were engaging in self-monitoring of their e-cycling. The data suggest that those who engaged in self-monitoring and/or set goals (as reported by the instructors' checklists) rode further over the course of the intervention than those who did not (Median[IQR], 184.55[144.1, 357.25]km vs. 20[11.13, 33.25]km). The use of self-monitoring has been reported to be an effective BCT in PA interventions promoting walking and cycling (478), general PA interventions (510), and PA interventions among individuals with T2DM (459). Other than self-monitoring, it is unclear how the participants engaged with the other BCTs incorporated in the intervention, or the relative impact of each BCT on the outcomes. Rather the current study sought to provide a detailed picture of what was delivered, and by whom, from which future interventions can build.

6.5.5 Acceptability of the intervention

All interviewed instructors felt comfortable delivering the cycle skills training as it was familiar. Confidence delivering the behavioural counselling varied based on experience of similar activities. Regardless of comfort the behavioural counselling was perceived as being beneficial to the programme enabling the instructor to build rapport with the participant. Overall, participants felt that the instructors were engaged and supported them in their e-cycling journey. This knowledge and support gave them the skills and confidence to ride the e-bike independently. However, when instructors were not engaged in the process this was noted by participants and had a negative impact on riding for those that were less experienced cyclists.

Instructors felt that more training on the intervention would have been beneficial prior to delivery both regarding intervention content and the degree to which they could adapt the intervention to meet participants needs. In the current trial instructors received two training sessions, one pertaining to conducting behaviour change interventions and a second focused on intervention content. However, there was a significant time lag between the instructor training and delivery. In addition, not all instructors attended every training session. A future trial should include more comprehensive training prior to intervention delivery. These training sessions should formally teach intervention content and include role playing of e-cycling training sessions to ensure the content is understood. In addition, instructors should be given examples of how to tailor the intervention if required with clear guidance on how to report adaptations at regular intervals throughout the trial to ensure the potential impact on the underlying causal mechanisms of change can be understood. Based on instructors' feedback, peer support groups should be developed and run regularly to enable instructors to share and learn from the experiences of others, particularly when conducting training in an unfamiliar population.

6.5.6 Acceptability of study procedures

The time commitment associated with the study was a burden for most participants, particularly those who were working. Furthermore, the anticipated time commitment meant two participants dropped out of the study after their first visit prior to randomization. The large time commitment was the most frequently reported reason for declining to participate in the study during recruitment. A study of participant experiences of taking part in NIHR funded studies highlighted that individuals' time was one of the most important factors impacting participation and should be respected (511). As such, reducing the time burden associated with the study, including having appointments in one location and reducing their length may encourage more individuals to engage in the study.

6.5.7 Harmful events

Six harmful events associated with e-cycling were reported. Five of these incidents did not involve other road users and three occurred during training sessions. Most events were low speed falls associated with loss of balance, including a serious adverse event which resulted in hospitalisation and a broken elbow. Some participants loss of balance may have been due to the weight and/or size of the e-bike. The weight of the e-bikes was a commonly reported concern for participants in the current study and has been reported in previous research, particularly among older adults and women (512). Both independently, and in combination, aging and T2DM are associated with a reduction in balance and increased risk of falls (513-515). Furthermore, balance issues have been associated with e-bike incidents (180). While

PA can positively impact balance in these populations (516-518), a future trial should provide e-bikes that are slightly smaller in frame size than would be conventional for the participants' height to help them manage the weight of the e-bike. This would enable the participant to firmly place their feet on the ground when required, helping with stability and control.

6.5.8 Strengths and limitations

This is the first study to examine the feasibility and acceptability of conducting an e-cycling intervention in adults with T2DM using a pilot RCT. However, there are some limitations that must be acknowledged. Specifically, the findings of this pilot RCT may not be generalisable to others with T2DM. The individuals in this study were highly motivated to understand their own health and make behavioural changes, therefore self-selecting themselves for the study. This is a common problem in PA research (484). However, due to the recruitment methods used, particularly the use of primary care practices, it is likely that a more diverse group of people was reached than previous e-cycling trials (171, 253, 519). Interestingly, the characteristics of the final sample appear to be representative of the Bristol population. Specifically, 25.0% of the study sample self-identified as non-white and 43.0% as female. The 2011 census reported that 16.0% of Bristolians identified as non-white and 50.2% females (520). Furthermore, primary care practices selected to act as PICs were selected to represent different socio-economic areas using the IMD to reach a diverse range of individuals. Whether this is representative of the T2DM community in this area is unknown. It is important to note that there were differences in self-identified ethnicity between conditions (90% versus 60% self-identified as white in the intervention and control condition respectively). As such, a future trial may want to consider stratifying based on ethnicity.

The use of quantitative and qualitative methods to examine the feasibility and acceptability of conducting an e-bike RCT provides insight into the reasons why participants chose to engage with the study and complete (or not) the outcome measures. This detailed information can be used to help guide the selection of outcome measures and to amend the intervention for a future trial. A rigorous approach was taken to qualitative analysis to increase trustworthiness in the current findings. However, a potential influence of the researcher is unavoidable (469, 521). The prior relationship of the researcher with the participants may have predisposed the participants to provide answers that they believed the researcher was looking for or not wanting to offend. To try and overcome this limitation participants were encouraged to provide honest answers to help improve the programme for future peers. In addition, the use of telephone interviews has been found to enable participants to be more open and honest with feedback (493). The use of participant validation ensured that the interpretation of the interview made by the researcher was consistent with the views of the participant. Interpretations made by the researcher and reviewed by the participants showed consistency in the current study, therefore increasing the trustworthiness of the findings.

As previously noted, the measures of implementation used in this study report the degree to which intervention components were delivered. They do not measure the extent to which the participants understood the information provided or engaged with the intervention components at appropriate times (i.e., problem solving or action planning (492)). These fidelity outcomes should be used in a future trial.

6.6 Contribution to this thesis

Chapter 6 addresses some of the key uncertainties ahead of a definitive trial through use of a pilot RCT. Collectively it is concluded that an e-cycling intervention is feasible and acceptable for individuals with T2DM and can be delivered in a community setting by existing cycling instructors. However, this trial has identified a series of actions that should be taken in a future trial to improve the chances of successfully completing an RCT and increasing the likelihood of intervention success. This is the first study to explore the feasibility of conducting a pilot RCT of an e-cycling intervention and demonstrates that high quality longitudinal research can be conducted to address key gaps in the literature identified in studies one and two. This chapter highlights that pilot studies are valuable pieces of work that are beneficial to the literature, particularly in the context of e-cycling where randomized trial work is minimal. It is hoped that future researchers conducting e-cycling interventions can use the insights obtained from this trial to inform future intervention design and evaluation.

7 Chapter 7: Impact of an e-cycling intervention on a range of clinical, physiological, and behavioural outcomes in adults with T2DM

7.1 Overview

Chapter 7 consists of a brief introduction, detailed methods, and results which, in part, answer the third objective of this thesis: *examine the association between an e-cycling intervention and a range of clinical, physiological, and behavioural outcomes in adults with T2DM*. The findings and how they contribute to the overall thesis are discussed.

7.2 Introduction

As the popularity of e-cycling has risen so has the associated body of literature (166). This research has focused on the impact of e-cycling on the domains of health and transport as reviewed in studies one and two. Regarding health, acute physiology studies have demonstrated that e-cycling provides PA of at least a moderate-intensity in both active and inactive adults (289, 522, 523). Though limited in number, longitudinal studies have reported that the use of an e-bike by inactive adults can lead to improvements in cardiorespiratory fitness (289, 319) and glucose disposal rate (168) in as little as four weeks of pedalling. Furthermore, engagement in e-cycling has been shown to increase PA behaviour (169).

Despite increases in PA there is concern that e-cycling may substitute for already active activities, such as conventional cycling. However recent research has shown that e-cyclists ride for longer and more frequently than conventional cyclists leading to greater weekly energy expenditure than conventional cycling (303, 524). There is also evidence that e-cycling replaces the sedentary behaviour of motorised transportation (170, 512, 519).

Among adults with T2DM the provision of an e-bike for five months has been found to lead to a 10% increase in power output, a sign of increased fitness (171). Given the low rates of PA in individuals with T2DM (269) and the positive impact of e-cycling on health outcomes reported by Cooper and colleagues (171) further research is warranted to examine how the provision of an e-bike impacts a wider range of health outcomes and travel behaviour in individuals with T2DM.

Therefore, this chapter will address the secondary aim of this pilot RCT: **examine the association between the intervention and outcomes measured to determine intervention promise** and answer the following research question:

What is the potential effect of the intervention on a range of individual clinical, physiological, and behavioural outcomes?

7.3 Methods

Building on Chapter 5, this section provides comprehensive detail of the methods used to address the secondary aim of study three reported above. JEB completed all data collection, including blood sampling. Research nurses assisted with obtaining consent, collection of anthropometrics and blood sampling. Post intervention data collection for seven participants was conducted by a project assistant who JEB trained and oversaw while on maternity leave.

7.3.1 Clinical outcomes

Outcomes deemed to be of importance to clinicians in the treatment of T2DM were assessed at baseline (T0) and immediately post-intervention (T1, see Table 5.2). Changes in medication from baseline to post intervention are reported in Appendix 7.1. Appendix 7.2 provides detailed justification for the choice of each outcome included in PEDAL2.

7.3.1.1 Anthropometrics

Body weight was assessed to the nearest 0.1kg using digital scales (TANITA Corp, Tokyo, Japan) and height was assessed to the nearest 0.1cm (SECA, 700 SECA, Hamburg, Germany). These measures were used to calculate BMI (kg/m^2). Waist circumference was measured using a non-stretch tape measure to the nearest 0.1cm (525).

7.3.1.2 Biochemical variables

Baseline blood samples were obtained by cannulation of the antecubital fossa from individuals in a fasted state (≥8 hour overnight fast) to measure glucose, insulin, glycated haemoglobin (HbA1c), lipids (total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol and triglycerides) and C-reactive protein. A total of 8mL of blood was taken at this time. After baseline blood samples participants completed an OGTT which involved consuming 113mL of Polycal (Nutricia Advanced Medical Nutrition, Trowbridge, UK) and 87mL of water, equivalent to 75g of anhydrous glucose, within five minutes. Further 7mL blood samples were drawn at 15, 30, 45, 60, 90 and 120-minute intervals. The first 5mL of each draw was discarded and 2mL of blood was taken for the analysis of glucose and insulin. The intravenous cannula was kept patent through flushing with 5mL 0.9% sodium chloride (B. Braun, Sheffield, UK).

Blood samples were transported immediately to the Bristol Royal Infirmary commercial laboratory and stored at -80°C until analysed. Samples were analysed individually by the laboratory technician. Basal insulin and glucose values were used to calculate insulin resistance and beta-cell function using the Homeostasis Model Assessment calculator (University of Oxford, Diabetes, Trial Unit).

Using values from the OGTT, incremental area under the curve (iAUC) for insulin and glucose were calculated using the trapezoid rule. In addition, a range of indices were calculated that examine insulin resistance and beta cell function based on the interrelations between insulin and glucose concentrations obtained while fasted and during the OGTT. Specifically, the Matsuda index was used to examine whole body (i.e., hepatic and peripheral tissue) insulin sensitivity (526). The original insulinogenic index ($IGI_{0\text{-}30}$) uses samples at zero and 30-minutes of the OGTT and was calculated to assess the early phase release of insulin (527). The total insulinogenic index ($IGI_{0\text{-}120}$) utilises all OGTT measurements and provides an estimate of overall beta cell function (528). The insulin secretion-sensitivity index-2 (ISSI-2) was used to assess insulin secretion while taking insulin sensitivity into account and is comparative to the disposition index which is calculated from an intravenous glucose tolerance test (529). Higher values for these indices are associated with better insulin sensitivity and/or insulin secretion. Once samples had been analysed the remainder of the aliquot was destroyed by the commercial testing laboratory in accordance with the Human Tissue Authority's Code of Practice.

7.3.1.3 Health-related quality of life (HRQoL)

The Short Form Health Survey (SF-36) was used to assess HRQoL (530). This 36-item generic inventory derives separate summary scores for physical and mental health. The physical component summary represents the average of the scales: physical functioning, role limitations due to physical health, bodily pain, and general health subscales. The mental component summary score is the average of the scales which assess energy/fatigue, social function, role limitations due to emotional health and emotional wellbeing subscales. Summary scores are reported in a range from zero to 100, with a lower score indicating lower quality of life. This measure has been found to be valid in a range of populations (531-533) including individuals with T2DM (534, 535).

7.3.2 Physiological outcomes

All physiological outcomes were assessed at baseline (T0) and immediately post-intervention (T1; see table 5.2)

7.3.2.1 Cardiorespiratory fitness

Cardiorespiratory fitness was determined by measuring maximum oxygen uptake (VO_{2max}) using a continuous incremental ramp maximal exercise test on an electronically braked cycle ergometer (Lode Excalibur, The Netherlands). The test started with a four-minute warm-up at 30 Watts, with participants cycling at a cadence of approximately 60 revolutions per minute (rpm). Following the warm-up, the resistance increased by one Watt every four seconds (15 Watts per minute). The test was terminated upon volitional exhaustion or when cadence fell below 50rpm. The staged increments in work rate were chosen to bring the participant to the limit of tolerance within eight to 12 minutes. Similar ramp protocols have been used in individuals with chronic health conditions, including T2DM (536-538). Expired gas was collected continuously by a metabolic cart (Parvomedics TrueOne 2400, Salt Lake City, Utah, USA). VO_{2max} was defined as the highest 15-breath moving average for VO_2 (in absolute [l/min] and relative [ml/kg/min] terms). Criteria for achieving VO_{2max} were: i) respiratory exchange ratio >1.1; ii) plateau in VO_2 (defined as a change of less than 0.05L/min between 30-second time sampling intervals); iii) ≥ 95% of age-predicted Hr_{peak} (220-age); and/or iv) volitional exhaustion (accepted as >17 on the Rating of Perceived Exertion scale)[3]. Participants were required to achieve at least two of the four criteria to state that VO_{2max} had been reached.

Hr was monitored using a Polar chest strap, which is integrated with the metabolic cart and cycle ergometer software (Lode Exercise Manager). A polar watch was also used to monitor Hr in case of a failed connection between the metabolic cart and the Hr strap. Hr readings from the polar watch were recorded by hand every minute. Hr_{peak} and peak power output (W_{peak}) were recorded as the highest values attained in the test.

Twenty-minutes after completing the incremental fitness assessment participants completed a supramaximal assessment to confirm the findings of the incremental assessment. This assessment followed guidelines outlined by Schaun (540). The multistage test consisted of a two-minute warm up at 30 Watts followed by one minute at 60% of the incremental

[3] The criteria for reaching VO2max was altered from the original protocol paper based on the review of criteria used in other studies in similar populations (537, 539). Specifically, the respiratory exchange ratio required to indicate maximum was reduced from 1.15 to 1.10 and participants were required to reach ≥95% age predicted maximum heart rate.

VO_{2max} then 110% of incremental VO_{2max} until volitional exhaustion or when cadence fell below 50 rpm (541). The work rate associated with 60% and 110% of VO_{2max} was estimated using linear regression models.

The purpose of the VO_{2max} verification assessment was to ascertain whether maximum oxygen consumption had been achieved in the first instance. Furthermore, the supramaximal verification provides a time-efficient strategy for obtaining an accurate VO_{2max} when using cycling ergometry for maximal exercise testing (500). Given that this was a cycling intervention, engaging in cycling could lead to increases in VO_{2max} scores at post-testing purely due to increased familiarity with cycling. The verification assessment was incorporated into testing as participants had experience of engaging in cycling, from the incremental fitness assessment, which could lead to an increased VO_{2max} result. Ideally, participants would complete two separate incremental fitness assessments at least a week apart. However, this procedure adds considerable burden to participants and was not feasible in the current study.

In the protocol paper it was stated that differences of $\leq$ 3% would be considered to demonstrate validation of the incremental VO_{2max} result. However, while this cut-off has been suggested to be appropriate in healthy, active and trained subjects it may not be appropriate for clinical populations (540). Less restrictive percentages may be necessary when comparing VO_{2max} between incremental and verification assessments in these instances (540). In the current study the verification assessment was used to enhance the precision of the incremental VO_{2max} rather than provide validation of the incremental VO_{2max} result. Therefore, the highest of the two tests was used. See Appendix 7.3 for details on the impact of the verification assessment on VO_{2max} results.

7.3.2.2 Body composition

Dual-energy x-ray absorptiometry (Hologic Discovery W, QDR software version 12.4.2, Bedford, MA) was used to assess body composition. Specifically, whole body fat and lean mass, trunk fat mass and leg fat and lean mass were estimated by differentiating the fat, bone and lean (non-bone non-fat) masses. Prior to each trial day a quality control scan was performed using a spine phantom as per the manufacturer's guidelines.

Participants were asked to wear the same light clothes for baseline and post-testing and to remove all metal items. In addition, participants were asked to record their breakfast at baseline and to have the same breakfast at post-testing. Participants were asked to be void before the appointment.

The participant lay supine on the scanning bed. The researcher positioned the participant such that body regions could be partitioned for analysis. During analysis, JEB manually placed the boundaries between discrete anatomical regions before using the manufacturers software to conduct the analysis. JEB conducted manual placement of the boundaries. Baseline and post-testing scans from the same individual were analysed at the same time to ensure consistency between scans.

Peripheral quantitative computer tomography (pQCT; XCT3000, StraTec Medizintechnik GmbH, Pforzheim, Germany) was used to measure lower thigh muscle cross-sectional area (mCSA), intramuscular adipose tissue area, subcutaneous fat area and muscle density (as a proxy for fat infiltration to the muscle). Prior to each testing day the pQCT scanner was calibrated using a phantom cone as per the manufacturer's guidelines. Prior to baseline testing the femur length of the dominant leg was measured with a tape measure from the great trochanter to lateral knee joint line whilst standing. To conduct the scan the participant lay supine on the bed. The leg was placed through the scanning gantry and the foot strapped into a foot plate. The calf was supported by a custom-made pad. To locate the end of the femur scout scans were conducted at the distal end of the femur. Single 2D slice scans were performed at 33% of the femur length proximally to the lateral femoral epicondyle, based on the bone length previously measured. Image quality was visually assessed prior to analysis using an ordinal scale of one to five (542). A score of one represented a scan with no movement and five represented extreme movement. Scans graded as four or five were not deemed appropriate for analysis. Scans were graded independently by two researchers (JEB & ASC). Images were analysed using the pQCT density distribution plugin for ImageJ (543). The specific method for distinguishing subcutaneous fat, muscle, and inter/intramuscular fat was developed by Owen and colleagues (544). This method of distinguishing different densities based on image pixels was designed specifically for soft tissue analysis in the femur (544).

7.3.3 Behavioural outcomes

7.3.3.1 Travel behaviour

Participants travel behaviour was assessed at baseline (T0) and in the final week of the intervention. Spatial location was recorded every five seconds using a personal GPS receiver (QStarz International Co. Ltd. Taiwan). Participants were asked to wear the GPS during waking hours and recharge it at night. The device was worn around the waist or in a pocket as desired. The GPS recorded data on trip start and end times, distance, speed, and route taken.

Participants also completed a seven-day travel diary over the same period as GPS monitoring. The travel diary was adapted from Neves and Brand (282) and is provided in Appendix 7.4 The travel diary was used to: a) capture contextual data related to trips (e.g., trip purpose); b) validate the GPS data and c) provide an alternative source of data in case the GPS device failed, was not turned on, or the battery died during wear time. Participants were asked to record their travel mode, the purpose of the trip, the start and end time of the trip and the start and end location. Participants classified their trip under one of seven categories: commuting, business, personal business, escort and education, shopping, social and visiting friends and family and recreation, in line with the NTS (545). Table 7.1 outlines the factors recorded and their method of measurement.

Table 7.1 Travel factors recorded and the method of measurement

	Measurement method	
Factor recorded	GPS	Travel diary
Trip origin/destination	+	+
Trip start/end time (duration)	+	+
Trip distance	+	-
Trip average speed	+	-
Trip purpose	*	+
Trip mode	*	+

+ measured, - not measured, * attribute derived if necessary

Raw GPS data were downloaded using Qtravel software (Qstarz International Co. Ltd. Taiwan) and extracted as .csv files. Raw GPS files were imported into an open-source tool, QGIS (QGIS Geographic Information System. Open-Source Geospatial Foundation Project. http://qgis.osgeo.org). Trip origin, destination, start, and end time were manually identified by JEB. GPS trip identification followed the method outlined by Neves & Brand (282). Specifically, a 'trip' was classified as travel between two locations, referred to as 'activity nodes'. An activity node was characterised as a collection of geo-coded points that were less than 60 meters from one another or more than two minutes from each other. When seven or more continuous points were recorded within a two-minute window and less than 60 meters from one another a 'stay' classification was applied. Spatial and temporal data identified in the GPS data was matched to the data recorded in the travel diary. If participants used multiple modes of transport but had to wait for longer than two minutes between the end of one mode and start of another (e.g., waiting for a train or bus after walking to the termination point) these instances were classified as one trip as participants were deemed not to have reached the desired activity node.

Trip duration, distance and average speed were primarily calculated from GPS data. Specifically, trip start and end times were used to extract the raw GPS coordinates using pandas package, v.1.2.2 (546, 547) in Python 3, v.3.7.5 (548). Geopy package, v2.1.0 (https://pypi.org/project/geopy/) was used to calculate trip distance. The time and distance were then used to calculate speed. Trip duration was calculated from the start and end times. All python coding was conducted by ASC.

When no GPS data were available, this information was deduced from travel diaries where possible. If similar, GPS recorded, journeys had been completed by the same participant during the same monitoring week the GPS trace was duplicated to calculate trip distance and speed, while duration was determined using the travel diary. If no similar journey had been conducted trip distance was calculated using the self-reported start and end destinations and entering this information into google maps directions. The shortest distance between activity nodes, for the specified mode, was used. In these instances, trip speed was not calculated. Trip purpose and mode were identified primarily using travel diaries. When travel diary data were not available, purpose and mode were deduced from the GPS data through the review of previous trips, examination of land use maps, average speed and routes taken.

The method used to identify travel behaviour deviated from the method proposed in the published protocol (549). The original proposal was to use an open-source tool merging GPS and accelerometer data to classify different modes of transport, the time spent in each transport mode and PA associated with each transport mode (108). However, the current study aimed to identify specific details of participants trips to develop an overall picture of travel behaviour, thereby requiring visual inspection of the data to ascertain more detailed information (e.g., individual trip characteristics and trip purpose). In addition, the algorithm did not detect cycling with high accuracy (69%) and was not trained on e-cycling, further necessitating manual inspection to determine these outcomes for e-cycling. As such, overall manual classification of trips was deemed suitable and feasible in the current study given the small sample size enabling more accurate identification of short-duration trips than the original proposed algorithm (108).

The travel data obtained was used to estimate changes in CO_{2e} emissions. The methods used to assess CO_{2e} emissions, and the results found are reported in Appendix 7.5.

7.3.3.2 Total PA

The amount of time spent in MVPA at baseline (T0) and in the final week of the intervention was assessed over seven days using the ActiGraph accelerometer (GT3X; Pensacola, USA). The GT3X is a tri-axial monitor that detects the frequency and amplitude of acceleration in three axes of the section of the body to which it is attached. The ActiGraph accelerometer was worn on an elasticated belt around the right hip and taken off when sleeping, bathing, or swimming. The accelerometer recorded raw acceleration data at a sampling frequency of 30Hz. The accelerometer was initialised to start recording at 00:00 the day after meeting with the researcher. Raw data from the monitors were downloaded and analysed using the manufacturer's software (ActiLife software v6.13.4; ActiGraph, Pensacola, FL, USA). Despite the extensive use of accelerometers there is no agreed upon method for accelerometer data analyses (16). Given that the accelerometer protocol and processing decisions can significantly impact the results it is important for these decisions to be clearly reported. As such, data collection protocol decisions, data processing criteria and justification for these decisions are provided in Appendix 7.6.

Data were reintegrated into 60-second epochs and non-wear time was assessed (550). Time spent in MVPA was estimated using Sasaki and colleagues vector magnitude cut points (551). Total time spent in MVPA was obtained by totalling the duration of all moderate and vigorous PA bouts for each day, which was then averaged over the number of valid days to determine mean time spent in MVPA per day. Average daily MVPA was multiplied by seven to give the total MVPA for the week. Participants with at least three-days of valid wear (≥600minutes/day) were included in the analysis. This measure has been extensively validated in both laboratory and free-living conditions (552) and has been reported to have a high completion rate in observational studies (553).

7.3.3.3 PA due to e-cycling

PA attributable to e-cycling was determined using travel data (i.e., GPS and travel diary data) and accelerometer data. Specifically, GPS and travel diary derived temporal trip data (i.e., time and date) for each mode of transport was matched with Actiheart data in Python 3, v.3.7.5 (548). Since the waist worn Actigraph poorly records PA when cycling (506), Actiheart data was collected specifically to address this outcome.

The Actiheart is a combined movement sensor and Hr monitor (Actiheart, CamNtech, Cambridge, UK) that has been found to be an accurate measure of free-living PA energy expenditure (505). It is a waterproof device worn on the participants' thorax below the apex of the sternum with the wire in a horizontal line to the left. The Actiheart is connected to the skin with standard electrocardiogram electrodes. Participants were provided with surplus electrodes to change the electrodes regularly. Data were collected for the same seven-days as the Actigraph, GPS and travel diary. Accelerometer and Hr data were recorded at 15-second epochs (the shortest epoch available). Using the Actiheart 5 software, Hr data were pre-processed to eliminate potential noise (554). The group calibrated branched equation model (555) was used to calculate instantaneous PA energy expenditure (kcal/kg/min). Sleeping Hr was averaged across wear days and entered. Resting energy expenditure was estimated using the Schofield equations (556) and was used in the estimation of metabolic equivalents (METs). The MET level is conventionally set to one kcal/kg/hour (3.5mlO2/kg/min), however, in the current study resting energy expenditure, individually estimated for each participant, was used in the calculation. Fifteen second activity data, expressed as METs, was downloaded using the Actiheart 5 software. The amount of time spent in MVPA (≥3 METs) associated with e-cycling was reported in relation to the total amount of time spent e-cycling. Total MET-minutes from e-cycling were also reported. In addition, mean Hr during e-cycling was determined and expressed as percentage of Hr maximum as determined from the maximal fitness test.

7.3.3.4 E-cycling during the intervention

The total distance travelled on the e-bike was determined through odometers integrated into the e-bike. The odometer automatically starts recording distance when the individual uses the e-bike. Odometer readings were taken, by the instructor, before the e-bike left LCUK and when it was returned.

In addition, the total amount of time spent e-cycling, the number of e-cycling trips, the distance of each trip and the purpose of e-bike use throughout the intervention was determined through use of a GPS unit (Garmin Edge 130) attached to the e-bike and/or paper activity logbook (Appendix 7.7). Average weekly distance ridden, and time spent e-cycling was determined by dividing the total distance recorded by the number of weeks the e-bike was on loan[4]. GPS data was downloaded at the end of the loan period. Logbooks were

[4] Due to COVID-19 two participants were unable to return the e-bike to LCUK until summer 2020. For these participants, the end date of the study was the point when the telephone interview took place.

collected and data entered manually into excel. For the GPS data, trip purpose was categorised into transport or recreation by visually inspecting the route track on Garmin Connect. Home and work postcodes provided in the survey were used to identify trip purpose. The logbooks were used to validate the GPS data if both were provided, or they provided standalone data pertaining to e-cycling if no GPS was used.

7.3.4 Analysis

Baseline values for the secondary outcomes were summarised by condition using descriptive statistics. The normality of the data was assessed for the whole sample, and by condition, through visual inspection of histograms by JEB and if required a second opinion was obtained from SL. When data are non-normally distributed researchers often log-transform the data. However, having a small sample size increases the likelihood of having a non-normal distribution, and log transformation does not always reduce sample variability sufficiently to achieve normal distribution and adds unnecessary complexity when analysing the data (557). Therefore, log transformations were not applied in the current study, and instead, non-parametric measures were reported where necessary.

Descriptive comparisons of the secondary outcomes were made between the intervention and control group. Evidence of promise of the intervention (i.e., whether the intervention can lead to changes in outcome measures) were examined using comparison of change scores between conditions for all secondary outcome measures (except e-cycling during the intervention). Effect estimates were presented with 95% confidence intervals; p values were not considered as the study was not powered to detect effectiveness. Analyses were carried out using Excel and Stata 16 statistical software.

7.4 Results

The results are organised into clinical outcomes (i.e., those deemed to be of importance to clinicians in the treatment of T2DM), physiological and behavioural outcomes. There were no apparent baseline differences in outcomes between the two conditions (Appendix 7.8).

7.4.1 Clinical outcomes

The results for all clinical outcomes are reported in Table 7.2.

7.4.1.1 Anthropometrics

The intervention had a favourable effect on weight, BMI and waist circumference. After removing one participant from the analyses in the control group who had gastric band surgery during the study, the difference in weight change scores between conditions was 1.47 (95%CI: -0.97, 3.91)kg. Specifically, the intervention group had a 1.9% reduction in weight, while the control group had a 0.4% reduction in weight.

The difference in change scores for waist circumference between conditions was 4.76 (95%CI: 0.47, 9.04)cm. Specifically, there was a 4.8% decrease in waist circumference in the intervention group and a 0.6% decrease in waist circumference in the control group.

Table 7.2 Differences in clinical outcomes between conditions based on individuals that completed baseline and post-testing assessments

Outcome	Intervention				Control				Difference in change (CI)
		Baseline	Post-testing	Change		Baseline	Post-testing	Change	
	N	Mean (CI) ([a]Median; IQR)	Mean (CI) ([a]Median; IQR)	Mean (CI) ([a]Median; IQR)	N	Mean (CI) ([a]Median; IQR)	Mean (CI) ([a]Median; IQR)	Mean (CI) ([a]Median; IQR)	
Anthropometrics									
Weight, kg	13	95.96 (84.16, 107.76)	94.11 (82.98, 105.23)	-1.85 (-4.10, 0.40)	17[b]	97.99 (85.39, 110.59)	97.61 (85.12, 110.11)	-0.38 (-1.82, 1.07)	1.47 (-0.97, 3.91)
BMI, kg/m^2	13	32.98 (28.64, 37.31)	32.37 (28.15, 36.60)	-0.60 (-1.32, 0.11)	17[b]	32.32 (29.21, 35.44)	32.18 (29.13, 35.24)	-0.14 (-0.61, 0.33)	0.46 (-0.32, 1.24)
Waist circumference, cm	13	113.27 (103.75, 122.78)	107.88 98.93, 116.84)	-5.38 (-9.09, -1.68)	17[b]	112.09 (103.43, 120.75)	111.46 (101.93, 120.99)	-0.63 (-3.36, 2.10)	4.76 (0.47, 9.04)
Fasting Bloods									
HbA1c, mmol/mol	13	55.15 (48.10, 62.21)	54.92 (48.11, 61.74)	-0.23 (-3.25, 2.79)	13[b]	53.77 (46.62, 60.92)	52.08 (44.49, 59.66)	-1.69 (-4.30, 0.91)	-1.46 (-5.24, 2.32)
Fasting glucose, mmol/L	13	7.84 (6.51, 9.16)	7.62 (6.44, 8.79)	-0.22 (-0.70, 0.26)	14[c]	7.14 (5.99, 8.29)	7.59 (5.57, 9.62)	0.45 (-0.94, 1.84)	0.67 (-0.77, 2.11)
Fasting insulin, mIU/L	13	20.31 (11.26, 29.35)	18.19 (12.30, 24.09)	-2.12 (-7.91, 3.68)	13[c]	16.97 (11.92, 22.02)	18.69 (12.17, 24.22)	1.72 (-2.48, 5.93)	3.84 (-2.94, 10.62)
HOMA-B, %	13	94.68 (52.01, 137.36)	93.95 (56.55, 131.36)	-0.73 (-16.91, 15.45)	13[c]	92.75 (63.50, 122.01)	105.18 (68.12, 142.24)	12.42 (-4.41, 29.26)	13.15 (-8.97, 35.27)
HOMA-IR, unitless	13	2.82 (1.66, 3.98)	2.53 (1.78, 3.29)	-0.28 (-1.04, 0.47)	13[c]	2.39 (1.68, 3.11)	2.69 (1.80, 3.59)	0.30 (-0.30, 0.90)	0.58 (-0.33, 1.50)
C-reactive protein, mg/L[d]	13	1 (0.9, 4.0)	2.0 (0.9, 4.0)	0.1 (0.0, 1.1)	14[c]	2.5 (2.0, 4.0)	3.0 (2.0, 4.0)	0.0 (0.0, 1.0)	
Total cholesterol, mmol/L	13	3.91 (3.30, 4.51)	3.95 (3.38, 4.51)	0.04 (-0.27, 0.35)	15	4.12 (3.70, 4.54)	4.46 (3.80, 5.12)	0.34 (-0.14, 0.82)	0.30 (-0.27. 0.87)
Triglycerides, mmol/L	13	1.82 (1.23, 2.42)	1.81 (1.30, 2.32)	-0.02 (-0.26, 0.23)	15	1.57 (1.16, 1.99)	1.51 (1.15, 1.87)	-0.06 (-0.26, 0.14)	-0.04 (-0.35, 0.26)
HDL cholesterol, mmol/L	13	1.32 (1.02, 1.61)	1.23 (1.01, 1.45)	-0.08 (-0.19, 0.02)	15	1.13 (0.98, 1.29)	1.19 (1.02, 1.35)	0.05 (-0.02, 0.13)	0.14 (0.02, 0.26)
LDL cholesterol, mmol/L	12	1.75 (1.35, 2.15)	1.93 (1.49, 2.36)	0.18 (-0.88, 0.44)	15	2.26 (1.88, 2.64)	2.58 (1.97, 3.19)	0.32 (-0.10, 0.74)	0.15 (-0.36, 0.65)

Non HDL cholesterol, mmol/L	13	2.59 (2.08, 3.10)	2.72 (2.24, 3.19)	0.12 (-0.19, 0.44)	15	2.99 (2.63, 3.34)	3.27 (2.66, 3.88)	0.29 (-0.18, 0.76)	0.16 (-0.40, 0.72)
Dynamic measures pf glucose homeostasis									
iAUC glucose, mmol/L/120min	9	693.33 (536.90, 849.77)	675.5 (552.48, 798.52)	-17.83 (-195.75, 298.5)	10[c]	502.35 (340.81, 663.89)	504.98 (418.29, 591.66)	2.63 (-89.34, 94.59)	20.46 (-114.21, 155.13)
iAUC insulin, mIU/L/120min	9	6515.08 (2823.02, 10207.14)	6844.58 (3184.05, 10505.12)	329.5 (-2685, 3122.25)	10[c]	4744.95 (1674.78, 7815.12)	5201.78 (2134.91, 8268.64)	456.83 (-412.58, 1326.23)	280.37 (-1003.66, 1564.40)
Matsuda index, unitless	9	2.29 (0.74, 4.06)	2.43 (1.05, 4.81)	0.13 (-1.69, 1.15)	10[c]	3.00 (0.91, 6.35)	2.37 (0.64, 4.42)	-0.64 (-3.38, 1.29)	-0.77 (-1.84, 0.30)
Original insulinogenic index (0-30mins), pmol/mmol [e,f]	10	46.33 (5.39, 77.5)	48.11 (6.23, 97.69)	1.77 (-28.67, 30.29)	11[c]	59.68 (6, 231)	61.71 (9.6, 148.8)	2.02 (-178.81, 137.29)	0.24 (-51.50, 51.99)
Total insulinogenic index (0-120mins), pmol/mmol[f]	9	63.60 (4.17, 135.09)	68.57 (5.60, 200.03)	4.97 (-25.21, 64.94)	10[c]	63.73 (18.59, 146.83)	61.83 (23.44, 168.59)	-1.89 (-43.19, 21.76)	-6.86 (-29.96, 16.23)
Insulin secretion sensitivity index 2, unitless	9	58.57 (13.21, 154.59)	66.74 (18.48, 142.07)	8.17 (-44.08, 68.90)	10[c]	80.39 (20.82, 199.58)	69.60 (12.15, 121.72)	-10.79 (-77.86, 44.34)	-18.97 (-50.41, 12.48)
Health related quality of life									
Physical component (0-100)	13	64.62 (51.82, 77.41)	68.89 (56.41, 81.38)	4.28 (-6.79, 15.35)	17	71.54 (62.34, 80.74)	69.67 (58.15, 81.18)	-1.88 (-13.05, 9.30)	-6.15 (-21.16, 8.85)
Mental component (0-100)	13	67.42 (56.07, 78.77)	71.02 (60.62, 81.42)	3.60 (-6.20, 13.40)	17	76.27 (67.95, 84.60)	75.46 (66.73, 84.20)	-0.81 (-11.54, 9.92)	-4.41 (-18.28, 9.46)

BMI=body mass index; CI=confidence interval; HbA1c=glycated haemoglobin; HDL=high density lipoprotein; HOMA-B=homeostasis model assessment of β-cell function; HOMA-IR=homeostasis model assessment of insulin resistance; IQR=interquartile range; LDL=low density lipoprotein; iAUC=incremental area under the curve

[a] When data are non-normally distributed, based on visual inspection, median and IQR are reported, [b] Data from one participant removed due to having a gastric band during the study, [c] Data from one participant removed due to taking antibiotics at baseline, [d]It was not possible to calculate the difference in change scores IQR between conditions, [e] Original insulinogenic index required blood samples at zero and 30 minutes, therefore two participants not included in other dynamic glucose measures were included in this calculation, [f] mIU/L was converted to pmol/L. The conversion factor of 1mIU/L=6 pmol/L was used (558)

7.4.1.2 Blood measures

7.4.1.2.1 Fasting glucose and insulin measures

The difference in HbA1c change scores between conditions was -1.46 (-5.24, 2.32)mmol/mol in favour of the control group. Specifically, in the intervention group there was a 0.4% reduction in HbA1c, while in the control group, after removing the participant who had gastric band surgery, there was a 3.1% reduction in HbA1c.

For all other glucose and insulin measures one participant was removed from the analyses due to taking antibiotics at baseline (see Table 7.2). There was a favourable effect of the intervention on fasting bloods measures related to glucose control. Differences in fasting glucose and insulin change scores between conditions were 0.67 (95%CI: -0.77, 2.11)mmol/L and 3.84 (95%CI: -2.94, 10.62)mmol/L respectively. Specifically, there was a 2.8% reduction in fasting glucose and a 10.4% reduction in fasting insulin in the intervention group. In the control group there was a 6.3% increase in fasting glucose and a 10.1% increase in fasting insulin.

Difference in insulin resistance (HOMA-IR) change scores between conditions was 0.58 (95%CI -0.33, 1.50). Within groups, the intervention group showed a 10.3% reduction in HOMA-IR, while the control group showed a 12.6% increase in HOMA-IR. The results suggested the intervention did not influence beta-cell function, with a difference in HOMA-B% change scores between conditions of 13.15 (95%CI: -8.97, 35.27)%. Specifically, there was a 0.8% improvement in beta-cell function in the intervention group and a 13.4% worsening of beta-cell functioning in the control condition.

7.4.1.2.2 Dynamic glucose and insulin measures

Twenty participants provided full data for baseline and post-testing and were included in the analyses. However, one participant was removed from the analyses due to taking antibiotics at baseline which impacted measures of glucose and insulin. The results showed a favourable trend of the intervention on iAUC for glucose with a 2.6% decrease in iAUC in the intervention group and a 0.5% increase in iAUC in the control group. The difference in change scores between the conditions for glucose iAUC was 20.46 (95%CI: -114.21, 155.13)mmol/L/min. There was a 5.1% increase in iAUC for insulin in the intervention group, compared to a 9.6% increase in the control condition, this equated to a difference in change scores of 280.37 (95%CI: -1003.66, 1564.40)mIU/L/120min.

There was a favourable trend in whole body insulin sensitivity following the intervention as measured by the Matsuda Index, with a difference in change scores of -0.77

(95%CI: -1.84, 0.30) between conditions. Specifically, the intervention group showed a 6.1% increase in whole body insulin sensitivity, while the control group showed a 21.0% decrease. Regarding beta cell function, a 3.8% and 7.8% increase in IGI_{0-30} and IGI_{0-120} were found in the intervention group. In the control group there was a 3.4% increase in IGI_{0-30} and a 3.0% decrease in IGI_{0-120}. Regarding beta cell function, while accounting for insulin resistance, the ISSI-2 showed a 13.9% increase in the intervention group and a 13.4% decrease in the control group, this equated to a difference in change scores between conditions of -18.97 (95%CI: -50.41, 12.48).

7.4.1.2.3 C-Reactive protein

The results suggest no favourable effect of the intervention on C-reactive protein with a median change of 0.1 (IQR: 0, 1.1) in the intervention condition and 0 (IQR: 0, 1) in the control group. Data from one participant was removed from the analyses due to taking antibiotics at baseline which could impact markers of inflammation, however this sensitivity analysis did not impact the results.

7.4.1.2.4 Lipids

A difference in HDL cholesterol change scores of 0.14 (95%CI: 0.02, 0.26)mmol/L was reported between groups. Specifically, HDL cholesterol decreased by 6.8% in the intervention group and increased by 5.3% in the control group. A 10.0% increase in HDL cholesterol would represent a clinically meaningful increase. There was no evidence of a positive impact of the intervention on total cholesterol, triglycerides, LDL cholesterol or Non-HDL cholesterol (see Table 7.2).

7.4.1.3 Health related quality of life

The difference in physical health quality of life change scores between conditions was -6.15 (95% CI: -21.16, 8.85), while the difference in mental health quality of life change scores between conditions was -4.41 (95% CI: -18.28, 9.46). Within group change showed a 6.6% and 5.3% increase in physical and mental health respectively in the intervention group and a 2.6% and 1.1% decrease in physical and mental health quality of life respectively in the control group.

7.4.2 Physiological outcomes

The results of all physiological outcomes are reported in Table 7.3.

7.4.2.1 Cardiorespiratory fitness

There was a positive trend in favour of the intervention with a difference in relative VO_{2max} change scores between conditions of -0.95 (95%CI: -4.21, 2.31)ml/kg/min. Within groups there was an 8.8% and 10.7% increase in absolute (L/min) and relative VO_{2max} (ml/kg/min) respectively following the intervention. In the control group there was a 2.6% and 1.9% increase in absolute and relative VO_{2max} respectively. The intervention had a favourable impact on the maximum power participants could put out with a difference in change scores between conditions of -18.73 (95%CI: -39.77, 2.30)Watts. Specifically, there was a 10.8% increase in maximum power output in the intervention group compared to a 3.6% decrease in maximum power output in the control group.

7.4.2.2 Body composition

One participant was removed from the analyses due to gastric band surgery. There was no evidence of an effect of the intervention on body composition as measured by DEXA scan. Specifically, decreases in percentage body fat and trunk mass were similar between the intervention and control groups. The difference in fat mass change scores between conditions was 0.40 (95%CI: -1.57, 2.38)kg, within group fat mass losses of 3.5% and 2.3% in the intervention and control groups. There was a 2.1% reduction of overall lean mass in the intervention group that was not seen in the control group (0.1% reduction), with the difference in lean mass change scores between conditions of 1.19 (95%CI: -0.28, 2.66)kg.

The pQCT results showed no favourable impact of the intervention on femur mCSA with a difference in change scores between conditions of 1.75 (95%CI: -2.64, 6.13)cm^2. Specifically, a reduction in femur mCSA of 2.6% was found in the intervention group, compared to 1.0% in the control group. No changes in muscle density or intramuscular adipose tissue area were found within or between groups. There was a 5.7% reduction in subcutaneous fat in the intervention group and a 0.8% increase in subcutaneous fat in the control group, with a difference in change scores between conditions of 2.80 (95%CI: -0.60, 6.20)cm^2 .

Table 7.3 Differences in physiological outcomes between conditions based on individuals that completed baseline and post-testing assessments

Outcome	Intervention				Control				Difference in change (CI)
		Baseline	Post-testing	Change		Baseline	Post-testing	Change	
	N	Mean (CI)	Mean (CI)	Mean (CI)	N	Mean (CI)	Mean (CI)	Mean (CI)	
Cardiorespiratory fitness									
Absolute $VO2_{max}$, L/min	9[a]	1.82 (1.34, 2.30)	1.98 (1.35, 2.61)	0.16 (-0.06, 0.41)	14	2.28 (2.03, 2.53)	2.34 (2.00, 2.67)	0.06 (-0.11, 0.23)	-0.04 (-0.34, 0.25)
Relative $VO_{2max,}$ ml/kg/min	9[a]	19.52 (15.30, 23.75)	21.61 (16.17, 27.04)	2.08 (-0.86, 5.02)	14	23.07 (20.67, 25.46)	23.50 (21.43, 25.57)	0.43 (-1.13, 2.00)	-0.95 (-4.21, 2.31)
Maximum power output, Watts	9[a]	147.99 (110.14, 185.84)	163.91 (112.70, 215.13)	15.92 (-5.15, 36.99)	14	188.68 (172.95, 204.41)	181.96 (164.91, 199.01)	-6.72 (-13.34, -0.11)	-18.73 (-39.77, 2.30)
Body composition									
Body fat, %	13	34.03 (28.28, 39.78)	33.79 (28.11, 39.48)	-0.24 (-0.99, 0.52)	16[b]	33.63 (29.82, 37.42)	33.24 (29.46, 37.02)	-0.38 (-1.34, 0.57)	-0.14 (-1.35, 1.07)
Fat mass, kg	13	32.4 (24.91, 40.00)	31.28 (24.34, 38.22)	-1.18 (-2.65, 0.30)	16[b]	33.73 (24.91, 40.00)	32.96 (26.48, 39.44)	-0.77 (-2.20, 0.65)	0.40 (-1.57, 2.38)
Trunk fat mass, kg	13	17.79 (13.52, 22.06)	17.13 (13.19, 21.07)	-0.66 (-1.46, 0.14)	16[b]	19.12 (15.15, 23.06)	18.64 (14.82, 22.47)	-0.47 (-1.29, 0.36)	0.20 (-0.92, 1.31)
Leg fat mass, kg	13	5.03 (3.77, 6.28)	4.86 (3.63, 6.08)	-0.17 (-0.41, 0.07)	16[b]	5.10 (3.97, 6.24)	5.02 (3.94, 6.09)	-0.09 (-0.31, -0.14)	0.08 (-0.23, 0.40)
Lean mass, kg	13	58.78 (50.98, 66.59)	57.54 (49.98, 65.10)	-1.24 (-2.18, -0.31)	16[b]	61.58 (54.53, 68.62)	61.52 (54.33, 68.71)	-0.05 (-1.21, 1.10)	1.19 (-0.28, 2.66)
Leg lean mass, kg	13	10.27 (8.79, 11.75)	10.09 (8.65, 11.54)	-0.17 (-0.30, -0.04)	16[b]	11.00 (9.49, 12.51)	10.97 (9.51, 12.46)	-0.01 (-0.21, 0.19)	0.16 (-0.08, 0.40)
pQCT femur mCSA, cm^2	12	104.63 (88.50, 120.75)	101.87 (85.94, 117.81)	-2.76 (-6.79, 1.28)	14	121.20 (105.66, 136.73)	119.99 (104.85, 135.12)	-1.01 (-3.64, 1.62)	1.75 (-2.64, 6.13)
pQCT femur density, mg/cm^3	12	61.63 (57.54, 65.71)	61.56 (57.25, 65.87)	-0.07 (-1.10, 0.97)	14	61.78 (58.06, 65.50)	62.44 (59.37, 65.52)	-0.03 (-1.78, 1.72)	0.04 (-2.09, 2.17)
pQCT IMAT area, cm^2	12	19.99 (15.35, 24.63)	19.25 (14.86, 23.65)	-0.74 (-1.09, 0.43)	14	23.94 (16.98, 30.90_	22.46 (17.64, 27.28)	-0.75 (-3.48, 1.98)	-0.01 (-3.20, 3.18)
pQCT SAT area, cm^2	12	48.97 (30.24, 67.70)	46.18 (27.08, 65.28)	-2.79 (-5.47, -0.12)	14	41.62 (25.94, 57.31)	41.97 (25.50, 58.45)	0.01 (-2.34, 2.36)	2.80 (-0.60, 6.20)

CI=confidence interval; IMAT=intramuscular adipose tissue; mCSA=muscle cross sectional area; pQCT=peripheral quantitative computer tomography; SAT=subcutaneous adipose tissue; VO_{2max}=maximum oxygen uptake, [a]One participant removed have was told to restrain from exercise for five weeks during e-bike intervention due to exploratory surgery, [b] One participant removed as had a gastric band

7.4.3 Behavioural outcomes

7.4.3.1 Travel behaviour

A total of 1142 trips were recorded at baseline ($Intervention_n$ =571; $Control_n$ =571) and 1005 ($Intervention_n$ =461; $Control_n$ =544) at post-testing (Table 7.4). At baseline, in both groups, more than 60% of all trips were made by car. At post-testing, the percentage of modal share attributable to car travel remained similar in the control group (66.5%) and decreased in the intervention group (55.9%). Similar amounts of walking were reported at baseline and post-testing for both conditions, accounting for over 25% of all trips made (range from 27.1% to 30.3%). In the intervention group at post-testing, e-cycling accounted for 7.2% of all trips made.

Table 7.4 Number of trips

	Intervention		Control	
	Baseline	Post-Testing	Baseline	Post-Testing
Trips, (n, % mode share)	571	461	571	544
• Car	361 (63.2)	258 (55.9)	383 (67.1)	362 (66.5)
• Public transport[a]	26 (4.5)	29 (6.3)	20 (3.5)	23 (4.2)
• Motorbike	0 (0.0)	0 (0.0)	8 (1.4)	0 (0.0)
• Taxi	8 (1.4)	2 (0.4)	0 (0.0)	2 (0.4)
• Walk	173 (30.3)	138 (29.9)	155 (27.1)	153 (28.1)
• Bicycle	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.7)
• E-bike	0 (0.0)	33 (7.2)	0 (0.0)	0 (0.0)
• Car/walk	0 (0.0)	0 (0.0)	5[b] (0.9)	0 (0.0)
• Rowing	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Multimodal trips, n	67 (11.7)	62 (13.4)	62 (10.9)	54 (9.9)

[a] public transport includes bus, train and tube, [b] These five journeys were made by one participant and involved repeatedly driving very short distances (e.g., 300m) and walking dropping of leaflets at houses. They are not part of his regular activities and have therefore been assigned their own category

Participants in the control group travelled an average of 5.1 (SD=1.6) trips per day at baseline and 4.8 (SD=1.5) trip per day at post-testing. The median daily distance was 27.81 (IQR:13.99, 63.25)km at baseline and 18.37 (IQR: 11.23, 29.14)km at post-testing. Participants in the intervention group travelled an average of 5.0 (SD=1.6) trips per day at baseline and 5.4 (SD=2.1) trips per day at post-testing. The median daily distance was 18.08 (IQR: 10.59, 33.29)km at baseline and 26.33 (IQR: 12.18, 58.84)km at post-testing.

Table 7.5 shows the distribution and cumulative share of individual trips by different modes and trip length. At baseline, in both conditions, over 80% of all trips were under 8km in length. Travelling by car was the main travel mode for these short trips (<8km), followed by walking. At post-testing similar levels of car use and walking were seen in the control group for trips under 8km. Post-testing results for the intervention group show an 8.8% reduction in car journeys under 8km, coupled with a 2.0% increase in bus trips and 3.0% increase in e-cycling trips. The remaining e-bike trips (4.1%) were between eight to 40km in length. The median time spent in an e-cycling trip was 38.15 (IQR: 18.58, 57.58)minutes and the median distance ridden per trip was 8.72 (IQR: 4.2, 13.0 km; Table 7.6). This is longer than the median time spent on a conventional cycling trip (25.12, IQR: 23.61, 27.29 minutes) or median distance covered on a conventional cycling trip (5.02, IQR: 4.77, 5.27km). The average e-cycling speed was 15.62 (SD=5.34)km/hr, which is faster than conventional cycling (mean=11.96, SD=1.71 km/hr) and a similar speed to travelling via bus (mean=17.81, SD=4.20 km/hr).

Table 7.5 Distribution and cumulative share of trips by mode and trip length expressed as percentages

	Baseline (Intervention n=571; Control n=459)[a]									Post-testing (Intervention n=566; Control n=544)[b]								
	Car	Bus	Train	Taxi	Motor bike	Walk	Cycle	E-cycle	Cumulative % of trip length	Car	Bus	Train	Taxi	Motor bike	Walk	Cycle	E-cycle	Cumulative % of trip length
Intervention																		
<2km	14.0	0.7	0.0	0.0	0.0	25.7	0.0	0.0	40.5	15.3	0.7	0.0	0.0	0.0	23.3	0.0	0.4	39.7
2-4.99km	24.2	0.9	0.0	1.2	0.0	4.7	0.0	0.0	71.5	19.8	2.8	0.0	0.0	0.0	6.1	0.0	1.7	70.2
5-7.99km	11.4	1.4	0.2	0.0	0.0	0.4	0.0	0.0	84.8	5.7	1.5	0.0	0.2	0.0	0.4	0.0	0.9	78.9
8-15.99km	6.5	0.4	0.0	0.2	0.0	0.0	0.0	0.0	91.8	7.4	0.4	0.0	0.2	0.0	0.2	0.0	2.8	90.0
16-39.99km	6.0	0.0	0.4	0.0	0.0	0.0	0.0	0.0	98.1	6.8	0.4	0.0	0.0	0.0	0.0	0.0	1.3	98.5
40-80km	0.7	0.0	0.4	0.0	0.0	0.0	0.0	0.0	99.1	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	99.1
>80km	0.5	0.0	0.4	0.0	0.0	0.0	0.0	0.0	100.0	0.7	0.0	0.2	0.0	0.0	0.0	0.0	0.0	100.0
Control																		
<2km	19.1	0.7	0.0	0.0	0.0	22.4	0.0	0.0	42.2	14.9	0.9	0.0	0.0	0.0	24.6	0.0	0.0	40.4
2-4.99km	20.1	0.2	0.0	0.0	0.7	4.2	0.0	0.0	67.5	23.0	0.7	0.0	0.0	0.0	3.3	0.4	0.0	67.8
5-7.99km	12.2	2.3	0.0	0.0	0.0	0.7	0.0	0.0	82.7	10.8	2.6	0.0	0.4	0.0	0.2	0.4	0.0	82.2
8-15.99km	9.5	0.4	0.0	0.0	0.7	0.0	0.0	0.0	93.3	10.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	92.5
16-39.99km	3.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	96.5	3.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	96.3
40-80km	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	97.5	2.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	98.9
>80km	2.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	100.0	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	100.0

[a]Five trips from one participant were not included as they present car/walk leafleting trips that involved numerous car trips (<300m) followed by dropping leaflets through doors. [b] Rowing (n=1 trip) and tube (n=1 trip) have not been included in this table

Table 7.6 Median (IQR) duration and distance of trips made by the most used modes of transport, mean (standard deviation) for speed[a]

Transport mode	Intervention						Control					
	Baseline			Post-testing			Baseline			Post-testing		
	Duration (mins)	Distance (km)	Speed (km/hr)	Duration (mins)	Distance (km)	Speed (km/hr)	Duration (mins)	Distance (km)	Speed (km/hr)	Duration (mins)	Distance (km)	Speed (km/hr)
Car	10.0 (5.25, 17.08)	3.65 (2.13, 7.17)	28.72 (11.85)	8.83 (4.58, 18.92)	3.65 (1.87, 9.4)	29.29 (11.42)	10.00 (5.25, 19.58)	4.03 (1.82, 7.83)	29.51 (15.54)	10.67 (5.92, 18.42)	4.00 (2.09, 8.55)	30.06 (15.65)
Bus	15.83 (11.08, 46.25)	5.46 (2.13, 7.76)	13.92 (2.83)	12.83 (9.17, 19.92)	4.00 (2.69, 5.73)	17.81 (4.20)	28.35 (15.79, 36.08)	6.95 (3.64, 7.29)	14.66 (4.02)	24.92 (10.08, 32.17)	6.50 (2.38, 7.12)	14.23 (3.80)
Train	38.98 (11.18, 72.98)	66.11 (17.00, 132.51)	83.44 (34.94)	153.00 (153.00)	160.00 (160.00)							
Motorbike							9.58 (7.88, 10.21)	6.82 (3.69, 9.34)	44.37 (16.45)			
Taxi	10.13 (7.17, 19.67)	3.29 (2.61, 4.15)	24.20 (10.23)	21.71 (20.33, 23.08)	8.17 (7.53, 8.81)	22.56 (0.49)				15.56 (14.95, 16.17)	5.80 (5.13, 6.30)	22.50 (3.92)
Walk	8.92 (4.63, 20.21)	0.60 (0.34, 1.33)	4.18 (1.05)	7.83 (3.83, 21.67)	0.52 (0.27, 1.64)	4.21 (1.11)	8.00 (3.67, 19.92)	0.62 (0.23, 1.28)	4.60 (2.10)	8.67 (4.5, 17.83)	0.58 (0.32, 1.10)	4.21 (1.14)
Bicycle										25.12 (23.61, 27.29)	5.02 (4.77, 5.27	11.96 (1.71)
E-bike				38.15 (18.58, 57.58)	8.72 (4.20, 13.0)	15.62 (5.34)						

[a] Modes of transport infrequently used and therefore not reported included dragon boating (n_{trips}=1); London underground (n_{trips}=1)

7.4.3.2 Trip purpose

Shopping was the most common purpose for travelling at baseline and post-testing (23.2 to 28.5% of total trips). Shopping trips were primarily made by car (17.2 to 19.8% of all shopping trips) or walking (4.9 to 7.5% of all shopping trips) with little change over the course of the intervention (see Figure 7.1a-d).

Of the 33 e-bike trips that were made at post-testing in the intervention group, 48.5% (n=16) were for reactional purposes, 18.2% (n=6) for commuting, 9.1% (n=3) for shopping; 12.1% (n=4) for visiting friends or family, 6.1% (n=2) for personal business and 6.1% (n=2) for escort or education.

In the intervention group there was a 6.3% increase in recreational trips from baseline to post-testing. This increase was attributable to an increase in walking (2.2%) and e-cycling (3.5%), with no reduction in car use for recreational purposes. A 3.6% increase in recreational trips was seen in the control group from baseline to post-testing. This was due to an increase in walking (1.7%) and car (1.9%) use for recreational purposes.

Car use for commuting purposes was similar at baseline and post-testing in the control group (10.9% and 11.8% of trips respectively). There was a 2.4% decrease in car use for commuting in the intervention condition following the intervention, and a 1.3% decrease in walking. Bus use for commuting increased by 1.3% and e-cycling for commuting contributed 1.3% to total trips made. However, there was a general decrease in commuting trips in the intervention group as a percentage of total trips (5.1%).

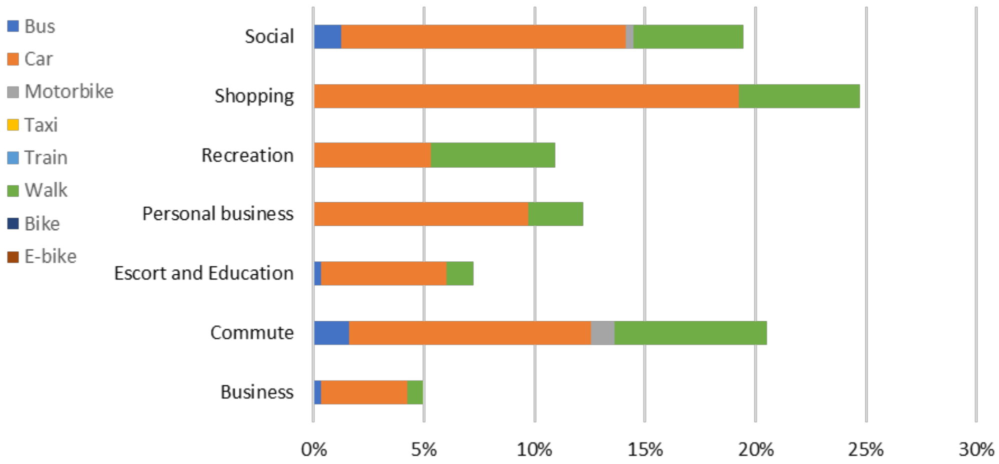

Fig. 7.1a Control group baseline

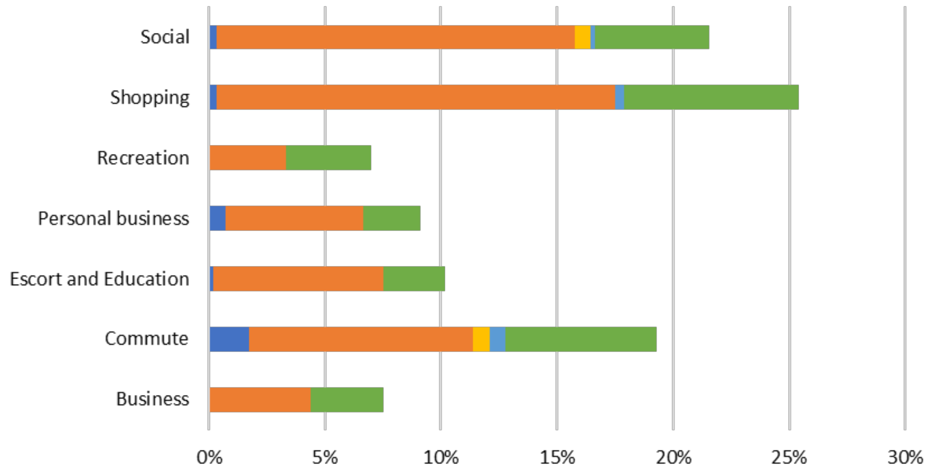

Fig. 7.1c Experimental group baseline

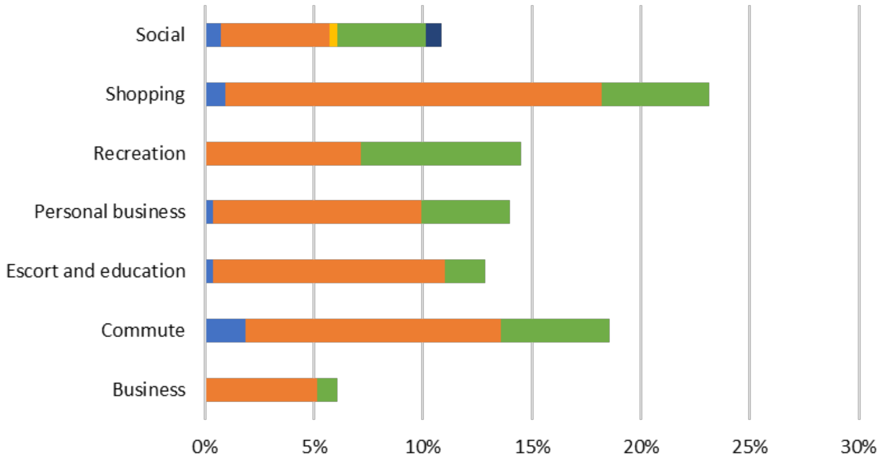

Fig. 7.1b Control group post testing

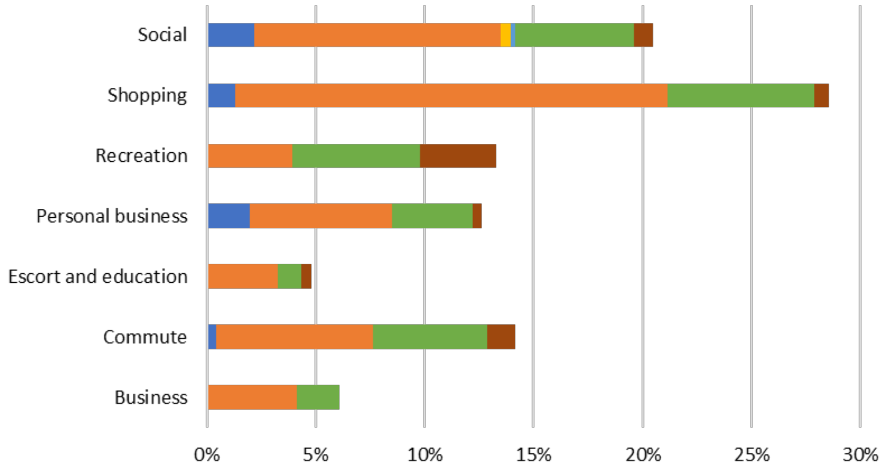

Fig. 7.1d Experimental group post testing

Figure 7.1 Purpose of use for each transport mode, by condition, expressed as a percentage of total number of trips

7.4.3.3 PA

As displayed in Table 7.7, the direction of trend suggests a positive effect of the intervention on increasing MVPA. Specifically, there was a mean increase of 17.72 (95%CI: -84.72, 120.15)minutes of MVPA per week in the intervention group compared to a -27.60 (95%CI: -110.9, 55.7)minute decrease in weekly MVPA in the control group. Weekly MVPA at pre-testing suggested that 80.0% and 73.0% of individuals in the control and intervention groups respectively were meeting the recommended 150-minutes of MVPA per week.

7.4.3.4 PA from e-cycling

Of the nine participants in the intervention group that provided valid Actiheart data at post-testing, one returned the e-bike prior to post-testing and two did not ride the e-bike during the testing week. As such, information on PA during e-cycling is available from six participants. Due to the small sample size, each participant's data are reported individually in Table 7.8. The table shows that for four of the six participants e-cycling was performed, on average, in a moderate intensity zone based on METs, while percentage of Hr maximum, suggests that five of the six participants were engaging in moderate intensity activity during e-cycling, based on 65% of Hr maximum indicating a moderate intensity activity (559).

Table 7.7 Differences in minutes of MVPA between conditions based on individuals that completed baseline and post-testing assessments, mean and confidence intervals are reported

Physical activity	Intervention				Control				Difference in change (CI)
	N	Baseline	Post-testing	Change	N	Baseline	Post-testing	Change	
Daily MVPA, minutes	11	49.12 (25.12, 73.11)	51.65 (24.82, 78.48)	2.53 (-12.10, 17.16)	15	46.72 (33.39, 60.05)	42.77 (26.93, 58.62)	-3.95 (-15.85, 7.95)	-6.91 (-15.17, 1.35)
Weekly MVPA, minutes	11	343.83 (175.86, 511.79)	361.55 (173.72, 549.37)	17.72 (-84.72, 120.15)	15	327.06 (233.75, 420.38)	299.42 (188.53, 410.31)	-27.64 (-110.94, 55.66)	-45.36 (-170.33, 79.61)

MVPA=moderate to vigorous physical activity

Table 7.8 PA associated with e-cycling during post-testing

Participant	Total time spent e-cycling, minutes	Mean Hr while e-cycling, bpm (SD)	Percentage of Hr max	Total time spent in MVPA while e-cycling (≥3 METs), minutes	Average METs while e-cycling	Total MET-minutes from e-cycling
PS002	82.25	109.57 (14.87)	66.01	66.00	3.81 (1.24)	313.12
PS008	58.00	76.78 (3.42)	59.99	6.00	2.61 (0.48)	151.40
PS011	230.00	113.92 (14.95)	81.96	212.25	5.08 (1.42)	1168.88
PS027	53.50	108.06 (14.00)	67.96	34.75	3.54 (1.56)	189.27
PS041	439.75	130.56 (11.04)	75.47	429.5	5.28 (1.15)	2320.05
PS049	65.75	112.43 (7.85)	83.90	3.00	2.24 (0.56)	147.50

bpm=beats per minute; Hr=heart rate; MET=metabolic equivalent of task; MVPA=moderate to vigorous physical activity; SD=standard deviation

7.4.3.5 E-cycling during the intervention

Of the 14 participants for which odometer data were available, the median distance travelled during the e-bike loan period was 144.20 (IQR: 66.00, 284.25)km. Figure 7.2 shows the breakdown of total distance travelled by each participant.

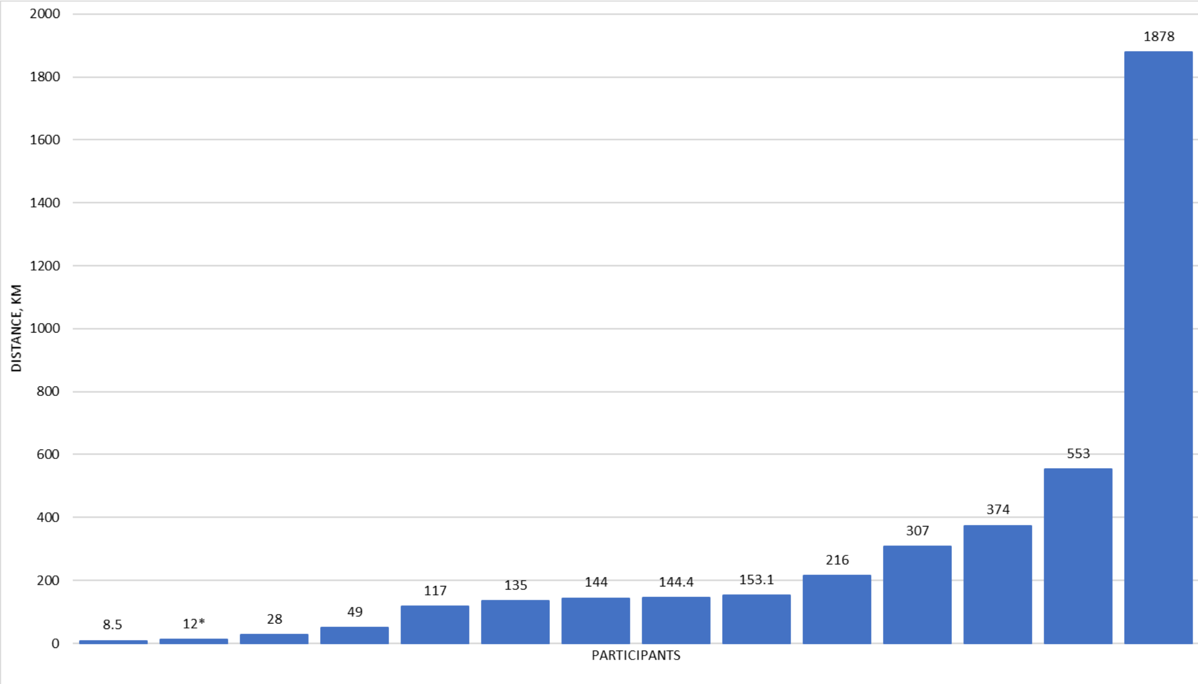

Figure 7.2 Total e-cycling distance ridden during the intervention for each participant, km, *Participant returned e-bike after eight weeks.

The median number of trips made was 22 (IQR: 12, 33) with a median weekly distance of 10.36 (IQR; 3.94, 18.00)km and median time of 66.00 (IQR: 32.00, 94.00 minutes, see Table 7.9). Participants engaged in more recreational trips than transport trips with median of 13 (IQR: 8, 19.75) and 7 (IQR: 2, 16) trips, respectively. Men cycled a median of 261.50 (IQR: 33.25, 508.25)km, while women cycled a median of 139.5 (IQR: 90.75, 144.40)km.

Participants travelled further and spent more time cycling for recreation than for transport. Median weekly kilometres and time spent cycling for recreation were 11.13 (IQR: 9.43, 17.19)km and 44.00 (IQR: 29.00, 67.00)minutes, whereas for transport, they were 2.31 (IQR: 1.00, 7.45)km and 23.00 (IQR: 3.00, 31.00)minutes.

Table 7.9 E-bike trip frequency, duration, and distance during the intervention (n=16)

Outcome	Median	(IQR)
Total time, mins (n=13)	1067.00	646.00, 1204.00
Total number of trips (n=13)	22	12, 33
Total distance, km (n=14)	144.20	66.00, 284.25
Weekly distance, km (n=14)	10.36	3.94, 18.00
Weekly time, mins (n=13)	66.00	32.00, 94.00
Transport		
Number of trips (n=13)	7	2, 16
Total time, mins (n=13)	305.00	40.00, 431.00
Average trip time, mins (n=13)	25.00	14.00, 50.00
Total distance, km (n=9)	101.02	23.05, 131.26
Average trip distance, km (n=9)	3.48	1.88, 8.54
Weekly distance, km (n=9)	2.31	1.00, 7.45
Weekly time, mins(n=13)	23.00	3.00, 31.00
Recreation		
Number of trips (n=13)	13	8, 19.75
Total time, mins (n=13)	646.00	480.00, 848.00
Average trip time, mins (n=13)	60.00	38.00, 72.00
Total distance, km (n=9)	178.15	129.89, 216.43
Average trip distance, km (n=9)	12.32	9.43, 15.97
Weekly distance, km (n=9)	11.13	9.43, 17.19
Weekly time, mins(n=13)	44.00	29.00, 67.00

Note: Weekly estimates are calculated by dividing the total value of the given variable by the number of weeks participants used the e-bike for.

7.5 Discussion

Chapter 7 examines the potential impact of an e-cycling intervention on a range of clinical, physiological, and behavioural outcomes among individuals with T2DM. The results revealed that the intervention demonstrates promise to positively impact glucose homeostasis, HRQoL and cardiorespiratory fitness. E-bikes were primarily used for recreational purposes and led to minimal substitutions in transport mode. These findings are discussed below and their implications for future research explored. The strengths and limitations of the measures used are reported.

7.5.1 E-cycling and health

The current e-cycling intervention demonstrates promise to positively improve clinically important health outcomes that are essential for the management of T2DM. Most strikingly, both fasting and dynamic measures of glucose homeostasis show a favourable impact of the intervention on insulin sensitivity. Conversely, measures of insulin secretion showed no change following the intervention. However, when adjusting for insulin sensitivity, the ISSI-2 showed improvements in beta-cell function. This suggests that the intervention led to improvements in whole body insulin sensitivity as opposed to improvement in beta cell function. Similar changes in metabolic outcomes have been reported in response to exercise in the same population (560, 561). Furthermore, Johansen and colleagues (560) reported that the volume of exercise performed was associated with the Matsuda Index and Disposition Index, but not the Insulinogenic Index, suggesting that exercise does not modify insulin secretion but rather is associated with increased insulin sensitivity. Furthermore, the reduction in incremental area under the curve in the current study supports the findings by Peterman and colleagues (168) and suggests reduced glucotoxicity. Given the detrimental effects of glucose variability, particularly in individuals with T2DM (401, 402, 407), a future trial should seek to evaluate the impact of e-cycling on dynamic measures of glucose homeostasis.

Regarding the long-term measure of glucose homeostasis, using HbA1c, the intervention showed promise to reduce HbA1c by 0.4% in the intervention group, while the control group demonstrated a 3.1% reduction in HbA1c. A sensitivity analysis was conducted to explore changes in HbA1c after removing individuals who had a change in their diabetic associated medication between baseline and post-testing. This analysis substantially changed the results, with the intervention group showing a 1.5% reduction in HbA1c and the control group showing a 0.2% reduction in HbA1c. The degree of change in the intervention group is similar to previous research examining the impact of exercise on HbA1c in the same population (419, 422). This highlights the importance of monitoring and controlling for changes in mediation during the trial. Beyond glucose markers, the current intervention had little impact on lipids or markers of inflammation and is similar to the findings of other exercise interventions in individuals with T2DM and previous e-cycling research (168, 562).

The current study also examined HRQoL, an outcome of central importance in current diabetes management (563, 564). Allocation to the intervention was associated with meaningful improvements in mental and physical HRQoL. Similar improvements in HRQoL following engagement in e-cycling have been reported in older adults (322) and are supported by qualitative findings highlighting the enjoyment associated with e-cycling (145, 512).

Weight loss was also considered of clinical importance in the current trial as it is a key outcome of many diabetes lifestyle interventions. The intervention group lost approximately 2kg weight compared to 0.4kg loss in the control group. This equates to approximately a 2% reduction in weight following the e-cycling intervention. This reported weight loss is similar to other RCTs of supervised exercise interventions with no caloric restrictions (426, 565-567). However, this does not meet the commonly accepted clinically meaningful weight loss of 5% from baseline levels (568). Some researchers argue that this 5% reduction in weight should not guide T2DM management, as engaging in PA at the recommended 150-minutes per week is unlikely to bring about a 5% decrease in weight yet numerous health benefits can be obtained with PA engagement and weight loss below this threshold (569). Specifically, Swift and colleagues (570) showed the 150-minutes of PA per week was insufficient to achieve a 5% weight loss over a six-month duration. Rather, engaging in >300 minutes of activity per week was needed for >5% weight loss. However, statistical evidence of reductions in insulin resistance were reported among individuals who lost between 3.0 to 4.9% of weight, therefore suggesting that improvements in insulin resistance are associated with only modest weight loss.

Despite weight loss, body composition as assessed through DEXA scan, revealed no difference in fat mass between the intervention and control groups, mirroring findings reported by Grace and colleagues (422). However, there was a 1.24kg reduction in lean mass in the intervention group compared to a 0.05kg reduction in the control group. Similarly, the pQCT results revealing a reduction in femur mCSA of 2.6% in the intervention group and 1.0% in the control group. These unusual findings are likely to be due to biological 'noise' associated with the protocol used. Participants were instructed to eat and drink prior to the scans. However, consumption of food and liquid has been found to substantially alter the reliability of DEXA estimates of lean mass and regional body composition in active adults (571, 572) and so are likely to have impacted the current findings.

The intervention led to a 2.10ml/kg/min increase in VO_{2max} and a 16 Watt increase in total power output in the intervention group. In comparison the control group reported an increase in relative VO_{2max} of 0.43 ml/kg/min and a seven Watt decrease in maximum power output. While the difference between conditions suggests intervention promise the within group difference in the intervention group is lower than reported in previous exercise trials in individuals with T2DM (422) and less than the commonly cited clinically meaningful change in VO_{2max} of 3.5ml/kg/min (573). However, reduced risk of morbidity and mortality have been associated with lower increases in fitness (574, 575) and the current changes in fitness are similar to previous e-cycling research in inactive and T2DM populations (168, 171, 253, 254).

7.5.2 Changes in PA behaviour

Changes in health outcomes maybe due to changes in PA behaviour. The current study revealed an 18-minute increase in accumulated average weekly MVPA in the intervention group and a 28-minute decrease in the control group. However, through visual inspection of the Actigraph data during periods of e-cycling, as identified through GPS data and travel diaries, it was apparent that the Actigraph classified e-cycling as a sedentary or light activity. As such, the changes in PA reported in the intervention group represent activity above and beyond that associated with e-cycling. The Actigraph has been reported to poorly classify cycling (506) and as such it is recommended that this accelerometer not be used in future trials wishing to examine e-cycling. The current PA measurement also showed that the majority of participants in both conditions were accumulating at least 150-minutes of MVPA per week. The same outcome was found when using the more conservative Freedson and colleagues cut points (576). This level of MVPA is common when looking at accumulated MVPA as opposed to bouts of 10-minutes or greater which has been the standard up until recently (577, 578) and researchers are encouraged to focus on PA change over time.

7.5.3 E-cycling behaviour and intensity

The e-cycling intervention positively impacted a range of health outcomes despite substantially lower reported weekly distances ridden than other e-cycling studies, suggesting lower energy expenditure. In the current trial participants rode a median weekly distance of 10.36km for a median duration of 66 minutes. In comparison, Peterman and colleagues (168) reported an average weekly distance of 69.4km and duration of 205 (SD=43.3)minutes. Similarly, Hochsmann reported an average weekly distance of 70km per week (253). However, these studies set weekly cycling goals for participants to reach. Studies exploring free living e-cycling behaviour reported substantially lower weekly distances of between 21 to 37km (171, 254).

Despite lower cycling distances, participants cycled at a self-selected moderate intensity zone ($Mean_{\%Hrmax}$=72.5bpm) similar to other acute physiological e-cycling studies (289). Interestingly, the average Hr associated with e-cycling was lower in the current trial (110.0, SD=17.5bpm) than reported by Cooper and colleagues in the same clinical population (125.2, SD=18.1bpm) (171). Participants in the current trial had a higher BMI and lower cardiorespiratory fitness at baseline than those in the Cooper and colleagues study (171).

These findings demonstrate that individuals of extremely low fitness and high BMI self-select an e-cycling intensity within a moderate intensity zone that can positively impact health.

The current study showed differences in e-cycling behaviour between men and women, with men riding a median of 100km more than women during the trial period. This is in line with previous research (171, 181, 182, 296). However, the amount of cycling reported among men was far more variable than among women and reasons for these differences require further investigation.

7.5.4 Purpose of e-cycling

Participants engaged in e-cycling for both recreation and transport purposes. However, participants engaged in nearly double the number of recreational trips ($median_{\#oftrips}$=13) than transport trips ($median_{\#oftrips}$=7). Furthermore, recreational trips were substantially longer than transport trips with an average trip distance of 12.32km versus 2.31km respectively. Retrospective surveys and qualitative research examining the purpose of e-bike use in older adults have reported similar results (182, 323, 579). However, the mean age of our sample was 57 years and only a quarter were retired. Based on the findings of our scoping review (512) we would have anticipated more utilitarian journeys to be made by e-bike. The process evaluation reported in Chapter 6 revealed that participants were reluctant to ride the e-bike for utilitarian purposes due to fear of theft. As such, individuals may have chosen to add e-cycling journeys into their day, enabling them to start and end their trips at home with a safe storage location. Similarly, data collected at baseline and at the end of the intervention showed a 6.28% increase in recreational trips following acquisition of the e-bike, suggesting that e-bikes are creating their own, new trips. That being said, at post-testing approximately half of all e-cycling trips were made for utilitarian purpose and approximately half for recreation, suggesting that this population are willing to engage in e-cycling for travel purposes but there are likely to be other factors impacting their use.

7.5.5 Impact of e-cycling on travel behaviour

A 7.3% decrease in car trips was reported in the intervention group which appeared to be substituted by e-bike trips, which increased by 7.2%. The degree of substitution of car trips with e-bike trips is much lower than reported in other studies (512). There are two possible reasons for this low substitution. Firstly, previous studies have primarily used retrospective reports of changes in travel behaviour which may not accurately reflect mode substitution. One experimental study has examined the impact of e-cycling provision on mode substitution using GPS tracking from which an increase in e-bike mode share of 17% was reported (519). However, the authors note that at baseline car mode share was over 70% in the intervention group, and participants were strategically selected based on having large substitution potential. In the current study car trips made up 63% of the modal share in the intervention group at baseline and 30% of modal share was attributable to walking. As such, there may have been less potential for substitution. Secondly, as highlighted above, participants in the current study were reluctant to use the e-bike for utilitarian purposes for fear of it being stolen, therefore providing less opportunities for modal substitution. No changes were seen in public transport, taxi use or walking following the intervention. This is unsurprising given that car journeys make up the largest portion of modal share in Bristol (580).

In the current study approximately 80% of all trips made by participants were under 8km. While between 25 to 30% of these trips were made by walking, over 40% of these trips were made by car. Given that the median trip distance ridden on the e-bikes was 8.72 (IQR: 4.20, 13.0)km many of these short car trips could be made by e-bike.

7.5.6 Implications for future research

The findings of this chapter demonstrate that longitudinal objective measures of health and behaviour can be collected as part of an e-cycling intervention and that such an intervention demonstrates promise to impact these outcomes. The primary purpose of assessing these outcomes as part of this pilot RCT was to guide the selection of outcome measures for a future trial.

Overall, many of the health outcomes explored in the current trial could be examined in a future trial. However, the positive impact of e-cycling on insulin sensitivity is of particular importance in this population, so warrants further investigation. While several lifestyle interventions use HbA1c as their primary outcome (426, 435, 458), primarily due to its diagnostic use, researchers are encouraged to consider the alternative of insulin sensitivity as measured through dynamic measures of glucose homeostasis. HbA1c, a measure of glycaemic control over the past three months, is closely linked to red blood cell count. When red blood cell turnover is decreased it will result in a disproportionate number of older red blood cells. This can occur in individuals with iron, vitamin B12, or folate deficiency (648-650). Inversely, increased red blood cell count turnover leads to a greater proportion of younger red blood cells and falsely lowered HbA1c values (649). Given that glucose variability has been found to be strongly and independently associated with CVD and mortality in individuals with T2DM (407-409) this outcome would be suitable as a primary outcome for a future RCT. If researchers wish to compare their proposed trial to existing work, then HbA1c maybe more appropriate, however, it is strongly recommended that researchers evaluate the impact of e-cycling on glucose variability in addition to HbA1c.

In line with previous research, the current study shows that e-cycling demonstrates promise to positively improve cardiorespiratory fitness and HRQoL, warranting evaluation in a full trial. However, while researchers are encouraged to examine basic anthropometric measures, the examination of body composition using DEXA and pQCT scans may not be justified given the significant impact that protocol deviation can have on the validity of the measures.

The use of the GPS devices and logbooks during the intervention allowed us to capture contextual information about e-cycling trips to be captured during the e-bike loan period in addition to distance information provided by the odometer. This information provides insight into the best way to promote e-bike use in the population of interest, and future researchers should gather data on e-cycling behaviour using GPS monitoring during an e-cycling trial. In addition, GPS monitoring of daily travel behaviour is necessary to capture objective changes in travel behaviour following e-bike acquisition. These two monitoring devices could be combined to reduce participant burden. Furthermore, the use of alternative devices to the Actigraph and Actiheart should be explored to capture accurate PA changes, ideally using Hr and accelerometery.

7.5.7 Strengths and limitations

The main strength of this study is the use of a longitudinal randomized controlled design to explore the potential impact of e-cycling on a range of outcomes. The methods used to examine the outcomes were selected to build on previous research using robust, objective measures where possible. However, these measures and the protocols used are not without their limitations. Specifically, duration of a diabetic diagnosis was not recorded in the current trial. Diabetes duration may moderate the association between the intervention and health outcomes, particularly metabolic and quality of life outcomes (581, 582). Future research should record how long a participant has been diagnosed with T2DM so the potential moderating effect can be explored. In the current study participants medication status was recorded, enabling identification of medication changes between baseline and post-testing.

The protocol used in the current trial may have negatively impacted the validity of the DEXA and pQCT scan results. Specifically, due to the location of the testing facility from participants home (approximately 45-minutes) and availability of the scanners, it was deemed inappropriate to ask participants to come to this appointment fasted, which is the standard scanning protocol. Attempts were made to standardise food and liquid intake across the time points by asking participants to consume the same intake at baseline and post-testing, and by booking appointments at a similar time of day. However, this was not always possible based on laboratory availability and participants schedules. Future research should aim to follow the standard procedures to increase the chances of collecting comparable scans. If this is not possible, researchers should consider whether deviations from the protocol are of such an extent that they impact the validity of the scans.

A strength of the current study is the use of a supramaximal fitness verification assessment. This assessment aids in the accurate assessment of VO_{2max} particularly among those who are unfamiliar with maximal fitness testing, such as clinical populations, who may terminate an incremental fitness assessment before maximal oxygen uptake is reached (583). A further strength of this study is the combination of objective GPS travel data with subjective diary data to assess travel behaviour. The combined measures provided a rich data set with contextual travel information that was used to gain a comprehensive understanding of participants travel behaviour. However, we cannot be certain that participants always turned on the GPS devices or completed the travel diaries and so some trips may have been missed. Regarding the measurement of e-cycling during the trial some odometers did not work, and some individuals did not want to use the GPS device or complete the e-cycling diary, therefore it is possible that we did not capture all e-cycling activity.

In the current trial, the Actigraph accelerometer was used to assess PA behaviour. However, visual inspection of the data showed that e-cycling bouts were classified as sedentary to light activity. This is like other studies which have shown that the device is unable to classify conventional cycling (506). In anticipation of this finding, the use of the Actiheart combined Hr and accelerometer was explored to measure e-cycling behaviour. The device was able to detect e-cycling but presented a considerable burden to the participant and heavily impacted data collection adherence. As such, Actiheart data while e-cycling was only available for six participants.

7.6 Contribution to this thesis

This is the first pilot RCT to explore the potential promise of an e-cycling intervention to positively impact metabolic, physiological, and behavioural outcomes in individuals with T2DM. The selection of outcome measures and methods of data collection were based on the evidence gaps identified in studies one and two. Specifically, a randomized study design and objective data collection methods were used. The findings of this research will help guide the selection of outcome in a future RCT. Specifically, outcomes that demonstrate sensitivity to change and are deemed to be of importance in this population will be selected. The results reported here, coupled with the data reported in Chapter 6 on the adherence to the different data collection methods, can inform researchers as to whether the methods used to assess the outcome measures are appropriate for future use or if alternative methods of data collection should be explored.

8 Chapter 8: Experiences of e-cycling among adults with T2DM

8.1 Overview

This chapter examines the experiences of e-cycling among adults with T2DM as part of the PEDAL2 pilot RCT. A brief introduction, detailed methods and results and discussion of the findings are presented, along with consideration of how they contribute to this thesis. Chapter 6 demonstrates that the PEDAL2 study is feasible in this clinical population, while Chapter 7 demonstrates that the intervention has a promising impact on PA behaviour and health outcomes. However, rates of e-cycling engagement varied substantially, and it is unclear why participants chose to engage (or not) in e-cycling at the levels reported in Chapter 7. Qualitative exploration of the factors influencing e-cycling engagement provides a starting point from which to identify the potential causal mechanisms of e-cycling in this population.

8.2 Introduction

In the context of AT, researchers have sought to identify and quantify the determinants of prevailing AT cross-sectionally (145, 584-588), longitudinally (589, 590) or in response to an intervention (591, 592), using a variety of conceptual and theoretical frameworks (291, 593, 594). The range of determinants that have been associated with AT is extensive including individual characteristics (i.e., socio-demographics), household characteristics (i.e., the influence of others within the household), trip characteristics (i.e., distance and travel time), the built environment (i.e., road infrastructure, aesthetics, area characteristics), the natural environment (i.e., weather, seasons, topography), work conditions (i.e., facilities that are offered by the employer) and psychological factors (i.e., attitudes, social norms and habits) (147, 148). Much of this research has explored different AT modes as a whole, however, while engagement in cycling and walking are influenced by similar factors the extent to which these factors influence the different AT modes varies (148).

The same is probably true for e-cycling. While e-bikes have many similarities with conventional bicycles, and thus may be impacted by similar determinants, the electrical assistance requires less physical effort and leads to greater riding distance and frequency (303, 512, 519). Therefore, it is likely that some determinants do not translate across modalities. In the context of e-cycling the majority of research has explored factors associated with e-bike purchase and use among e-bike owners (512). This is not surprising as the uptake of e-bikes is an essential first step in changing behaviour. Specifically, perceived health benefits, the ability to maintain cycling, to be able to ride with friends and family, to replace some car trips, overcoming hills and to ride with less effort are the most commonly reported reasons for e-bike purchase among adults in the USA, the UK and the Netherlands (296, 316, 331).

Although less prevalent, qualitative research has begun to explore the determinants of e-cycling engagement in response to the provision of an e-bike (512). The findings from e-bike trials are not dissimilar to those from surveys of e-bike owners. Specifically, the ability to ride further, faster, on hillier terrain all with less physical effort than a conventional bicycle and the ability to ride with friends and family are commonly reported factors that encourage use. Conversely, bad weather, poor infrastructure and theft concerns are common barriers to engagement (512, 519). To date, studies have primarily explored the determinants of e-cycling in response to an intervention among healthy adults. Clinical populations, for whom engagement in AT is low (226), may experience e-cycling interventions differently and be impacted by different contextual factors than a healthy adult population. Understanding the processes through which an e-cycling intervention evokes behaviour change and the contextual factors that impact change in clinical groups can guide future e-cycling initiatives. Two studies have specifically explored factors associated with e-bike engagement in clinical populations. Boland and colleagues (595) examined the use of adapted e-bikes in three individuals recovering from a stroke. The level of social support, motivation for riding, level of physical impairment all impacted riding. Among individuals with T2DM, Searle and colleagues (491) reported that e-cycling was perceived as enjoyable and enabled individuals to cycle with friends and family. However, Searle and colleagues did not conduct a comprehensive evaluation of the data to explore the determinants of e-bike use, rather the researchers were interested in understanding how e-cycling impacted participants management of their diabetes.

Having a clear understanding of the factors that impact engagement in e-cycling in response to provision of an e-bike is important to identify the mechanisms through which an intervention impacts behaviour and the contextual factors that impact engagement. Understanding how participants experience e-cycling, particularly the barriers and facilitators to riding, will enable the development of a conceptual understanding of the factors that are most influential on e-cycling behaviour in this population and can guide the selection of quantitative measures to examine potential moderating and mediating effects as part of a full-scale evaluation.

Therefore, this chapter will, in part, assess the primary objective of this study: **to assess the feasibility of conducting a randomized controlled e-cycling trial among adults with**

T2DM. Specifically, this chapter will focus on the factors that influence engagement in e-cycling among individuals with T2DM as part of an e-cycling intervention. As such, this chapter will address the following research question:

What are the experiences of e-cycling among individuals with T2DM?

8.3 Methods

Chapter 5 outlines the study design and methods used in PEDAL2. Building on this the current section provides in-depth detail of the qualitative methods used to answer the research question above.

Specifically, the potential mechanisms of impact on e-cycling were explored through semi-structured interviews with participants in the intervention group. The interview topic guide was developed using the TDF (208) and based on guidance by Atkins and colleagues (596). The TDF consists of 14 theoretical domains that consider the environmental, social, cognitive, and affective influences on behaviour. The TDF provides a pragmatic framework that can be used to identify key determinants that can assist in the explanation of current behaviour and identify areas for future intervention. The TDF was initially developed to better understand the behaviour of health care professionals in relation to the implementation of clinical practices (596). However, it has been extended to understand behaviour in the general population, including PA (597, 598). The interview guide included at least one question for each theoretical domain to comprehensively consider the possible influences on e-cycling. Follow up probes or prompts were included to delve more deeply into each domain (596). The order in which questions were asked was flexible to enable flow during the interview. These interviews were used to understand participants experiences of e-cycling, with a focus on identifying the barriers and facilitators to e-cycling. The identified factors associated with e-cycling in this population were used to create a conceptual model of the factors that impact e-cycling. The COM-B model, onto which the TDF directly maps, was used to frame the conceptual model (203).

8.3.1 Analysis

As reported in section 5.4.12, interview data were analysed using the framework method (460) and guide by Gale and colleagues seven-stage analysis process (461). In the current analysis stages three and four were reversed due to the deductive nature of the analyses, followed by inductive coding within domains (See Table 8.1). Interviews were conducted with 16 participants in the intervention group ($mean_{age=}$ 60, SD=7 years). Data analyses were primarily conducted by JEB with close discussions with AS.

Table 8.1 The seven stages of the framework method of qualitative analysis and how they were applied to the qualitative analysis using the Theoretical Domains Framework (TDF)

Procedure for analysis	Application in the current study
Stage 1 Transcription	All interviews were conducted by JEB and transcribed by Transcription UK. The transcripts were checked against the original recordings to ensure reliability.
Stage 2 Familiarisation	JEB listening to each audio recording and read each transcript. AS read two interview transcripts (10%). The transcripts were selected by JEB to represent diverse experiences of e-cycling.
Stage 3 and 4 Development of analytical framework and coding	Exerts of the two transcripts were deductively assigned into one or more of the 14 domains reflected in the TDF. Exerts that were deemed important but did not fit into one of the 14 domains were placed in an 'other' category. This was done independently by two researchers who met to discuss assignment. Following this, inductive coding within each domain took place to identify what were termed sub-domains. This was done independently by JEB and AS who met to discuss assignment and an analytical framework was developed. The two researchers independently coded two more transcripts, noting any new sub-domains. The researchers met again to discuss the coding and to revise the initial framework to incorporate new or redefined sub-domains.
Stage 5 Applying the analytical framework (Indexing)	JEB used this framework to code the remaining transcripts using NVivo software. If a new sub-domain was required, this was discussed with AS before adding it to the analytical framework. If a new sub-domain or domain (which did not fit the TDF) was added, previously coded transcripts were checked for relevant data.
Stage 6 Charting data into the framework matrix	After finalising sub-domains and domains, a framework matrix was developed. N-Vivo was used to create matrices that encapsulated data from each domain and sub-domain. Following this, each participants data was described and summarised to develop a chart. This was conducted in Excel and consisted of participants in rows with summaries of domains and sub-domains in columns. AS checked the summaries of the first two transcripts to ensure they captured the essence of the data. Two participants were sent a copy of their interview transcript and an interpretation of their data. They were asked to review their transcribed data and comment if they felt the interpretations represented or misrepresented their views.
Stage 7 Mapping and Interpreting the data	The significance and implications of the domains, and how they relate to one another was examined to generate broader themes. This was done by JEB and AS collaboratively. In addition, the key barriers and facilitators to e-cycling were identified and a conceptual framework developed. The findings were reported narratively with illustrative quotes.

8.4 Results

Five overarching themes emerged through population of the domains in the framework. Table 8.2 provides an overview of the final coding structure and Appendix 8.1. provides details of the codebook development. Each overarching theme is summarised below with example quotes. The facilitators and barriers to e-cycling are summarized in Tables 8.3 and 8.4 respectively.

Table 8.2 Themes, TDF domains and associated sub-domains

Overarching Theme	TDF Domain	Sub-themes
Beliefs and motivation around e-cycling	Beliefs about consequences	Ability to ride further, longer, and hillier terrain; Environmental and financial impact of e-cycling; Increased awareness and empathy for cyclists; Long- and short-term health benefits of e-cycling
	Reinforcement	Habit of e-cycling; Sense of achievement
	Emotion	Riding the e-bike enjoyable and satisfying
	Behavioural regulation	Using technology to self-monitor rides
	Goal	Planning and scheduling e-cycling
	Optimism	Optimistic that e-cycling would be a positive experience
	Intentions	Desire to continue riding; E-cycling intentions
	Knowledge	Benefits of physical activity
Actual and perceived capability to e-bike	Beliefs about capabilities	Confidence riding on roads or in traffic; Perceived competence riding an e-bike
	Skills	Ability to ride and manoeuvre the e-bike; E-bike training was helpful or insufficient; Impact of previous cycling experience
Complexity of making journeys by e-bike	Knowledge	Familiarity with cycle routes; Knowledge of riding on roads; Understanding of how to operate the e-bike
	Memory, attention and decision processes	Remembering to charge e-bike or specific equipment; Decision to engage in e-cycling
Participants role as an e-cyclist and the influence of others	Social Professional Role and Identity	Perception of self as a cyclist; Cycling advocacy
	Social influences	Practical support; Verbal and emotional support
Environmental influences	Environmental context and resources	Access to infrastructure for riding and parking; E-bike size and design features; E-bikes are expensive to buy; Impact of weather and resources; Personal health issues that impacted riding; Time constraints; Traffic concerns; Concerns about e-bike theft

Theme 1: Beliefs and motivation around e-cycling

The primary motivation for engaging in e-cycling was to have a positive impact on health:

'It was all health [the reason for signing up to the study]. *I wasn't really thinking about the environmental factor, at all. I just thought it was something I needed to do'*

(PS049, Male, 68years)

Prior to the study participants were aware of the benefits of engaging in PA, in general, and for diabetes management, and were optimistic that e-cycling would positively impact their health:

'I'm hoping cycling will help [manage diabetes]. *I've always tried to do a bit of exercise. But I've also cut back on one of my medication as a result of health problems, so I'm hoping that this is going to equate to the extra Metformin'*

(PS002, Male, 62years)

Following the e-bike loan participants felt that e-cycling positively impacted a variety of health outcomes including a) diabetes management, through notable decreases in blood sugar levels, b) improved mental health and c) increased fitness:

'Yes, my legs are definitely stronger than what they used to be. I've got more energy to do things'

(PS013, Female, 64years)

'I had more stamina through the day riding it. Yes, I felt better. More alive. Usually I just sit, like I'm doing now, on the couch, with the cat and the television on'

(PS008, Female, 59years)

Men and women reported similar health benefits from engaging in e-cycling. The anticipated and perceived health benefits were important facilitators to e-cycling (Table 8.3).

The potential environmental and financial implications of e-cycling were of minimal importance to this population who viewed e-cycling more as a means of improving health as opposed to altering their transport behaviour:

'For me, it's [e-cycling] *very much rightly or wrongly, very much about the health benefits'*

(PS007, Male, 58years)

As such, the environmental and financial consequences of e-cycling were infrequently reported. Two participants commented that e-cycling saved them small amounts of money from reduced public transport or car use and they felt this saving would be greater if they owned an e-bike:

'It's probably saved me a few quid in bus fares and train fares. Yes, it does save a little bit, but the amount that I use the car, really, unless I got rid of it completely, which I can't imagine myself being able to do… Most of the cost is involved in tax and insurance on a car, rather than on fuel for me, so, yes, it saves me a little bit in fares, but not hugely'

(PS027, Male, 63years)

All participants reported that the e-bike, due to the electrical assistance, enabled them to travel farther, faster and on hillier terrain in comparison to a conventional bicycle, this was a common facilitator to e-cycling (Table 8.3):

'I mean, even the steepest hills were easy enough to go up on the e-bike, you just turn down the gears and put on the turbo'

(PS002, Male, 62years, 553km ridden)

As such, participants rode routes they would not have previously attempted:

'In the knowledge that I had the assistance, I would tackle routes and push myself a bit further than I would normally on my own cycle'

(PS049, Male, 68years, 216km ridden)

The ability to ride new and longer routes meant e-cycling was perceived as both rewarding and enjoyable:

'There were routes that I chose with the electric bike that I haven't embarked on with my ordinary cycle, despite having it 27 years…. I must admit, I found it quite a rewarding experience'

(PS049, Male, 68years, 216km ridden)

'It's actually a pleasurable experience, riding an e-bike, to be honest, it takes out the grind of going up and down hills, so it takes out the… it makes the difficult parts of cycling become more enjoyable'

(PS002, Male, 62years, 553km ridden)

Cyclically, the enjoyment associated with riding led participants to ride further and more frequently than they had anticipated:

'I thought it was such a nice morning, I came back through the country route, so I came back over the common. That's how much I enjoyed it. I extended the distance and the time it took me to return home'

(PS013, Female, 64years, lots of cycling experience, 135km ridden)

Several participants found e-cycling enjoyable and rewarding due to being outside, enjoying the scenery and fresh air:

'I sort of had to map it out before I went but actually when I started off, I actually really enjoyed it. I went down the river for a bit and then I went up into XX and it was lovely, really exhilarating'

(PS044, Female, 67years, 144km ridden)

At the end of the study, 12 participants wished to continue riding an e-bike, with five actively seeking out e-bike purchasing options and one purchasing an e-bike part way through the study:

'*I've applied for the cycle scheme and I'm just waiting for the voucher to come through; I've already decided what bike to get, it's a Raleigh Motos Grand Tour. It can do as much as 150 miles on one battery'*

(PS041, Male, 55years, 1878km ridden)

Two participants wanted to continue riding on a conventional bicycle following the study:

'I've got a push bike and I think it has galvanised me into getting my push bike serviced and I'll probably use my push bike now'

(PS044, Female, 67years, 144km ridden)

Of those seeking out e-bikes half reported that an e-bike was out of their price range and expressed a need to save up or wait for a change of circumstances (e.g., retirement):

'Well, again, it's now work hard, save up the money, and get one'

(PS043, Female, 64years)

Some participants monitored their e-cycling over time using digital technology (e.g., smart phones, study GPS or apps such as Strava) and set frequency goals. This motivated participants during rides:

'I go on Strava and you put it on and you get personal records when you do a ride. I don't know if you've used it, but it's really obscure, I think people download it, so it might be pub to pub or bridge sprint; it's totally meaningless but the fact that you've done your best. If I did a trip 20 times, every day I'd have a personal best in there somewhere. And at the hill, there is like 0.1 of a mile up the hill and you get a record, but you knew you did because you were really pushing it. When you get there, you think, "Oh, I actually got the best time.'

(PS041, Male, 55years, 1878km ridden)

Prior to the study participants planned to use the e-bike for recreational and utilitarian purposes. Regarding utility use some participants wanted to use the e-bike for shopping and/or commuting as a replacement for the car. However, due to a range of individual and environmental factors, discussed below, participants engaged in less utilitarian riding than intended:

'My intentions were to take it to work. Then when you hear of people having their bikes stolen and I'm thinking, "Hang on a minute'

(PS015, Male, 59years, 49km ridden)

One participant, who planned to use the e-bike purely for leisure, used it primarily for commuting:

'At the start of the programme, how did you think you were going to use the bike?

'Just leisure. I planned to commute once. Then I started going longer and I thought it's a little bit too far to cycle to work and I thought I'd just do it once and then I must have done it maybe a dozen times or maybe twenty times during the trial. I find it a lot easier than I thought it was going to be'

(PS041, Male, 55years, 1878km ridden)

Theme 2: Actual and perceived capability to e-bike

Of the 16 participants who were interviewed, 15 were able to ride the e-bike. Fourteen of those 15 had some degree of cycling experience and fundamentally understood how to ride a bike prior to the study. However, the weight of the e-bike was a concern for some participants:

'It was a very heavy bike, for what it is. Quite frankly, that particular bike wouldn't be my choice of bike if I was looking to purchase an electric cycle'

(PS049, Male, 68years, lots of cycling experience, 216km ridden)

In addition, some participants felt the e-bike was too large and hard to manoeuvre:

'Because it was so high, if I got to a junction or came to a stop, I always felt I had to be by the kerb, to sort of lean over. So I never felt comfortable, for example, going into the middle of the road to turn right at a junction or things like that'

(PS007, Male, 58years, lots of cycling experience, 307km ridden, Instructor 01)

These factors negatively impacted confidence riding the e-bike:

'I have to be honest, I never felt comfortable with the bike that I was given because I found the frame too high'

(PS007, Male, 58years, lots of cycling experience, 307km ridden, Instructor 01)

Participants reported how the instructors made a series of alterations to the seat height or provided a smaller size e-bike to increase their comfort and ability to ride. With practice, and alterations to the equipment, participants felt more confident riding the e-bike:

'As far as riding it is concerned, a little bit lacking in confidence to begin with, because it's quite big and quite heavy and you're quite high up, but over time, I gained my confidence with it and worked out how to use the gears and engine quite efficiently'

(PS027, Male, 63years, a little cycling experience, 374km ridden, Instructor 02)

'How did you feel riding the second bike?'

'Fine. A lot better, yes. Because I just felt a lot more manoeuvrable and confident in, if I needed to stop, I could do it without worrying that I was going to topple over'

(PS007, Male, 58years, lots of cycling experience, 307km ridden, Instructor 01)

One participant was unable to ride the e-bike independently:

'I couldn't go myself riding on the bike. I haven't [become] *an independent pedaller'*

(PS023, Female, 56years, no cycling experience, cycling distance not available, Instructor 01)

Participants with recent cycling or motorcycling experience (two to three years) were more confident riding the e-bike itself and in traffic than those who had limited experience or who had not ridden for a long time:

'Well I ride a motorbike anyway, so I'm not unconfident on a road on a bike'

(PS002, Male, 62years, a little cycling experience, 553km ridden)

'When I started, I found I was more uncomfortable on a bike than I thought. I did find the e-bike slightly heavy to handle and I do suffer a little bit from hearing loss, so I was a little bit uncomfortable in traffic to start off with'

(PS013, Female, 64years, lots of past cycling experience, 135km ridden)

While several participants engaged in frequent cycling at a younger age many were surprised at how different e-cycling was to conventional cycling and the poor conditions of the roads compared to when they used to cycle. These unexpected perceptions negatively impacted their riding confidence:

'I think it decreased [confidence]. *Because I think I was a bit taken aback because I had expected to not be nervous, because I've cycled before. So, it was a bit of a surprise. When I headed off to do my journey, I was completely confident, you know, that it wouldn't be difficult. So, it was a bit of a surprise, yes'*

(PS009, Female, 62years, lots of cycling experience, 12km ridden).

Overall participants confidence riding the e-bike impacted confidence riding on the road. Specifically, participants that were more confident riding the e-bike were also more confident riding on the road. While those who were uncomfortable on the e-bike reported greater anxiety riding on the roads due to not being able to respond to changing situations and interactions with cars:

'Yes, I felt confident on the bike'

(PS049, Male, 68years, lots of recent cycling experience, 216km ridden)

'I quite happily went out with the traffic. Traffic doesn't bother me that much, as much as I am a driver and I do cycle, so it wasn't much of a problem. I felt confident enough amongst it'

(PS049, Male, 68years, lots of recent cycling experience, 216km ridden)

'I did find it quite a large machine, but I needed that because I'm tall and my knees are not good. So, you know, I think the bike was right for me. Obviously, because of my age, I was quite nervous of falling off'

(PS009, Female, 62years, lots of cycling experience, 12km ridden)

'*First day, took it out, planned to go from home to XX and do some jobs and literally was sort of terrified fairly quickly. I had to go down onto the main road and I just found it terrifying and decided I had to just go'*

(PS009, Female, 62years, lots of cycling experience, 12km ridden)

The e-bike training was perceived as useful. Prior to attendance, some participants, with previous pedalling experience, felt it may have been unnecessary. However, all participants reported learning new skills, specifically how to ride safely on roads and in traffic:

'Oh, yes. That [the training] *was really useful actually because I was a bit, you know, "I don't need to do this," kind of, thing "I've always cycled, I don't need to be shown what to do." But it was actually quite useful just to do some basics'*

(PS007, Male, 58years, a little cycling experience, 553km ridden, Instructor 02)

Most of the participants reported developing a relationship with the instructor and feeling supported throughout the trial, making the experience more enjoyable:

'The instructor was very good. The second lesson where we went for maybe a 45-minute ride on the road and the cycle paths, that was good, and they're always there for help'

(PS041, Male, 55years, a little cycling experience, 1878km ridden, Instructor 01)

In addition, while the sessions during the e-bike loan period were not always deemed necessary, participants discussed enjoying the time to ride with the instructor and have an informal chat:

'It was more of a fun ride and a chance to have a chat about different things'

(PS002, Male, 62years, a little cycling experience, 553km ridden, Instructor 02).

In contrast three participants felt the training was limited and reported having no contact with the instructor after taking the e-bike home, for one participant this was deemed to negatively impact his confidence and riding amount:

'It was all a bit quick, but I mean- And I thought they should have said something about more training at a later date'

(PS047, Male, 68years, lots of cycling experience, 9km ridden, Instructor 03)

Theme 3: Complexity of travelling by e-bike

Following the training all participants, except one, felt that they had sufficient knowledge to ride safely on the roads:

'It reinforced the road awareness that I think is quite important, particularly if you haven't ridden a bike for a while. As I said to you before, I've done quite a lot of cycle riding, so I'm fairly adept at it and I'm a regular driver, so I know the things to look out for'

(PS027, Male, 63years, a little cycling experience, 374km ridden)

Furthermore, all participants felt they were able to change gear and use the electrical assistance, becoming more efficient with deployment over time:

'When I first started, I was flicking the buttons all the time. But then I realised that you don't have to do that, the bike will kick in by itself. That was absolutely fantastic, I really enjoyed that function. If things got a little bit tricky, it would just kick in and you'd go up a gear and it was brilliant'

(PS013, Female, 64years, lots of cycling experience, 135km ridden, Instructor 03)

When choosing where to ride some participants reported sticking to familiar routes, for which they knew the cycling infrastructure and/or traffic levels. While others enjoyed using the cycling maps to plan rides and exploring bike paths near them:

'Because cycling out there seems to have got better, as in you've got paths to go on, and I found some really interesting paths'

(PS008, Female, 59years, a little cycling experience, 153km ridden, Instructor 02)

'I tended to have a particular circuit that was around the XX. Even if it was just forty-five minutes so I had a particular circuit around the XX'

(PS007, Male, 58years, lots of cycling experience, 307km ridden, Instructor 01)

Remembering to charge the e-bike battery was not a concern for participants:

'When I go out anywhere I come home and then I put it straight onto charge, and then it's fully charged'

(PS011, Female, 57years, a little cycling experience, 117km ridden)

Overall, riding for utilitarian purposes required more organisation and some participants reported forgetting certain pieces of equipment (e.g., helmet, lock, battery):

'I did make a schoolboy error one day, because I wore the helmet all the time, and I went into work and I was coming out and I was like a mile or two miles home and I always wore

glasses as well. They're safety work glasses but they look quite sporty. One is a blue pair and one is a red pair. I could just feel the wind in my hair and I thought, "I haven't got my glasses on. I haven't got my helmet on either.'

(PS041, Male, 55years, a little cycling experience, 1878km ridden)

Participants who had cycled regularly in the past reported keeping all required equipment in one location or running through mental checklists before leaving:

'You just got used to getting your bag. Well, the bag was half packed anyway. And I would always take the lock for it. I would always take that with me'

(PS008, Female, 59years, a little cycling experience, 153km ridden)

The overall decision to engage in e-cycling for leisure was influenced by the weather, cycling infrastructure available and participants confidence level. When considering cycling for utilitarian purposes additional factors were considered included parking facilities for the e-bike at the destination and time constraints. In some instances, participants reported weighing up the pros and cons of cycling versus using a different mode of transport.

'I would say that commuting was definitely one reason to get me out on the bike, because it was just very easy to get to work. Where I work is in the middle of town and there isn't any parking allowed, except for special reasons where you have to book it a long time in advance and give a definite reason. There are only four parking spaces for the company, and I think there are probably about 200 employees in the company. All around there the car parking is very, very expensive. So, let's look at it from the other side, the next choices are taking the public transport and the buses are often very full at that commuter time and often go straight past you. So, you can end up not getting the bus. The other option is to walk or drive down to the local train station and, again, the train is very crowded. The final option is to get on the bike, go through a couple of back roads and get on the cycle path, whizz down the cycle path, cross over one major road and then some minor back-roads and there's plenty of bike parking in the cellar of the building and it's secure and monitored with cameras and locked with barriers and automatic gates, so that the bikes are very safe there, so you've got no worry about that. In that respect, it is the best option'

(PS027, Male, 63years, a little cycling experience, 374km ridden)

Theme 4: Participants role as an e-cyclist and the influence of others

For several participants using the e-bike for three months made them feel more like a cyclist. However, the degree to which participants felt like cyclists varied. Specifically, participants who reported a stronger e-cycling habit, and greater distances travelled, saw themselves more as cyclists than those who did not get in the habit of cycling regularly and travelled less distance:

'How do you think you managed to get yourself in that habit?'

' Just wanting to get out there, just wanting to ride. I just loved being out there, and because I was feeling the gains'

(PS041, Male, 55years, a little cycling experience, 1878km ridden)

'My views before, because I am not a cyclist, or I consider myself I am now but before I wasn't a cyclist and I thought I never would. But the trial coming along just gave me that confidence and just changed my total outlook on it, but I do feel I am a cyclist now'

(PS041, Male, 55years, a little cycling experience, 1878km ridden)

'No, I wouldn't say I got into the habit of riding it on a daily basis. I wish I did, but I just rode it whenever I could. But certainly, I think it's a habit I could get into'

(PS013, Female, 64years, lots of cycling experience, 135km ridden)

'I regard myself more as a cyclist than I did before and if it wasn't for this project I wouldn't have even considered getting out on the bike'

(PS013, Female, 64years, lots of cycling experience, 135km ridden)

Three participants shared how they would encourage e-cycling to others, while another three reported having more specific discussions around the benefits of e-cycling and saw themselves as role models:

'I've spoken to quite a few people about them and said, "You've got to give them a go, they're loads of fun and if you don't like cycling, it'll make it a lot easier for you to go back onto a bike". As I said, we've even got one for use of people at work and I keep saying to various people, "Go on, jump on it and have a go, you'll have some fun."'

(PS027, Male, 63years, 374km ridden)

The amount of practical support received and/or desired ranged greatly between participants. Participants with no previous cycling experience desired more practical support to enable them to ride or motivate them ride than those who knew how to cycle:

'No, no, because [partner] used to walk the dogs while I rode around the park. He was always there, so he'd take the dogs, because he'd take the dogs every day anyway, round the park, so he used to do it when I would go'

(PS012, Female, 42years, no cycling experience, 144km ridden)

Several participants reported cycling with friends and family which was enjoyable and motivational:

'I've got a friend, we cycled home for maybe six miles. He would get off the cycle paths at XX and I would carry on and he is a good cyclist so he'd have to slow down for me, but that was motivational as well because he'd be pushing, I'd be trying to keep up with him and then we'd get on the downhill bits where I could get up to 20, 30 miles an hour and he'd be with me, so that was good'

(PS041, Male, 55years, a little cycling experience, 1878km ridden)

There appeared to be a gender difference with men being happy to cycle alone and women desiring greater practical riding support:

'I do find it quite an activity that's quite therapeutic on your own. You can set your own pace. You know, you haven't got to worry about somebody else and what they're doing. You can stop and start when you want. Choose your route. So I suppose I'm quite happy to cycle on my own most of the time'

(PS007, Male, 58years, lots of cycling experience, 307km)

'Well it would be nice to have a family event. We haven't had a family event like that for a long, long time. It would be nice to get out and do things together'

(PS013, Female, 64years, lots of cycling experience, 135km ridden)

Similarly, while some participants found verbal support to be encouraging, others felt their decision to ride was not influenced by others. For individuals who were unsure about whether e-cycling was appropriate for them the feedback from others was impactful, either giving them motivation to continue or confirming their decision to stop:

'Did that make a difference to how you rode the bike or when you rode it? Yes, I think generally positive feedback helps make you, you know, if you are feeling a bit doubtful about whether it was something that was the right thing to do for someone of my age, for example, then that positive feedback probably helped me get over that'

(PS007, Male, 58years, lots of cycling experience, 307km, Instructor 01)

For one participant, who was struggling with e-cycling, the feedback from her friends impacted her decision to stop riding:

I tried it one more time, just local, but yes, by then I think friends were saying to me they thought it was too risky and I shouldn't do it'

(PS009, Female, 62years, lots of cycling experience, 12km ridden)

There were no apparent differences in the perception of verbal support based on gender.

Theme 5: Environmental influences

Participants reported a range of environmental factors that impacted the amount they rode the e-bike. Environmental factors were the most reported barriers to engaging in e-cycling (see Table 8.4).

Cycling infrastructure, parking facilities and traffic

As reported in the process evaluation (section 6.4.4) several participants were concerned about the e-bike being stolen when leaving it in a public space, especially when the parking facilities were deemed inadequate:

'I mean, I have got sisters that live about a mile and a half away, and I didn't even want to go up and see them in it because there was nowhere to put the bike safely. Even with the lock, I wasn't happy about it, you know'

(PS047, Male, 69years)

This anxiety regarding theft was exacerbated by the e-bike being on loan and participants being unclear of the financial implications for themselves if the e-bike was stolen. Participants reported that they would have been less anxious about locking the e-bike up in public spaces if it belonged to them.

Having limited e-bike storage at home also impacted cycling. Several participants had to keep the e-bike indoors which required effort to get the bike in and out the house:

'The only thing storing the bike, I had to put it in the kitchen because I live in a high rise flat, and there's nowhere else to put it'

(PS011, Female, 57years)

Regarding riding, participants were reluctant to ride on roads with no cycling infrastructure, primarily due to traffic concerns:

'The main way I would have gone into work would have been to go down XX Road. And I don't think there's a cycle lane there and it's very, very busy so… It's put me off. Really'

(PS007, Male, 58years)

Participants who felt they were close to segregated cycle paths were willing to cycle short distances on the road to reach these paths. Participants' level of confidence riding the e-bike and riding on roads impacted the degree to which segregated cycling infrastructure was deemed a necessity. For those with limited confidence riding on roads, not having easy access to segregated paths negatively impacted their e-cycling. For participants with high levels of confidence riding on the road the absence of cycling infrastructure, while not enjoyable, did not stop them from engaging in that specific ride:

'How about location cycle routes and paths, did they influence your decision to ride the bike?'

'They did a little bit, but I don't mind riding on the roads either, so I didn't say because there isn't a cycle track going in that direction I wouldn't ride the bike'

(PS002, Male, 62years, a little cycling experience)

There was some concern regarding cycle paths including the volume of users and the complications of mixing cycling and pedestrians. In addition, a few participants reported that in the dark the cycle paths felt isolated, and participants felt vulnerable:

'When I'm on early shift, I get up early and I just stick to the roads because I'm not overly confident going on the cycle path at five in the morning in the pitch dark, and coming back at night, I don't really want to be on there at ten or eleven o' clock either, just all the wispy shadows and people stood behind the bridges and that, it's just a little bit concerning, but I am fine on the roads'

(PS041, Male, 55years, a little cycling experience)

'That was quite difficult actually [a particular cycle path] *because it was shared as a footpath. I seemed to be coming across pedestrians every hundred yards'*

(PS007, Male, 58years, lots of cycling experience).

Time and weather constraints

Work and personal caring responsibilities negatively impacted e-cycling for some participants, particularly those in full time employment:

> *'The extra work I was doing at work, I was also tired. I'd always come home, have dinner and a bit of a sleep. So, by the time, say, I felt like going on the bike, it was blinking dark at 4:00pm'*
>
> (PS043, Female, 64years, working full time [FT])

Heavy rain and darkness were the two weather related barriers frequently reported by participants:

> *'Because the weather was really bad lately and I couldn't go on the e-bike, so I had to go on the bus to get to places'*
>
> (PS011, Female, 57years, working part time [PT])

> *'So the weather, I guess, the only thing that impacted on me later on was in September. Later in September and early October, where it was dark by the time I got home. I didn't enjoy cycling in the dark very much. I did do it sometimes, but not a lot'*
>
> (PS007, Male, 58years, working FT)

For some participants having wet weather gear and good lights helped to overcome these issues, while others actively chose not to cycle in these conditions.

E-bike specific issues

The weight of the e-bike was apparent to all participants and in some cases made the e-bike hard to manoeuvre:

> *'I think the electronic bike was so heavy and not manageable'*
>
> (PS023, Female, 56years, no cycling experience, Instructor 01)

In addition, for some participants the e-bike frame was perceived as being too large, leading to feelings of discomfort. Many participants, potentially due to the weight of the bike, wanted to be able to comfortably put their feet on the ground when stationary. Issues with the perceived size and weight of the frame impacted participants confidence both riding the e-bike and riding on the road:

> *'It was too high, because I didn't feel comfortable not being able to put my feet flat on the floor, so I had to wait for a seat, because the first seat, still my feet didn't touch the floor.*

Yes, because obviously where I haven't rode a bike, I needed to be able to put my feet on the floor'

(PS012, Female, 42years, no cycling experience, 144km ridden)

There were few comments on the e-bike battery range with only one participant reporting it to be inadequate. However, several participants found the battery itself to be inconvenient and heavy to carry around:

'It was a bit of a pain when you had to… when you locked it up, especially when you were out shopping, to take the battery out, you know, take it off and… because it's quite heavy'

(PS002, Male, 62years)

Several participants commented that they would like to continue cycling after the study but that the cost of the bike meant they were unable to do so. For some participants this meant conventional cycling, while for others this meant not engaging in cycling until they had saved sufficient money to purchase an e-bike:

'I'd never ridden an e-bike and it was really good. When I had to give the e-bike back I tried to use my normal bike and I couldn't use my normal bike and I was struggling with it. So, I'm going to sell that one and save up for an e-bike, it's really hard trying to get an e-bike because it costs so much money'

(PS011, Female, 57years)

Personal health issues

During the study personal health issues arose for several participants that impacted cycling. These were both acute and chronic in nature. The chronic conditions occurred in participants over 60 years of age:

'Well the only other barrier I had was this operation I had. The lead up to it I was told not to overdo it and then the operation itself'

(PS002, Male, 62years)

'I had an abscess on my tooth, and then I had to have it come out, that impacted riding'

(PS012, Female, 42years)

Four participants reported having pre-existing health conditions. For two participants this negatively impacted riding (arthritis in hand and difficulty lifting their arm to signal due to cancer treatment) while the other two were able to develop strategies to deal with the health condition (blind in one eye and hearing loss in one ear):

'I do suffer a little bit from hearing loss, so I was a little bit uncomfortable in traffic to start off with. But my confidence grew the more I went out'

(PS013, Female, 64years)

'They had to cut nerves in my neck, to get to the lymph nodes. So, lifting it up is difficult. I can do it, but it takes great mental, physical strength, or whatever you'd like to call it. I just find it very difficult. So, cycle paths are fine, but on the road, no'

(PS043, Female, 64years)

Based on findings reported here a conceptual model was created to understand the impact of the intervention and contextual factors on e-cycling in individuals with T2DM. Figure 8.1 provides an overview of how these social, environmental and individuals factors are associated with one another in the current population using the COM-B model as a guide (479).

Table 8.3 Facilitators to engaging in e-cycling during the study

Individual	Social	Physical
Improved health (physical and mental)	Positive encouragement from others was motivational	Cycling infrastructure • Access to cycling specific infrastructure. • Safe parking facilities at home, work and public spaces
Enjoyment associated with e-cycling	Riding with friends and family	Useful and supportive e-bike training
Past cycling experience, knowledge of how to ride a bike	Riding with organised group	Ease of using the gears and assistance
Confidence riding the e-bike in traffic		Ability to ride hilly terrain
Increased confidence riding the e-bike		Ability to ride further and longer distance than CB or than anticipated
Knowledge of how to ride safely on roads		Ability to exercise outside in the fresh air and nature
E-cycling perceived as a form of exercise		Having e-cycling equipment ready, in one location
Knowledge of cycle routes and paths		Owning cycling gear (gloves, waterproofs etc.)
Optimistic of the impact of e-cycling on health		Cost saving compared to other transport
Setting e-cycling goals and planning rides		Faster than other transport modes (car/public transport)
Monitoring e-cycling		
E-cycling is rewarding		
Increased e-cycling habit		
Reduced physical effort compared to conventional cycling		

Table 8.4 Barriers to engaging in e-cycling during the study

Individual	Social	Physical
Lack of confidence riding on roads with traffic	Lack of people to ride with or support riding, partners did not ride	Weight of e-bike
Lack of confidence riding the e-bike	Friends and family expressing concern about e-cycling	Weather • Rain • Limited daylight
Personal health issues that limit riding		Amount of traffic
Lack of past cycling experience		Theft concerns
E-cycling is not exercise		Time constraints
		Size of e-bike
		Cycling infrastructure • Lack of access to segregated cycle paths • Potholes on roads • Bumpy cycle lanes • Bicycle paths are isolated • Lack of safe cycle parking • Riding with other bicycles and pedestrians can be dangerous
		Lack of bicycle storage at home
		Battery • Weight of battery to carry around • Difficult to remove • Charge decreases rapidly
		Unsupportive and insufficient e-bike training
		Lack of waterproof gear
		Organisation involved in e-cycling compared to other transport

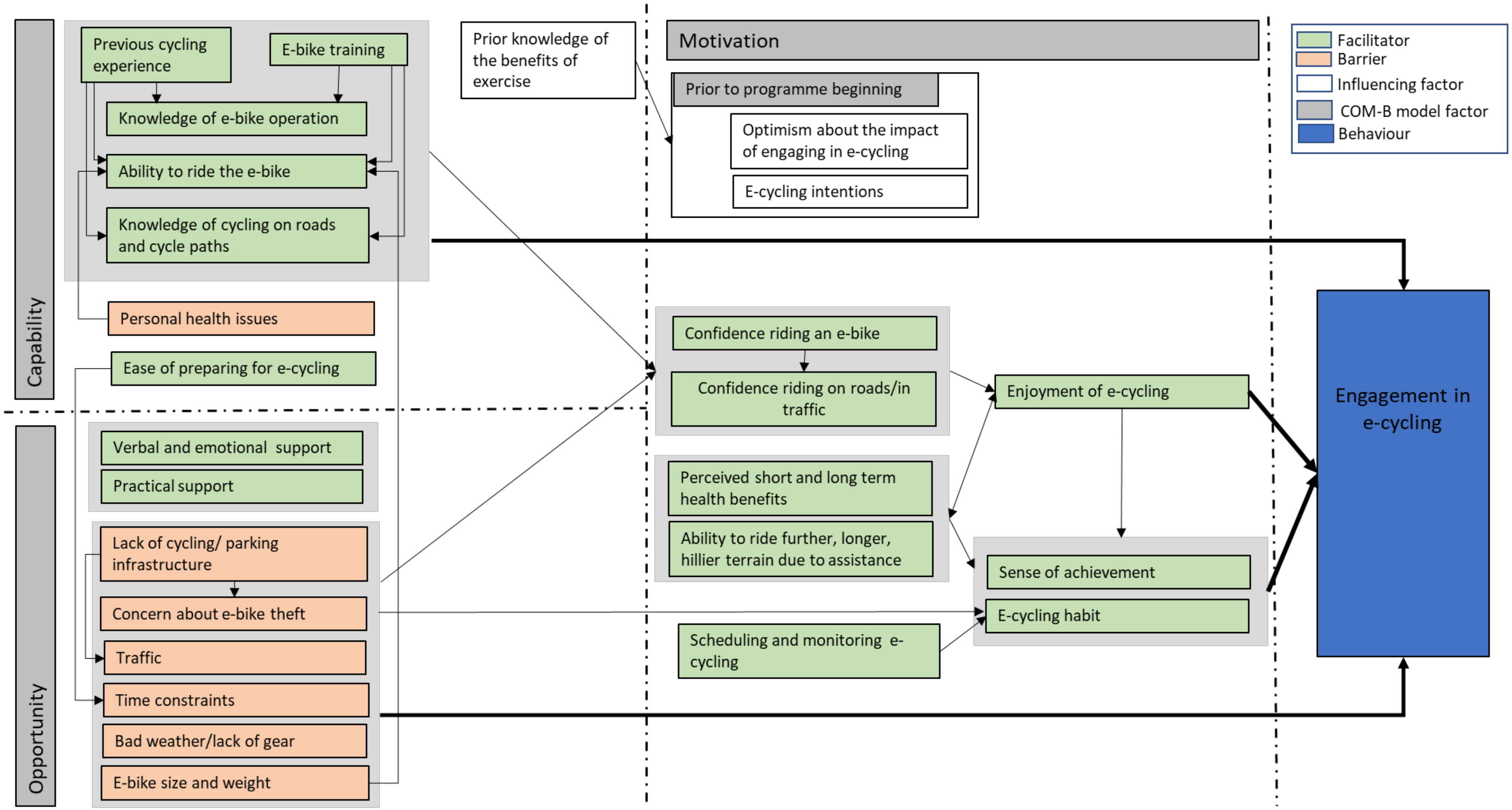

Figure 8.1 Conceptual model of e-cycling in adults with T2DM, including barriers and facilitators to e-cycling

8.5 Discussion

The aim of this chapter was to systematically examine the factors associated with engagement in e-cycling among individuals with T2DM, with a particular focus on identifying barriers and facilitators to engagement. This information can be used to refine the current intervention and guide future initiatives aimed at increasing e-cycling more broadly.

8.5.1 The importance of e-bike training

Regardless of previous cycling experience the e-bike training was perceived as beneficial, providing participants with e-cycling skills, knowledge of how to safely ride on roads and where and how to access segregated cycling infrastructure (with the provision of cycling maps). Consequently, participants reported increased confidence riding the e-bike, riding on the road and exploring new cycling routes. This increased confidence was greatest among individuals who had not cycled for a considerable period. Similar increases in confidence have been reported among older adults in the UK following e-bike training (579). A recent review of conventional bike skills training programmes concluded that training led to increased riding confidence, and was positively associated with increased cycling frequency (160). These findings highlight the importance of training to target key individual level predictors of e-cycling, namely skills, knowledge, and confidence.

Despite the apparent positive impact of training on cycling behaviour, e-bike interventions rarely report the details of training provided. This maybe because no formal training is conducted, training is minimal, or researchers do not consider the impact of the e-bike training on behaviour. Lack of reporting of intervention content and duration is a similar problem in conventional cycling studies (160). An understanding of what is delivered as part of an e-cycling intervention is important to determine what does and does not work. E-bike training maybe of particular importance to older adults or clinical populations who may have pre-existing health concerns that require adaptations to the e-bike, riding style or riding location. These issues can be addressed and overcome with support from an instructor, as was the case in the current trial.

In addition, more support maybe required for women who had less cycling experience than men when entering the study, a finding echoed in another e-bike trial (599). Subsequently men completed higher levels of skills training (National Cycling Skills levels two and three) than women prior to taking the e-bike home and cycled further, on average, than women during the trial. Previous cycling research has shown that higher levels of

National Skills Cycle training completed are associated with more riding (600). As such, women should be supported to reach these higher levels of skills training prior to an e-bike loan.

The additional riding sessions conducted during the e-bike loan made participants feel supported and offered an informal setting in which to discuss e-cycling and practice riding. Furthermore, participants that attended these sessions rode further than those that did not. Serali and colleagues (160) found that cycling frequency decreased over time following training and recommend that training should be followed up by post training support to ensure that participants consolidate the skills and confidence gained during training. This recommendation is supported by the findings of the current study and suggest that the additional support provided in the current study, above and beyond delivering skills training, is important to practice skills and maintain confidence. Conversely, when participants reported instructors to be disengaged in the training this negatively impacted confidence. As such, instructors need to be comprehensively trained, not only on the skills training, for which they were confident, but also on how to offer support and effectively engage with a population who may require more support than the instructors are used to providing.

8.5.2 E-bike size and weight concerns

Despite comprehensive training several participants reported that the e-bike was too large making it difficult to manoeuvre, leading to decreased confidence riding the e-bike in general and in traffic. While the e-bikes provided were an appropriate size based on participants' height, participants wanted to be able to put their feet firmly on the ground. E-bike size concerns are not a commonly reported barrier to e-cycling and could be due to the characteristics of this sample. Specifically, the current sample were classified as obese and had extremely low fitness levels which could have negatively impacted balance. In addition, a T2DM diagnosis is associated with reduced balance (513-515). This reduced balance and low fitness could have meant participants found it hard to manage the weight of the e-bike when stopping and starting. In the current study the provision of a smaller frame size, which enabled the participant to fully plant their feet on the ground, was associated with increased confidence riding the e-bike and riding on roads. As such, the provision of smaller e-bike frames than is standard would likely increase riding confidence and engagement in e-cycling in this clinical population.

8.5.3 Psychosocial factors that impact riding

Participants were motivated to engage in e-cycling to improve their health as opposed to impacting the environment. This optimism regarding health was largely met, with participants perceiving improvements in fitness, mental health and diabetes management, findings echoed in previous e-cycling research (491). Engaging in e-cycling was perceived as an easier way of managing their diabetes than diet or other types of exercise, largely due to the enjoyment of riding. Enjoyment came from the ability to ride a bike comfortably due to less physical exertion than a conventional bicycle and the ability to ride further, faster and on hillier terrain than previously possible. These benefits are consistently reported in the e-cycling literature (512). A substantive body of literature now demonstrates that positive enjoyment during exercise is associated with greater future engagement (601) and is a unique aspect of e-cycling over other forms of AT such as running or conventional cycling. High levels of enjoyment appeared to increase the habit of e-cycling in the current sample, with participants who felt e-cycling had become habit accumulating greater kilometres ridden than those who did not.

In the current sample, the degree to which support was required, or desired, varied based on level of experience and gender. Specifically, individuals with low levels of cycling experience, who were primarily women, required and desired more practical support from both the instructor and friends and family. One participant attributed her inability to become an independent cyclist on a lack of social support. In addition, women reported wanting to ride with friends or family to a greater extent than men. Conversely, men reported that e-cycling alone was relaxing and enjoyable. This has been reported in other e-cycling studies among older adults (182, 579). In the current study verbal support was less influential than practical support. This may be due to the higher-than-average rates of cycling in Bristol and potentially a community acceptance of cycling in general (602).

8.5.4 The impact of the natural and built environment

Access to safe parking infrastructure was a commonly reported barrier to utility e-cycling. Specifically, a lack of safe parking facilities and fear of theft negatively impacted riding. While these are commonly reported barriers to cycling (147, 512) these fears were exacerbated in the current study due to the e-bike not being owned by the participant and concerns over the financial implications of e-bike theft. While there is scant evidence of the impact of bicycle parking in cities on cycling behaviour, Heinen and colleagues report that the supply and quality of parking can impact cycling behaviour (157).

Home parking facilities were also an issue for some participants. Specifically, participants reported having to park the e-bike in the house and the effort required to get the bike in and out negatively impacted riding. Very little research has explored the impact of home parking facilities on cycling behaviour. This concern maybe more pertinent to e-bikes which are heavier and bulkier than conventional bicycles (166). In the current study two participants reported regularly commuting to work. These individuals reported having access to safe bicycle storage and showers and in one case the company had restricted car parking making e-cycling more attractive. Workplace facilities and polices such as these have been found to be positively associated with cycle commuting (603-606).

The cycling infrastructure to which an individual had access also impact riding. Specifically, participants were more willing to cycle when they had access to a segregated cycling path close to their home. Providing infrastructure that supports the needs of cyclists is recognised as a key strategy to encourage more cycling in cities (607-609). Two recent systematic reviews show that cycling behaviour increased following the introduction of new infrastructure or upgrading existing infrastructure (610, 611), however evaluation of environmental interventions is complex and findings vary based on the method of evaluation used (156).

Overall factors associated with the natural and built environment were instrumental in participants decision to engage in e-cycling or take an alternative mode of transport. In some cases, participants removed any notion of utility cycling and stuck to recreational rides due to these barriers. While participants were encouraged to engage in problem solving and action planning to overcome such barriers the extent to which individuals engaged in these activities at appropriate times is unknown.

8.5.5 The prohibitive cost of e-bikes

Trialling an e-bike led to 12 of the 16 participants wanting to purchase an e-bike to continue riding, largely due to the high level of enjoyment. This is in line with other research which has reported that the desire to purchase an e-bike substantially increases following a e-bike trial and is associated with enjoyment, positive attitudes towards e-bikes and perceived benefits (599, 612). While many individuals are willing to pay the large expense of an e-bike (181, 599, 612) for others, including individuals in this study, although willing, they do not have the financial security to be able to purchase an e-bike (599). Following completion of an e-bike trial period, purchasing an e-bike has been reported to be an independent predictor of e-bike use over time (599) and is associated with a reduced habit association for car use (299). As such, ways of helping participants to view e-bikes as a financially viable option is of upmost importance.

8.5.6 Strengths and limitations

A strength of this research is the use of the TDF and COM-B frameworks to examine experiences of e-cycling in this population. These frameworks, through the incorporation of numerous theories of behaviour change, allow for the identification of key mechanisms through which the intervention impacts e-cycling. Their use allowed exploration of factors beyond skills and knowledge-based considerations and to develop an understanding of the impact of context on e-cycling engagement. This information can be used to develop a programme theory, identifying hypothesised causal pathways, which can be tested in future trials. However, there are several limitations. Firstly, a limitation of using the thematic approach is the combining and summarising of data. This means that individual level detail maybe lost (466). The aim was to bring forward unique cases into the matrix and report these in the results. Secondly, thematic analysis focuses primarily on what the data shows, thus failing to consider potential areas that are not discussed. While this is hard to avoid, use of the TDF ensured that a wide range of topics were covered. Thirdly, the role of the researcher may have impacted the data obtained, the analysis and the findings. The prior relationship the researcher had with participants may have impacted how participants responded to questions. To try and overcome this a distinction was made between the e-bike training and the study to help the participant view them as different components to encourage honest opinions to be shared. Participants were asked to give frank answers to enable intervention improvements for future participants. In addition, the primary interviewer and the data analyst were both commuting cyclists at the time of the study. This may have influenced interpretation of the data. However, interpretations made by the researcher and reviewed by the participants showed consistency, therefore increasing the trustworthiness of the findings.

8.5.7 Implications for future research

Using the information obtained from this analysis, researchers should refine the intervention to address some of the highlighted concerns (e.g., bike size allocation). Following refinement, a programme theory should be developed to generate hypotheses about how the intervention impacts cycling in this population. This can be used to guide the selection of quantitative mechanistic outcomes and contextual variables that should be examined in a future evaluation. Further research should be conducted to differentially examine the impact of such e-cycling interventions on individuals new to cycling or who have not ridden for a considerable amount of time, as the degree of training required appears to be different. In addition, such an intervention should be trialled in different populations to examine how experiences compare across clinical populations.

While training is important, it needs to be part of a multifaceted approach including infrastructure and policy to encourage e-cycling engagement. As such, future research should involve working with stakeholders to establish how we address some of the contextual barriers to e-cycling.

8.6 Contribution to this thesis

This chapter forms a key part of pilot and feasibility testing by providing an in-depth understanding of experiences of e-cycling in adults with T2DM and identifying barriers and facilitators to engagement. The findings represent a first step in developing a clear understanding of the mechanisms through which the e-bike training impacts individual capability and motivation and identifying the importance of different environmental factors on e-cycling engagement. This is the first step in addressing the need for longitudinal data examining the determinants of e-cycling identified in study two. The findings from this chapter provide insights into the findings from Chapter 7 and why people chose to use an e-bike. This understanding can help us improve the quality of bicycle skills training, guide the selection of mechanistic outcome measures for future evaluation, guide scale-up and inform policy makers of what further actions need to be taken to enable people to adopt e-cycling.

9 Chapter 9: Discussion

9.1 Overview

This chapter revisits the objectives of this PhD thesis and presents the main findings that answer these objectives to provide an overall discussion of this work with recent studies. The implications of these findings for practice and policy are discussed and the future research priorities stated. The strengths and limitations of this research are presented with a conclusion for the thesis.

9.2 Summary of findings across studies of the thesis

E-cycling has been highlighted as a potential activity through which to increase PA. As such, the primary aim of this doctoral work was to explore the use of e-bikes in improving health through increased PA. More broadly, the research sought to understand whether e-cycling was associated with improved health outcomes in adults and to explore how e-bikes were used in everyday life and their impact on PA and travel behaviour. Three studies were conducted to address this broader aim, each designed to explore specific research questions relating to the impact of e-cycling on health and behaviour.

The systematic review showed that e-cycling is performed at between 4.9 to 8.3 METs, providing PA of a least a moderate intensity. The level of intensity associated with e-cycling suggests that engagement in e-cycling has the potential to positively impact health. The review showed that there is moderate evidence that e-cycling can lead to improvements on cardiorespiratory fitness in physically inactive adults. This is the first review to collate and summarise the physiological evidence exploring the intensity of PA associated with e-cycling and potential health benefits. Since publication in November 2018, this systematic review has been cited over 25 times.

The scoping review revealed that e-cycling primarily substitutes for short car journeys or conventional cycling. However, the evidence suggests that individuals cycle for longer distances, greater duration and more frequently than a conventional bicycle and as such the difference in weekly PA and energy expenditure between conventional cycling and e-cycling are similar. Furthermore, among older adults e-cycling overcomes physical limitations which negatively impact conventional cycling, enabling individuals to ride further, faster, and on hillier terrain than on a conventional bicycle. Therefore, e-cycling may serve to prolong the cycling careers of older adults. The review revealed that younger adults have different motivations for e-cycling than older adults. Specifically, younger adults engage in e-cycling more for environmental reasons and to be able to carry heavy loads while older adults e-cycle for exercise and to improve their health. This is the first study to collate and summarise the evidence exploring how e-bikes are used and their impact on other modes of transport. Collectively the review suggests that e-cycling has the potential to increase PA, through substitution of motorised vehicle use, or maintain PA in those that maybe contemplating stopping cycling due to physical limitations. Since publication in August 2020 the scoping review has been cited five times.

Study three assessed the feasibility of conducting a randomized controlled e-cycling trial in adults with T2DM. The findings demonstrated that targeted recruitment through primary care practices was the most effective way of recruiting this population due to their large reach. A total of 95.0% of consented individuals were randomized and a retention rate of 87.5% was recorded. Attendance at data collection was 87.5% and 62.5% of all specified intervention sessions were attended. Participants' perceived the training as helpful, providing them with increased confidence to ride the e-bike and ride on the road. Women, who had less cycling experience, required more support than men. Instructors were comfortable delivering the e-bike skills training but would have liked more training on how to effectively deliver the behavioural counselling and how to appropriately adapt the intervention. In addition, more peer support was required. E-cycling was perceived as enjoyable by participants and as having a positive impact on health. The enjoyment associated with e-cycling was reported to positively impact participants motivation to e-cycle. Outcome measures collected at baseline and post intervention showed that the intervention demonstrated promise to positively impact a range of clinically important physical and mental health outcomes and increase PA. This is the first pilot RCT of an e-cycling intervention to be conducted and report on the feasibility and acceptability of such an intervention in inactive adults with T2DM. The findings suggest that conducting a definitive trial is appropriate given that four of the five progression criteria were met. While the current study found that only 5% of individuals who received study information were interested in participating (compared to the 20% proposed in the progression criteria), it is hard to determine the exact number of individuals who were reached and were eligible based on the loose database screening conducted. Prior to a definitive trial there are a series of amendments to the study design, intervention and measurement tools that must be undertaken. Suggested refinements resulting from the trial are reported in Appendix 9.1.

9.3 Implications for practice

The findings of this thesis suggest that e-cycling is an appropriate approach to promoting PA at an individual level, particularly among adults with compromised health for whom engagement in conventional cycling may not be appropriate. The findings of this thesis have several implications for clinical practice and community-based PA promotion.

9.3.1 Sharing knowledge of the health benefits of e-cycling

E-cycling has several benefits (e.g., reduced physical exertion and/or load on the joints) in comparison to other AT modes, including walking, running, and cycling, that make it more appealing and achievable for older adults and clinical populations who may experience a range of health issues which negatively impact AT and PA. These benefits could increase the diversity of individuals that engage in cycling. This is important given that older adults are currently underrepresented in the cycling population and AT space (354) and the same is most likely true for clinical populations. An on-going evaluation of an e-bike initiative for individuals recovering from bowel cancer in Scotland reported that individuals are engaging in between 1.2 to 2.6 hours per week based on GPS data (https://nhsforthvalley.com/biking-for-bowel-surgery/).

Despite reduced load and physical exertion compared with conventional cycling, physiological evidence reported here suggests that in the absence of setting speed and distance goals both inactive healthy adults and clinical populations self-select to ride at a moderate intensity and engagement is associated with positive physical and mental health benefits. While engaging in any intensity of PA has been found to be beneficial to health, recent research suggests that for those who are inactive engaging in at least moderate intensity exercise is associated with lower mortality, over and above its contribution to the total volume of activity (613). Therefore, the intensity of PA associated with e-cycling provides a strong argument for expanding the promotion of e-cycling particularly among physically inactive individuals.

Furthermore, the systematic review shows that e-cyclists ride longer distances, for longer duration and more frequently than conventional cyclists, leading to similar weekly energy expenditure. This knowledge is important to communicate with PA promoters and prescribers to ensure that the impact of e-cycling on overall PA is clearly understood and may help remove the stigma of e-cycling as ‘cheating’ in comparison to conventional cycling due to the electrical assistance provided.

9.3.2 Focus on positive affective responses

In the current pilot RCT participants were motivated to initiate e-cycling to improve their health, in particular diabetes management. However, continued engagement in e-cycling was related to overall enjoyment, with high levels of enjoyment associated with greater e-cycling habit formation and distances ridden. Participants commented that this enjoyment came from the reduced physical exertion which enabled them to cycle further, faster and on hillier terrain than on a conventional bicycle. Therefore, e-cycling was perceived as achievable, in comparison to conventional cycling, enabling participants to ride new routes and explore nature. Similar results were reported in a recent qualitative study which explored the experiences of e-cycling among 21 inactive adults (614). In this study, participants who were loaned an e-bike for up to eight months were originally motivated to e-bike as a means of increasing PA and improving their health. However, sustained e-cycling was associated with the enjoyment felt during e-cycling. The authors concluded that there had been a shift from external motivation for using the e-bike (i.e., to improve health) to more autonomous, internal motivation for e-cycling (i.e., enjoyment). These findings are in line with a systematic review which reported that while health is an important contributor to the initiation of PA it was not sufficient for maintenance (615). Rather PA enjoyment and habit formation are highly associated with maintenance.

As such, while e-cycling promotion campaigns should highlight long-term health benefits of e-cycling, to help initiate e-cycling engagement, these messages should be coupled with information on the immediate affective responses associated with riding including enjoyment, well-being, and vitality. In addition, the immediate benefits of riding further and faster and experiencing nature should be emphasised. This maybe of greater importance among inactive individuals who anticipate less positive affect from PA than active individuals (616) and moves away from the traditional PA promotion messages which have focused on disease prevention and treatment (617). Focusing on the more immediate impact of e-cycling will help to increase long term engagement in e-cycling.

9.3.3 Tailoring promotional material to the target audience

In addition to focusing on immediate benefits the promotion of e-bikes should be tailored to the outcomes of importance to the target population. This research showed that motivation for e-cycling varies based on age and gender. Specifically, older adults, including those in the current pilot study, are motivated to e-bike as a means of improving health and to enable continued riding, while younger adults e-bike for environmental reasons and to carry heavier loads. Regarding gender, women are more likely to report wanting to ride with friends and family while men are happy to e-cycle alone.

As such, future e-cycling promotion campaigns focused on younger adults could emphasize the environmental impact of switching one car journey per week to e-bike and the long-term reductions in CO2 emissions based on this behaviour change as well as the ability to carry children and shopping. While for older adults campaigns should focus on the immediate health benefits of e-cycling including boosting mood and vitality as well as the longer-term benefits including increased fitness. Campaigns aimed at increasing female e-cycling should focus on the ability to cycle with friends and family.

Targeted messages that are positively framed and emphasise the short term social and mental health benefits, as well as the long term benefits of PA, have been highlighted as important for promoting PA engagement (618) and should be used to promote e-cycling.

9.3.4 Tackling the e-bike stigma

To help encourage e-bike use it is important to tackle the stigma associated with e-cycling. Research suggests that younger adults view e-cycling as an activity for overweight and unfit individuals due to the electrical assistance provided (316, 331, 334, 619). However, these negative attitudes towards e-bikes often dissipate following engagement in e-cycling (327, 330, 334, 340). Specifically, a 2012 European e-bike loan project revealed that attitudes towards e-bikes were substantially more positive following a single test ride (620). As such, e-bike trial days should be conducted, and individuals encouraged to try out e-cycling. These should be conducted in local communities and run by community organisations to encourage attendance. Trialling an e-bike is positively associated with e-bike purchase (599), while e-bike purchasing is positively associated with e-bike use (599, 621). As such, e-bike trials could have a positive impact on long-term e-cycling behaviour. Trial days should be targeted based on the population of interest, for example trial days for younger adults should include the option to test out an e-cargo bike. This will likely require community organisations to collaborate with e-bike manufacturers and retailers to provide a variety of e-bikes.

Concerns around e-cycling stigma may vary based on the overall cultural norm of cycling among the general population. However, the current research suggests that this stigma is apparent in both countries with high (e.g., Sweden) and low (e.g., the USA and the UK) levels of conventional cycling rates (316, 320, 331, 335). A recent review of 11

European countries found no difference in e-cycling stigma based on the percentage of mode share to which cycling contributed (619). As such, publicity campaigns should focus on presenting e-cycling as a normal part of the mobility landscape regardless of the cycling culture to increase awareness of e-bikes. This social barrier to e-cycling engagement may reduce as more diverse electric bicycles reach the market (e.g., more aesthetically pleasing e-bikes and e-cargo bikes) and a greater number of people are seen riding them.

This shift appears to have already begun. Since 2017 e-bikes have received considerable media attention in the USA, the UK and Australia and findings from a European survey revealed that there was an 11% increase in the percentage of individuals likely to purchase an e-bike from 2019 to 2020 (619). In March 2020 leading cycling brands, retailers and organisations launched a joint campaign to show the UK public that #BikeIsBest in an attempt to normalise cycling, including e-cycling, and encourage new cyclists to engage. Furthermore Halfords, one of the UKs largest e-bikes retailers, reported sales of e-bikes increasing by 220% in 2017 and 96% in 2019.

9.3.5 Provision of e-cycling training

The current pilot RCT demonstrated the importance of e-bike training to provide participants with exposure to e-cycling and the provision of knowledge, skills, and confidence to ride. The impact of e-bike training on e-cycling has not been examined previously. In the context of conventional cycling adult Bikeability courses delivered in the community in London, UK have been found to lead to increases in riding confidence and cycling behaviour (449, 600, 622). Furthermore, bicycle training provided to overweight low-income adults (84% female) in Wisconsin, USA has been reported to lead to increases in self-reported PA and overcoming barriers to engagement including knowledge of where to ride and confidence to ride in traffic (623). A reduction in these barriers to engagement were maintained at 20-weeks post training. As such, community-based organisations should deliver free, or heavily subsidised, e-bike training to increase individual's capability to ride an e-bike safely and confidently. This maybe particularly important among women who express a desire for more practical support for riding and who were found to have less cycling experience and clinical populations who may require adaptations to cycling style to increase cycling comfort.

9.3.6 Increase e-bike access

One barrier that cannot be addressed through promotion and training is the cost of e-bikes, a commonly reported barrier to e-cycling in the current research and cross-sectional surveys

(619, 624). Given that purchasing an e-bike is significantly associated with e-bike use (599, 621), finding ways to increase access to e-bikes that are financially viable for all individuals is imperative.

E-bike share schemes have increased in recent years (345) and may serve to increase e-cycling participation through increased awareness and consideration of e-bikes as a means of public transport while removing barriers of cost and accessibility (625). E-bikes have been reported to provide a means of transport for those with low incomes and provide a flexible means of transport for shift workers whose work patterns may not align with public transport (626).

Furthermore, e-bike share schemes may act as a gateway for individuals to discover e-cycling and may provide incentive for individuals to seek out e-bike purchase options, with 29% of all shared e-bike users reporting that they would like to buy an e-bike (626). As such adding e-bikes to existing bicycle share systems should be considered where possible. E-bike share schemes will also help increase the profile of e-cycling in a city and will help to normalise cycling as a means of transport.

For those wanting to trial e-bikes for a longer period, e-bike loans should be made available. While such schemes are currently available, they come with high price tags. For example, in North Somerset and South Gloucester, UK, e-bike loans are available free of charge for a month. However, the applicant must pay a £250 deposit for the e-bike loan. Finding ways to loan e-bikes to individuals who do not have the financial resources to put down such a deposit is of the upmost importance. As an alternative, employers could invest in a fleet of e-bikes for employees that could be loaned out to encourage e-cycling engagement.

9.3.7 Increase facilities

The current research found that there are several micro environmental changes that should be made to increase e-cycling. Most urgently is the need to address concerns over e-bike theft which has been found to negatively impact riding. Environmental restructuring from workplaces and local communities will likely help promote e-cycling and has been reported to increase conventional cycling in potential cyclists (157, 604). Workplaces should offer safe bicycle storage and showering facilities to employees. Going one step further restrictive changes such as the reduction in workplace parking has been associated with increased walking and cycling (606) and may similarly impact e-cycling. Simultaneously, local authorities should increase bicycle storage that is suitable for parking e-bikes safely in city centres and at transport hubs. Of equal importance is the need to address a lack of home bicycle storage and can discourage engagement. This is of particular importance for e-bikes which are heavier than conventional bicycles. Councils should look to provide on-street secured parking in residential areas to allow those without e-bike storage capacity within their homes to easily access and use their e-bike.

Several of the recommendations highlighted above align with commonly reported actions used within the context of conventional cycling to promote increased behaviour at the individual and organisational levels. (163). These recommendations should be used to guide future e-cycling initiatives.

9.4 Implications for policy

In the political domain e-cycling has primarily been viewed by governments as a means of tackling transport issues such as congestion and climate change concerns. However, this research shows that e-cycling has the potential to address health related issues such as physical inactivity. Therefore e-cycling should be encouraged from a public health perspective as well as a transport perspective and publicly endorsed by the government. The current research has several policy recommendations.

9.4.1 Reducing costs

To address the barrier of cost governments should seek to provide ways of subsidising the cost of e-bikes. Recognising the need for help to reduce the upfront costs of purchasing an e-bike, the UK government funded Cycle to Work scheme enables employed individuals, whose organisations participate in the scheme, to save up to 40% of the cost on a new bike. In 2019 the value of a bike that could be purchased on the scheme increased from £1000 to £2500 with the aim of enabling more individuals to purchase an e-bike. While positive, this scheme is only open to employees of participating organisations and those wishing to cycle to work. A universal subsidy programme including self-employed, retired, and unemployed individuals who currently have no means of accessing e-bikes is required. This issue has been recognised by the government and in November 2020 a national e-bike support programme was promised in the Governments 'Gear change' document (627). The programme is expected to include loans and subsidies to increase the diversity of individuals cycling. Pilot schemes are reportedly being conducted with the findings anticipated in early Spring 2021. However, the results are yet to be seen and no commitment to the scheme has been approved. Based on this research and the vast uptake of e-bike subsidy schemes in Europe (619), committing to policies to provide financial incentives for e-bike purchasing, particularly to individuals with health conditions or disabilities who struggle to ride a conventional bicycle is recommended. In a review of e-bike grants and incentives across Europe, Newson and Sloman (628) argue that an e-bike grant of £250 would be effective at increasing e-bike purchasing. In the Channel Islands e-bike subsidy schemes have been found to be highly successful with 80% of purchasers reporting being more active and healthier than before having the e-bike (628).

Governments should also explore the potential for offering interest free loans to individuals wishing to buy an e-bike and spread the financial cost over time. Such a scheme was launched by the Dutch government in January 2020 in which individuals could spread the cost of an e-bike over several months (https://www.rijksoverheid.nl/onderwerpen/fiets/fiets-van-de-zaak). While in Scotland, residents can obtain an interest free loan to support the purchase of e-bikes, e-cargo bikes or adaptive e-bikes with a four-year repayment plan (https://energysavingtrust.org.uk/grants-and-loans/ebike-loan/).

9.4.2 Free bicycle training

As reported in section 9.3.5. the provision of e-bike training is essential to foster independent confident cycling and to increase cycling numbers. Governments are encouraged to engage with community organisations to provide adult e-bike training to all individuals wishing to learn how to e-cycle. In a drive to increase AT, in April 2021 the government announced £18 million for cycle training for children and adults to ensure that more people feel comfortable cycling. Bikeability, the training course funding by Department for Transport, now includes an e-bikeability level one with specific e-cycling skills incorporated into the training. However, individuals are required to have an e-bike prior to this course which may not be feasible for several individuals. Governments and community organisations should work together to offer e-bike trials, coupled with training to provide e-bike exposure and the skills to ride should they wish to engage in the e-cycling in the future.

9.4.3 Addressing environmental barriers

As highlighted above there are several avenues through which policy initiatives can help increase individual's capability and opportunity to ride a e-bike. However, the current research highlights several concerns regarding a lack of cycle infrastructure and facilities that policy makers, city planners and corporations are urged to address collaboratively.

Specifically, governments and employers must collaborate to construct suitable end-of trip facilities including lockers, underground garages, and secure parking at home and in city centres to encourage riding. Storage and safety issues maybe particularly pertinent for e-bikes which are heavy and therefore hard for users to manoeuvre into small spaces and due to their price tag are often the target of thieves.

Overall effective approaches to increase e-cycling participation require integrated approaches targeting individuals and their social and physical environments as shown by the multiple influences on e-cycling engagement reported in the current pilot RCT and scoping review and supported by other research in the context of conventional cycling (149).

9.4.4 Setting national e-cycling targets and monitoring e-bike use

In the UK, the latest walking and cycling strategy released by the Department for Transport sets the target of doubling cycling by 2025. However, no specific targets for increasing e-bike use have been set (629). Similarly, Europe states a goal of pushing and promoting e-mobility, including e-bike use, however they provide no estimates as to by how much or when (630). This means there is no clear guidance or incentives to focus e-bike initiatives. This current research suggests that e-bikes have a role to play in mobility behaviour and as such there needs to be clarity from the UK and European governments on the role of e-bikes in transport policy through setting of e-bike use targets, distinct from cycling.

Data on the prevalence of e-cycling and its impact on mobility patterns is required to set such targets and provide insight into the effectiveness of e-cycling promotion campaigns and purchasing. However, conventional bicycles and e-bikes are currently not distinguished in the UK NTS and there are currently no plans to distinguish between the two. Alternatively, e-cycling could be monitored using health surveys to assess e-bike use and the impact on health, wellbeing, and PA.

Without widespread collection of data pertaining to e-bike use it is hard to recognise the potential of e-cycling to impact transport and health. This information is important at a policy level to provide evidence to guide investment. The Netherlands have been collecting data on e-bike use since 2013 and this data is being used to map changes in e-bike use over time and across different user groups. The data reveals large increases in e-bike use for commuting and education purposes (631). The UK is encouraged to follow suit and begin the process of monitoring e-bike use.

Furthermore, modelling the health and environmental implications of switching from different modes of travel to e-cycling is difficult without prevalence data. Scenario modelling in the UK estimated that if 25% of the English population became regular cyclists and all new cyclists had access to e-bikes, reductions in years of life lost due to premature mortality would be 93,000 and reductions in CO_2 emissions due to reduced car miles would be approximately 2.7% (134). However, this data was based on the Dutch NTS, a nation with high rates of cycling. This data is also needed for health impact assessments. Given the lack of e-cycling prevalence data a health impact assessment exploring the impact of changes in e-mobility, including e-cycling, in Barcelona is using data from the cities cycling share scheme 'Bicing', which includes e-bikes, to estimate the impact of e-cycling on health. The lack of inclusion of data from private e-bike owners may therefore underestimate the health impact of e-cycling. Again, this highlights the importance of monitoring e-cycling behaviour, potentially through the NTS or health survey.

9.5 The COVID-19 pandemic, PA and AT

In March 2020, and the final month of study three, COVID-19 was declared a global pandemic. Over 100 countries enforced social distancing measures to reduce transmission which became known as 'lockdown'. The severity of the lockdown varied between countries and regions within countries, impacting work, education, and recreation to varying degrees. In addition, travel decreased substantially due to the stay-at-home advisory. While individuals were encouraged to leave their home once per day for exercise, emerging data from several countries suggests that these lockdown measures had a negative impact on overall PA (632-635). Furthermore, following the relaxation of these measures PA has failed to rise to pre-COVID19 levels (634). While worrying, much of the data reported used unvalidated self-report measures or smartphone algorithms to measure PA. As such the extent to which COVID-19 social distancing measures impacting PA is hard to determine.

Despite apparent decrease in PA there was a substantial increase in cycling, particularly for leisure, during the lockdown period (636). This increase was seen across genders, age, and socio-economic groups. Regarding AT, in a survey of 2000 English adults, 43% of key workers reported cycling to work during the pandemic stating that it felt like a safer option than public transport (637). This boost in cycling was reflected in sales with Halford, the UKs largest bike retailer, reporting that bike sales in 2020 were up by 193% from 2019. Many of the individuals who began cycling report intentions to continue cycling post lockdown (637, 638). Regarding e-cycling, sale data from Halfords UK showed that in 2020 24% of all bicycles purchased during the pandemic were electric (637). It appears that the pandemic has served to increase awareness of e-cycling as a viable activity and mode of transport.

9.5.1 Impact of COVID-19 on AT policy

The increases in walking and cycling seen during the pandemic led to a window of opportunity in which to promote walking and cycling as means of transport. As such, in May 2020, the UK government announced a £2 billion investment package to boost cycling and walking. An initial £250 million emergency AT fund was made available and led to several 'pop-up' bike lanes in cities across the country. Following this funding announcement in July 2020 the UK government published *'Gear change. A bold vision for cycling and walking'* (627). The strategy laid out the ambitious target for half of all journeys in towns and cities to be either cycled or walked by 2030. To achieve this, a range of initiatives were proposed including piloting the promotion of cycling through GP prescriptions, offering cycle training to children and adults, improving the National Cycle Network, introducing segregated cycle ways, strengthening the highway code to protect pedestrians and cyclists, improving bicycle parking in public places and bicycle storage at peoples' homes, offering £50 bike repair vouchers and extending the number of low traffic neighbourhoods. As part of the strategy the government committed to establishing a national e-bike support programme as previously discussed and the results are eagerly awaited. This programme was proposed to involve e-bike loans, subsidies, and other financial incentives to encourage e-bike use with the purpose of engaging older adults and individuals with disabilities to engage in cycling. In the summer of 2020 Scotland, who along with Wales have legislative competence for AT, extended funds to their already successful e-bike scheme by offering just under £1 million for a variety of initiatives including; to enable local authorities and community groups to apply for money to purchases e-bikes for community loan or trial schemes, for the development of an e-bike grant fund to offer businesses a chance to trial an e-cargo bike for a 12-month period, and for a scheme to encourage e-bike projects to support Scotland's key and essential workers (639). As such, while there has been increased national support for e-bike engagement, how this translates to wheels on the road is yet to be seen.

It appears that the COVID-19 pandemic has provided a unique opportunity to create societal shifts in AT and encouraged long term changes in infrastructure to promote engagement. However, how these government initiatives will be implemented and the impact they will have on AT in the long term is unclear. Collaboration and shared decision making across sectors is needed to understand how best to implement these initiatives in the local context (640).

9.6 Strengths and limitations

The work included in this thesis has several strengths but there are also limitations that must be acknowledged. Each chapter provides a discussion of the strengths and limitations relative to each study as such, this section summarises strengths and limitations that exist across studies of this thesis.

Overall, the major strength of this research is its novel contribution to the e-cycling literature. The research questions addressed in the studies of this thesis have not been previously considered, allowing new insights into how e-cycling can impact PA.

9.6.1 Study design

One of the major strengths of this research was the use of systematic process to review the current literature. No previous reviews of the e-cycling literature have adopted these rigorous, and transparent, methods. As such, these reviews contribute to the e-cycling literature and are being frequently cited by other authors. These reviews were the starting point for determining the suitability of future research and to indicate what to include in future e-cycling interventions. As such, the research questions and study design for study three were informed by studies one and two, leading to a coherent set of studies and conclusions which build upon one another.

The development of the e-cycling intervention delivered in study three was thorough and transparent and involved engagement with members of the clinical population. This approach to intervention development is considered best practice in the fields of health and complex intervention research (194, 198, 209). This is the first study to comprehensively report the specific content of an e-cycling intervention, which can be used by researchers wishing to develop and conduct similar e-cycling interventions.

This is the first pilot RCT to be conducted in the field of e-cycling, with appropriate outcomes reported. The use of a pilot trial provided insight into the elements of the study procedures and design that were suitable to take forward while also highlighting which components required amendment. The incorporation of qualitative methods provided insight into the findings and allowed for triangulation of the findings through comparisons with study two. The incorporation of qualitative methods as part of pilot and feasibility testing is encouraged by the MRC guidance (193, 198).

However, there are some limitations of the study designs chosen. Firstly, due to the timeline of the thesis, a follow-up period of three months was selected after e-bike training in Study three. However, PA behaviour in the general population, and specifically among those with T2DM, tends to decline over time following a PA intervention (427, 437, 438) and this research provided no insight into the long-term impact of e-cycling on health and behaviour. To date, no longitudinal research has examined the impact of e-cycling provision on behaviour over a 12-month period.

Regarding the reviews, the quality of the data included was predominantly weak for study one and unclear for study two. As such, the conclusions drawn, although aligning with study three may not be valid. Given that study three was a pilot RCT, whilst there was demonstration of promise across a variety of clinical, physiological, and behavioural outcomes any definitive conclusions about the impact of the e-cycling intervention on these outcomes cannot be made.

9.6.2 Participants

In the studies reviewed or conducted in this thesis most participants were between 45 to 65 years of age. While this can help comparison across the studies it does mean that the findings may not be generalisable to younger adults (i.e., 24 to 35 years of age). Recent research suggests that adults between 24 to 35 years use e-bikes for different purposes than older adults (619) and therefore the determinants of use maybe different.

There is limited research examining the impact of gender on e-cycling behaviour and what has been done suggests that the results are mixed. We know that in high-cycling countries there is limited difference in the proportion of cyclists who are male and female. However, in low-cycling countries men hold more of the cycling share than women (609). Study three recruited similar numbers of men and women and the qualitative findings suggested that there were differences in barriers and facilitators to e-bike use based on gender. However, due to the small sample size the differential impact of e-bike access on behaviour and health could not be further examined.

In study three an ethnically diverse sample, of varying socioeconomic backgrounds, was recruited. This is a strength of this study given that these individuals are often under-represented in PA interventions (641-643) and generally display low levels of PA (644-646). Individuals from low socio-economic backgrounds maybe less likely to access e-bikes than those with more disposable income and it is important to understand factors that impact their e-bike use. Furthermore, there maybe different determinants of e-cycling among ethnic minorities that require exploring. The ethnicity and socio-economic status of those participants included in the reviews is unclear, demonstrating that this in an area requiring more research. It is also important to note that studies included in the review and participants in the pilot RCT were from developed countries. As such, the impact of e-cycling on transport behaviour and health in less developed countries is unknown.

9.6.3 Measures

Studies one and two identified gaps in the literature due to the use of self-reported measures of PA and transport behaviour. Study three addressed these limitations by using objective measures to assess a series of clinical, physiological, and behavioural outcomes.

The use of objective GPS and accelerometery measures, combined with subjective travel diaries enabled the identification of trip distance and duration, purpose and mode and the PA associated with different transport modes. This method provided a rich dataset from which to examine travel behaviour and the associated PA, and this method is encouraged in future research. Furthermore, exploring the use of two different accelerometers gave valuable insight into the appropriateness of these devices for use in future trials and will serve to reduce research 'waste'. This information is important as many trials fail to measure outcomes of interest due to lack of participant adherence or inaccuracy in the measures selected (484).

Due to the heterogeneity in study designs and outcome measures reported in the two reviews comparisons across studies was difficult. It was not possible to estimate the associations between e-cycling and health or behavioural outcomes and as such narrative syntheses were conducted. Quantifying the relationship between e-cycling and health and behaviour is important to policy makers but requires more research with homogenous outcomes.

9.6.4 Data analysis

To improve the validity of resulting conclusions, methods were used to minimise the potential for bias where possible. Within the reviews, two reviewers completed all stages of the review process and regular meetings were held with the supervisory team to discuss study inclusion.

However, it is possible that relevant research was missed despite the broad search terms used. In addition, the decision to exclude e-bike studies conducted in China, due to the predominant form of e-bikes being throttle powered (166), may have meant China-based studies that utilised pedal assisted e-bikes may have been excluded.

As part of the qualitative analysis several steps were taken to increase trustworthiness and reproducibility of the findings. These included having two coders and using member checking with both participants and instructors. Use of the highly recognised framework method and transparent reporting of results enables readers to understand the process through which the study findings were developed and make their own assessment about the trustworthiness of the findings. Acknowledgment and reporting of researcher reflexivity was also conducted. However, qualitative research always involves a degree of subjectivity, and this limitation is acknowledged (689).

It is important to remember that the current pilot RCT was not powered to determine intervention effectiveness and as such the potential of promise between the intervention and outcomes does not, and cannot, imply causal association. Furthermore, the effect estimates, calculated as the difference in change scores between conditions and associated confidence intervals, cannot be taken as indicative of the likely effects of a definitive RCT. However, the findings of this pilot RCT are essential to inform whether completion of a definitive trial is warranted for evaluation of causal effects.

9.7 Future research

This doctoral research may direct future research in several ways. First and foremost, the evidence presented here suggests that e-cycling has the potential to increase PA and positively impact health. As such further investigation of e-cycling as a behaviour change strategy is warranted. In line with the MRC guidance (193), which has framed the research in this thesis, the next logical step is to evaluate the effectiveness of the intervention in an adequately powered RCT following intervention and study procedure refinements outlined in Appendix 9.1. A definitive trial should incorporate a longer follow-up period (i.e., >12-months) to explore the maintenance of e-cycling over time. An appropriate primary outcome should be determined based on the outcomes that demonstrate sensitivity to change reported here and a sample size calculation should be conducted. In addition, objective measures including GPS and accelerometery should be used wherever possible.

The qualitative data collected as part of the process evaluation should be used to identify key determinants of e-cycling behaviour in this population and appropriate quantitative measures selected to examine the potential mediating processes through which the intervention impacts behaviour. In addition, a full economic evaluation should be conducted to determine the cost associated with such a trial and e-bike training.

The potential of e-cycling as a PA behaviour change strategy should be explored in different clinical populations for whom PA engagement is low (164). While findings from the current pilot RCT can be used to inform future trials, the use of pilot trials is encouraged to explore uncertainties that are specific to that population. In line with this recommendation, pilot RCT work is currently being developed in Bristol to examine the impact of e-cycling on the physical and mental health of men and women recovering from prostate and breast cancer, respectively.

In addition to building the body of evidence surrounding the impact of e-cycling on health, it is important to determine the pathways through which clinical populations can access e-bikes, potentially as part of a treatment care package. This should involve engaging with key stakeholders including clinical commissioning groups, GPs, e-bike manufacturers and retailers and city councils to determine the avenues through which e-bikes can be made more accessible to these populations.

The impact of e-bike trial days should be explored and evaluated to examine the degree to which trying out an e-bike impacts attitudes towards e-bikes and the impact on future purchasing and behaviour.

Finally, to understand the full impact of e-cycling on long-term health, health impact assessments are required. These rely on the use of estimates of the impact of a behaviour, such as cycling and walking on health outcomes (e.g., mortality). As such, more information about who uses e-bikes and the impact on health outcomes are needed ideally through surveillance measures and the incorporation of e-bike specific questions into large scale travel surveys and/or health surveys with the use of objective measures of behaviour where possible. This data would also give insight into how e-bike use is changing over time and subsequent changes in other transport modes.

9.8 Conclusions

The findings of this thesis support the use of e-cycling as a means of increasing PA behaviour, with promise to positively impact physical and mental health in inactive and clinical populations. The knowledge gained from this research supports further investigation into the role of e-bikes in helping address the physical inactivity pandemic. Future RCTs are needed to examine the causal relationship between e-cycling and health. Furthermore, e-cycling behaviour needs to be monitored on a large scale to examine the impact of e-bike use on mobility patterns to understand their role in transportation. To ensure equitable access to e-bikes, universal grant and loan schemes should be considered and their impact on e-bike use monitored. In addition, governments and communities need to work together to provide e-bike training opportunities, as well as safe spaces for cycling and storing e-bikes. As the e-bike market continues to grow it is hoped that e-bike research continues in the same manner and that the evidence of the impact of e-bikes on health and behaviour continues to develop. I plan to be part of this e-cycling research and promotion movement.

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Appendix 3.1 PROSPERO systematic review registration

The impact of electric bikes on health through increased physical activity: A systematic review

Jessica Bourne, Sarah Sauchelli Toran, Rachel Perry, Angie Page, Ashley Cooper, Clare England, Sam Leary

Citation

Jessica Bourne, Sarah Sauchelli Toran, Rachel Perry, Angie Page, Ashley Cooper, Clare England, Sam Leary. The impact of electric bikes on health through increased physical activity: A systematic review. PROSPERO 2018 CRD42018086544 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42018086544

Review question

The aim of this systematic review is to synthesise the current literature pertaining to the use of electric bikes (e-bikes) and their impact on health through increased physical activity. The search aims to include literature that is relevant to answer the following research questions:

1. Does the use of an e-bike lead to sufficient physical activity (duration, frequency, and intensity) to promote health benefits?

2.Does use of an e-bike lead to changes in cardiorespiratory, metabolic or muscular outcomes?

3.How do physiological responses on an e-bike compare to other modes of active transportation (e.g. bicycling and/or walking)?

Searches

The following electronic databases will be searched from their inception: ISI Web of Science, PsycINFO, EMBASE, MEDLINE, CINAHL Complete, SPORTDiscus, and Scopus. The search strategy will include terms relating to electric bikes. The search strategy will be similar for each database but revised appropriately for the specific database to take into account differences in syntax rules. No restrictions regarding the language of the article will be imposed. Non-English papers will be translated where possible. Reference lists of all full-text articles will be hand searched for additional studies. In addition, the first 20 pages of Google Scholar will be searched. Experts in the area will be contacted to enquire about the existence of unpublished work.

Types of study to be included

Included: Empirical intervention (RCTs and non-randomized) and observational (longitudinal, cohort) studies

Excluded: Qualitative research, discussion articles, commentaries or opinion pieces

Condition or domain being studied

Physical activity is associated with health and fitness benefits. However, most adults do not do enough activity to meet the recommended guidelines of 150 minutes of moderate to vigorous physical activity per week. The promotion of active transportation, through cycling and walking, has been highlighted as an effective means through which to increase physical activity behaviour. However, physical, topographical and practical barriers are often reported as factors that impede active transportation. Electrically assisted bicycles (e-bikes) may overcome some of these barriers, offering an alternative mode of active transportation that could have a positive impact on health. However, there is currently a lack of review work synthesising studies that have examined the impact of e-biking on increasing physical activity and subsequent health related outcomes.

Participants/population

Inclusion: Adults over 18 years of age - no upper age limit

Exclusion: Children and adolescents (under 18 years of age)

Intervention(s), exposure(s)

The review will consider any studies that have examined the impact of e-biking on objectively measured physical activity and associated health related outcomes. The e-bike used by the individual must have pedals and be operated in part by the individual (i.e., energy must be expended when cycling on the e-bike). Studies that examine use of e-bikes that are operated solely by a motor will not be included. E-biking can be for any purpose including, but not limited to, commuting, leisure, shopping etc.

Comparator(s)/control

There is no specific inclusion or exclusion criteria for the intervention studies comparator group

Main outcome(s)

Studies will be included if they report on objectively measured physical activity including exercise intensity, duration and/or frequency (e.g., METs, energy expenditure, time spent in MVPA). Health related outcomes will be reported if applicable including a) Cardiorespiratory outcomes (e.g., heart rate, maximum oxygen uptake, blood pressure, maximal aerobic power); c) Muscular outcomes (e.g., muscular endurance, isometric strength); d) Metabolic outcomes (e.g., glucose tolerance, insulin sensitivity); or e) Quality of life measures.

Additional outcome(s)

Comparison of physiological responses to other modes of activity (e.g., bicycling or walking)

Data extraction (selection and coding)

Selection process

Once all literature searches have been conducted the titles and abstracts of search results will be screened by two reviewers independently. Studies that have insufficient information to be excluded or are deemed eligible for inclusion will be retrieved for full text analysis. Full texts will be screened by two reviewers independently to determine eligibility. The reference list of included studies will be reviewed by both reviewers and full-text screening of potential studies for inclusion will be conducted. Agreement statistics between reviewers will be calculated and any discrepancies will be resolved through discussion. Reasons for exclusion will be recorded.

Data extraction

Study data will be extracted using extraction forms designed specifically for this review in Excel. Data will be extracted by two independent reviewers, who will then compare extraction forms for accuracy and completeness. Any discrepancies in data extraction will be resolved through discussion, and re-evaluation of the studies. Where discrepancies still remain, a third reviewer will contribute to the discussions, and re-extract if necessary. For all studies data will be extracted on: study design, sample, participant characteristics, main outcomes (i.e., physical activity related or physiological/psychological responses to electric biking), analysis methods, study limitations. We will contact the authors of articles in the event that the required information cannot be extracted from the studies and is essential for interpretation of their results.

Risk of bias (quality) assessment

Two independent reviewers will assess the quality of included studies; discrepancies will be resolved through discussion or their party adjudication. The quality of studies will be evaluated using the Quality Assessment Tool for Quantitative Studies.

Strategy for data synthesis

A narrative synthesis of the study findings will be provided and formatted around the reported outcomes. Study quality will also be reported narratively and visually in tables.

Analysis of subgroups or subsets

None planned

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Type and method of review

Systematic review

Anticipated or actual start date

04 December 2017

Anticipated completion date

24 September 2018

Funding sources/sponsors

The research is funded by the National Institute for Health Research (NIHR) Bristol Nutrition Biomedical Research Centre based at University Hospitals Bristol NHS Foundation Trust and the University of Bristol. The views expressed are those of the authors and not necessarily those of the NHS or the NIHR

Conflicts of interest

None known

Language

English

Country

England

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Bicycling; Electricity; Exercise; Humans; Publications; Research; Transportation; Walking

Date of registration in PROSPERO

23 January 2018

Date of first submission

19 January 2018

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

23 January 2018

Bourne et al. International Journal of Behavioral Nutrition and Physical Activity (2018) 15:116
https://doi.org/10.1186/s12966-018-0751-8

International Journal of Behavioral Nutrition and Physical Activity

REVIEW Open Access

Health benefits of electrically-assisted cycling: a systematic review

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Abstract

Background: Electrically assisted bicycles (e-bikes) have been highlighted as a method of active travel that could overcome some of the commonly reported barriers to cycle commuting. The objective of this systematic review was to assess the health benefits associated with e-cycling.

Method: A systematic literature review of studies examining physical activity, cardiorespiratory, metabolic and psychological outcomes associated with e-cycling. Where possible these outcomes were compared to those from conventional cycling and walking. Seven electronic databases, clinical trial registers, grey literature and reference lists were searched up to November 2017. Hand searching occurred until June 2018. Experimental or observational studies examining the impact of e-cycling on physical activity and/or health outcomes of interest were included. E-bikes used must have pedals and require pedalling for electric assistance to be provided.

Results: Seventeen studies (11 acute experiments, 6 longitudinal interventions) were identified involving a total of 300 participants. There was moderate evidence that e-cycling provided physical activity of at least moderate intensity, which was lower than the intensity elicited during conventional cycling, but higher than that during walking. There was also moderate evidence that e-cycling can improve cardiorespiratory fitness in physically inactive individuals. Evidence of the impact of e-cycling on metabolic and psychological health outcomes was inconclusive. Longitudinal evidence was compromised by weak study design and quality.

Conclusion: E-cycling can contribute to meeting physical activity recommendations and increasing physical fitness. As such, e-bikes offer a potential alternative to conventional cycling. Future research should examine the long-term health impacts of e-cycling using rigorous research designs.

Keywords: Electrically-assisted bicycle, E-bike, Physical activity, Health

Background

Given the high rates of global physical inactivity [1] a growing body of research has focused on the potential of active travel to increase physical activity behaviour and potentially lead to population health benefits. Engagement in active travel, specifically commuting, has been shown to be predictive of a lower BMI [2] and reduced risk of diabetes diagnosis [3]. A recent prospective study reported that active commuting, involving cycling, was associated with a lower risk of all-cause mortality and cancer incidence and mortality [4]. In addition, commuting by bicycle or on foot was associated with a lower risk of cardiovascular disease incidence and mortality [4]. The greatest gains in health outcomes from active commuting are reported in the least active individuals [5, 6].

Travel is an essential part of everyday life for most people, and the adoption of active travel represents an efficient way to increase daily physical activity. For example, Falconer and colleagues [2] found that active commuting was associated with an additional 73 weekly minutes of moderate to vigorous physical activity in men and 105 weekly minutes in women with type 2 diabetes, compared to those commuting using motorised transport. With half of all car journeys in the UK being between 1 and 5 miles in length [7], the substitution of many car journeys by walking and/or cycling may be an achievable aim.

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Due to a growing body of evidence, the UK National Institute of Health and Care Excellence (NICE) now endorse active travel, with a particular focus on commuting, as a feasible method to incorporate physical activity into daily life [8]. However, rates of active commuting are low [9].Common barriers to cycle commuting include the physical constraints associated with hilly terrain, poor physical fitness, lack of time and the distance to work [10].

Electrically assisted bicycles (e-bikes) have been highlighted as an alternative method of active travel that could overcome some of the commonly reported barriers to cycle commuting [11]. The term e-bike includes a range of designs including throttle-controlled bikes which do not require the rider to pedal and electrically assisted bikes which provide electrical assistance only when the rider is pedalling, through sensors which detect pedalling speed and force [11]. It is through pedalling that electrically-assisted cycling may serve to increase physical activity. With lower motor power and maximum speeds compared to throttle-controlled e-bikes, electrically-assisted bikes are legally classified as bicycles. [11]. For this review the term e-bike will be used exclusively to refer to electrically-assisted bicycles which require the rider to pedal.

In recent years e-bikes have become commonplace in European countries [11] with projected global sales of 47.6 million by the end of 2018 [12]. E-bikes are increasingly used for both leisure and commuting purposes [13]. The assistance provided has been reported to motivate novice cyclists and increase the likelihood that these individuals will continue to cycle in the future [10]. Given the increasing interest in e-bikes, and their use for active travel, there is a need to understand their potential to promote physical activity of a sufficient intensity to gain clinical benefit (i.e., moderate-to-vigorous intensity [14]) and to examine their impact on broader health outcomes. Such research is required to inform relevant health economic assessments and public health policy. To date, there has been no systematic review on the physical activity intensity and health outcomes associated with e-cycling. As such the aims of this systematic review are to answer the following research questions:

1. What is the intensity of physical activity associated with riding an e-bike?
2. Does use of an e-bike lead to changes in health outcomes including cardiorespiratory, metabolic or psychological outcomes?
3. Do physiological responses to riding an e-bike differ to those generated by other modes of active transportation (i.e. walking and conventional cycling)?

Methods

A review protocol was registered at the PROSPERO database: Registration number CRD42018086544 (http://www.crd.york.ac.uk/prospero). This review was conducted according to the guidelines outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [15].

Search strategy

The following databases were searched from their inception to November 2017: PsychINFO, MEDLINE and Embase (via Ovid), ISI Web of Science, CINAHL complete, SPORTDiscus and Scopus. Search terms were *'pedelec,' 'e-bike,' 'electrically assisted bicycle,' 'electrically assisted cycle,' 'electrically assisted bike,' 'pedal-assist,' 'electric bicycle,' 'electric bike,' 'electric cycle,' 'electric mobility'* (see Additional file 1 for example). Reference lists from all selected articles were hand-searched for relevant studies. OpenGrey and Google Scholar (first 20-pages) were searched using the term *'electrically-assisted bicycle'.* Hand-searching occurred until June 2018.

Inclusion criteria and selection process

Studies were eligible for inclusion if they met the following criteria:

1) participants: adults ≥18 years of age,
2) electrically-assisted bicycle must have pedals and be operated by the individual, with assistance available from an electric motor
3) at least one of the following outcomes; objective measure of physical activity intensity whilst e-cycling (e.g., metabolic equivalents, energy expenditure), cardiorespiratory, metabolic or quality of life (as a measure of psychological health),
4) type of study: experimental or observational studies.

Studies could be published or unpublished in any language. For articles in a language other than English the title and abstract were translated using Google Translate. If full text screening was required, the article was translated by an individual fluent in the language. Studies were excluded if they reported using bicycles that did not require the individual to pedal to provide power, were review articles or commentary pieces, and/or used self-reported measures of physical activity. Title and abstract screening was conducted by two reviewers independently (J.E.B. and S.S.). There was a 93% agreement between reviewers on title and abstract screening. Full texts were screened by the two reviewers independently and any discrepancies were discussed.

Quality assessment and strength of the evidence

The quality of included studies was assessed using the Quality Assessment Tool for Quantitative Studies (EPHPP; [16]). The tool appraises studies on six components; 1) selection bias, 2) study design, 3) control of confounders, 4) blinding, 5) reliability and validity of data collection methods and 6) withdrawals and dropouts. Each component was rated as; strong, moderate or weak for each study based on outcomes of interest.

A global rating for each study was then determined based on the criteria; 1) strong when no weak ratings were reported, 2) moderate when one weak rating was reported, and 3) weak when two or more components were rated as weak. This tool has been used in a previous review examining the impact of cycling on health [6]. The blinding component was not included in the overall study rating as participants are unable to be blinded to condition allocation following randomisation in physical activity interventions. The overall strength of the evidence was assessed based on previously specified best evidence synthesis criteria [17] (Additional file 2).

Data extraction and synthesis

Members of the review team (J.E.B and either S.S. or A.R.C) independently extracted data for each study. Quality assessment was confirmed by a fourth reviewer (R.P.). Data were extracted using an adapted version of a Cochrane Data Extraction Form, which was piloted prior to use. Discrepancies regarding data extraction were resolved through discussion between reviewers. Data extracted included study design, characteristics of participants, outcomes measured, and results. Due to the heterogeneity of study design and outcomes reported, a meta-analysis was not deemed appropriate. Data were synthesized and presented narratively. The effect of the intervention on physical activity and health outcomes for each study was summarized based on reported statistical significance and effect size, both within group (pre-post) and between group where possible, or by examining means or medians when no hypothesis testing was conducted.

Results

A total of 4399 articles were identified through initial searches (Fig. 1). After removing duplicates 2894 titles and abstracts were screened, resulting in 119 studies which underwent full text screening for inclusion. Sixteen articles met the criteria for inclusion plus one included after author contact. Eleven studies assessed the acute response to e-cycling (i.e., one bout of e-cycling), and six examined the longitudinal effect of e-cycling (i.e., more than one bout of e-cycling, including pre-post measurements). Reasons for exclusion included no measure of specified outcomes, study not related to e-bikes, studies focused on the engineering of e-bikes, qualitative studies or not presenting original research. Three studies were identified through clinicaltrials.gov but were excluded for the following reasons: 1) data not published, 2) currently recruiting, 3) authors were not reachable.

Study characteristics

Acute studies

Eleven studies examined the acute physiological impact of e-cycling using cross over designs, five of which were randomized (Table 1). Nine studies were conducted in Europe and two in the USA. Sample sizes ranged from 3 to 22 with a total of 147 participants. Participants were aged between 20 and 70. Three studies recruited physically inactive individuals [18–20] and one study included individuals with coronary artery disease [21]. Six studies compared e-cycling to conventional cycling [18, 21–25] and five compared e-cycling with assist to riding an e-bike without assistance [19, 20, 26–28]. Two studies included walking as a comparator [18, 23].

Rest periods between conditions ranged from 2-min to 1 month and distance ridden from 3.54 to 27 km. Nine studies were conducted in a natural setting with topography ranging from flat to elevations between 33.5 and 260 m. Four studies specifically examined the impact of topography on physiological outcomes by separating rides into different topographical sections (Additional file 3). Four studies required participants to stop and go during rides to simulate typical riding conditions [20, 26] or delivering mail [24, 25]. In seven studies participants were instructed to ride at a self-selected pace.

Longitudinal studies

Six studies examined the longitudinal impact of e-cycling, using a variety of study designs (Table 1). All studies were conducted in high income countries including Belgium, Switzerland, Norway, UK ($n = 2$) and the USA. Sample sizes ranged from 20 to 32, with a total of 153 participants. Most participants were between 30 and 50 years of age. Four studies recruited physically inactive individuals [13, 29–31]. One study included individuals with type 2 diabetes [32] and for one study the health status of individuals was unclear [33]. Interventions ranged from 4-weeks to 8-months in length. One study included published data from mid-point of the intervention, but not post intervention [33]. Three studies provided participants with guidelines on minimum riding requirements, all of which specified riding the e-bike for commuting purposes at least three times per week [13, 29, 30].

Physical activity intensity

Studies reported a range of outcomes related to physical activity intensity. Given the heterogeneity between studies regarding route length and topography, mean values and/or percent of maximum values during conditions are reported to enable comparison between studies. Physiological outcomes reported within the manuscript include oxygen uptake, metabolic equivalents,[1] energy expenditure per minute, heart rate and power output (Table 2). Additional outcomes are reported in Additional file 4 and Additional file 5.

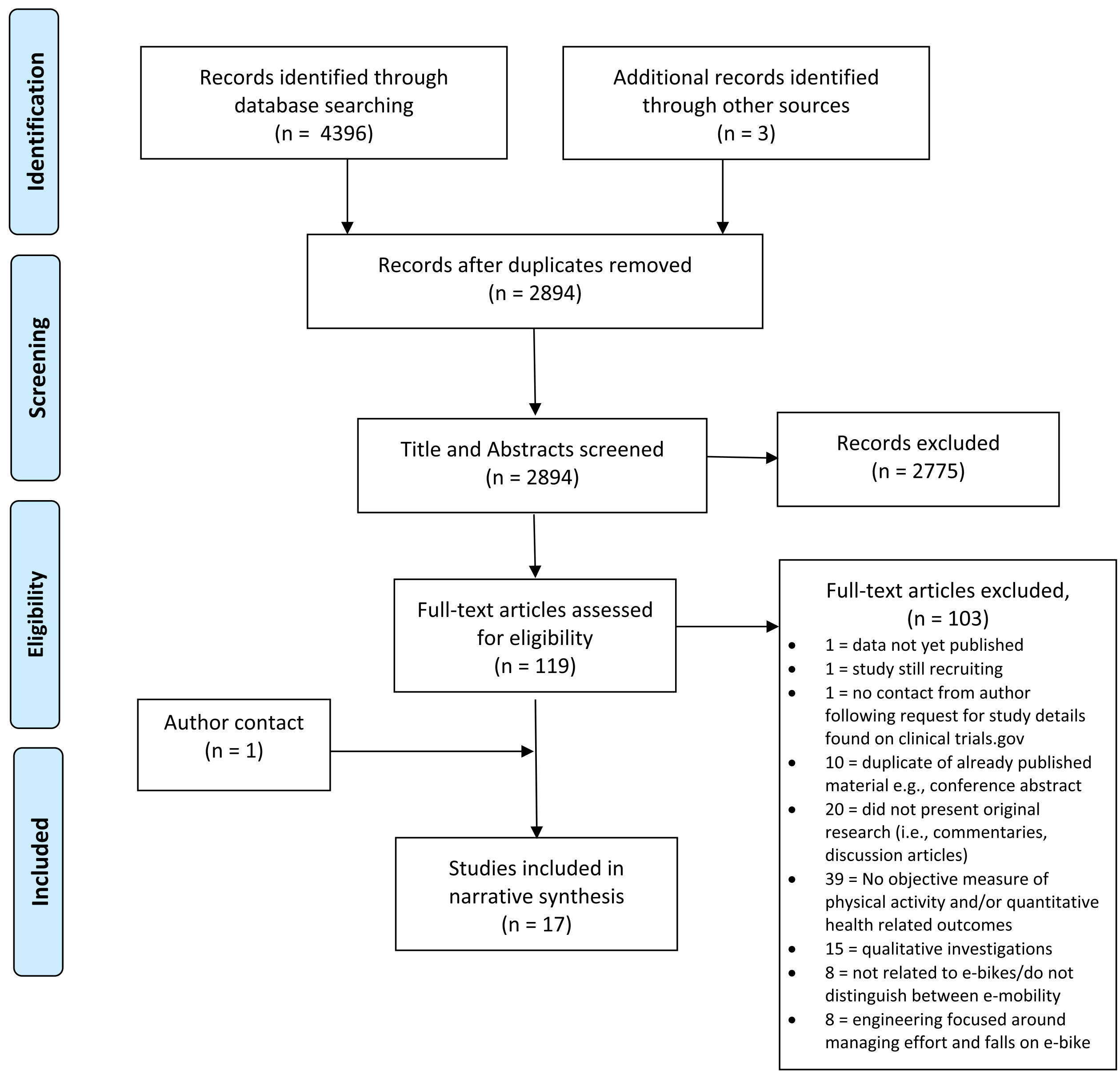

Fig. 1 Flow chart of literature search

Oxygen uptake

Eight studies reported oxygen uptake [18, 19, 21–23, 25–27]. Riding an e-bike led to a relative mean oxygen uptake of 14.7 to 29 ml/min/kg or 51 to 74% of maximum oxygen uptake. E-cycling required lower oxygen uptake than conventional cycling (19.3 to 37 ml/min/kg) or e-cycling with no assistance (22.9 to 23.4 ml/min/kg), with statistically significant differences reported in four studies, one of which reported an effect size of 1.73 [19]. Walking elicited lower oxygen uptake compared to self-selected e-cycling [23] and e-cycling on low assist [18].

Metabolic equivalents (METs)

Nine studies reported mean estimated METs while riding an e-bike at a self-selected intensity [13, 18–23, 26, 27], which ranged from 4.9 to 8.3 METs. Overall, e-cycling led to a lower mean MET score than conventional cycling or e-cycling without assistance. However, the significance of the difference is inconclusive. One study reported a difference in mean METs between walking and e-cycling only during uphill sections [23], while another study reported no difference between walking and e-cycling over varied terrain [18].

Table 1 Summary of included studies

First author, year, country	Study design	Participants; gender (%female); Age, years (mean, SD); BMI, kg/m^2 (mean, SD)	Clinical status	Exposure conditions	Length of intervention	Ride characteristics Distance (km), Topography, Distinctive features, Ride instructions
Acute studies						
Bernsten, 2017, Norway [22]	Randomized cross over	*N* = 8, 25% Age (*Mdn, IQR):* 39(3) BMI (*Mdn, IQR):* 24(7)	Active adults	E-bike vs. CB (*4 conditions, hilly* vs. *flat terrain)*	Trials conducted on same day, 2-min break between trials	Route 1: 8.1 km, flat route Route 2: 7.1 km, one hill climbed twice 130 m elevation gain. Self-selected intensity
Gojanovic, 2011, Switzerland [18]	Non-randomized cross over	*N* = 18, 33.33% Age: 35.7 (±9.7) BMI: 24.0 (±3.3)	Inactive adults	E-bike LA vs. E-bike HA vs. CB vs. walking	Trials conducted over 2-days. 30-min break between trials conducted on same day	Biking: 5.1 km, 178 m elevation gain, average gradient 3.4% Instructed to ride at comfortable pace maintaining 60 rpm Walking: 1.7 km, uphill, 110 m elevation gain, average grade 6.5%
Hansen, 2017, Belgium [21]	Randomized cross over	*N* = 17, 13% Age: 64 (±7)	Coronary artery disease	E-bikes LA vs. E-bike HA vs. CB	Trials conducted on separate days (3–4 days between)	10 km, 102 m elevation change No traffic or stop and go points Instructed to cycle at self-selected pace on prespecified mode
La Salle, 2017, USA [26]	Randomized cross over	*N* = 12, 50% Age: M = 25(±1), F = 22(±1) Body Fat %: M = 16.8(±1.9), F = 23.4 (±3.3)	Active adults with cycling experience	E-bike pedal assist vs. E-bike NA	Trials conducted in same day. Average time between trials 12-min	3.54 km, hill 0.64 km 11% gradient Seven pedestrian crossings participants required to dismount and walk. Self-selected pace
Langford, 2017, USA [23]	Non-randomized cross over	N = 17, 35% Age: < 20 yrs. = 3, 20-30 yrs. = 10, 31-40 yrs. = 2, > 50 yrs. = 2 BMI: M = 26.1, F = 23.1	Adults, part of e-bike sharing system	E-bike vs. CB vs. Walking	Trials conducted on separate days (minimum 24h rest)	4.4 km, 1.6 km downhill (– 33.2 m), 1.8 km flat (– 0.3 m), 1.0 km uphill (+ 33.5 m). Self-selected pace
Louis, 2012, France [27]	Randomized cross-over	*N* = 20 (10 T, 10 UT) Age: *T* = 38.7 (±14.8); *UT* 28.9 (±6.3) BMI: *T* = 22 (±1.1), *UT* = 22.2 (±3.7)	Highly active adults (T) Recreationally active adults (UT)	E-bike NA vs. E-bike LA vs. E-bike HA	Trials conducted on same day. 5-min breaks between trials	Completed on indoor trainer. Instructed to pedal at specified mode for total of 45-min at pre-specified speeds: 15-min at 16 km/hr., 21 km/hr. and free speed totaling 45-min.
Meyer, 2014, Germany [28]	Non-randomized cross over	*N* = 3, 0% Age: 25, 25, 27 Weight (*Kg):* 74, 71, 79	Active adults, recreational cyclists	E-bike pedal assist vs. E-bike no assist	Trials conducted on separate days, 1-day apart.	27 km track divided in 5 sections
Simons, 2009, Netherlands [20]	Non-randomized cross over	*N* = 12, 50% Age: 52.2 (8.7), range 32–60 BMI: 24.5 (2.6)	42% inactive adults 58% recreationally active adults	E-bike NA vs. E-bike LA vs. E-bike HA	Trials conducted in same day. One-hour rest between trials.	4.3 km, flat route, two stop and go section participants required to dismount and restart. Self-selected pace on pre-specified intensity
Sperlich, 2012, Germany [19]	Randomized cross over	*N* = 8, 100% Age: 38(±15) BMI: 25.3 (±2.1)	Inactive adults	E-bike pedal assist vs. E-bike no assist	Trials conducted in same day. One-hour rest between trials.	1.9 km × 5 = 9.5 km, 200 m uphill 1, 5.9%, 700 m downhill, 300 m uphill 2, 5.8%, 700 m flat. Self-selected pace and gear
Theurel, 2011, France [24]	Non-randomized cross over	*N* = 22, 18% female Age: M = 41(±11), F = 34(±9) Weight (*Kg):* M = 68(±18), F = 76(±10)	Active postal workers	E-bike vs. CB	Trials conducted on same weekday, 1-month apart	Postal route, one group completed rides in residential neighbourhood, the other completed the ride in downtown location

Table 1 Summary of included studies *(Continued)*

First author, year, country	Study design	Participants; gender (%female); Age, years (mean, SD); BMI, kg/m^2 (mean, SD)	Clinical status	Exposure conditions	Length of intervention	Ride characteristics Distance (km), Topography, Distinctive features, Ride instructions
Theurel, 2012, France [25]	Non-randomized cross over	*N* = 10, 50% female Age: F = 30 (±12), M = 35 (±14)	Active adults	E-bike vs. CB	Trials separated by 1 week	30-min of intermittent cycling on inside track alternating cycling of 10 sec duration and recovery of 20 sec. Aimed to complete 60 m in 10 sec (average speed = 21.6 km/hr)
Longitudinal studies						
Cooper, 2018, UK [32]	Single group feasibility	*N* = 20 (report on 18) Age: 58.1 (±7.9) BMI: 30.2 (4.4)	Type 2 Diabetes	One group e-bike	Up to 5 months	E-bike training provided. Provision of e-bike for up to 5-months. Support for mechanical issues provided. No instruction on how or when to ride bike
De Geus, 2013, Belgium [29]	Non-randomized cross over	*N* = 24, 46% Age: M = 47(±7) F = 43(±6) BMI: M = 27.0 (±2.8), F = 24.7 (±4.6)	Inactive adults [a]	E-bike vs. Control	Control = 4 weeks E-bike = 6 weeks	Instructed to ride e-bike at least three times per week to commute to and from work
Hochsmann, 2017, Switzerland [30]	Pilot randomized controlled trial	*N* = 32, 13% Age, (*Mdn, IQR):* F = 35(34–45), M = 43(38–45) BMI, (*Mdn, IQR)* E-bike = 29 (27,31), regular bike = 28 (26,29)	Inactive adults	E-bike vs. CB	4 weeks	Instructed to use bike for active commute to work on at least 3-days per week, over 6 km. Self-selected pace
Malnes, 2016, Norway [31]	Single group pilot	*N* = 25, 72% Age: 42(±12) BMI: M = 25.4(±12.3), F = 28.7(±15.8)	Inactive adults	One group e-bike	Up to 8 months	3 sites: 2 provided e-bikes for up to 8-months, 1 e-bike up to 3-months. Instructed to use bike as desired. In 2-centres if e-bikes not used they were withdrawn from participant. Group was separated into high and low fitness groups based on baseline testing
Page, 2017, UK [33]	Non-randomized two group	*N* = 31, 80% Age Range: 21-55 years	Unclear	E-bike commuting vs. passive commuting	Data reported mid-way into intervention – 2 months	No instructions on how to ride bike, full roadside assistance provided.
Peterman, 2016, USA [13]	Single group	*N* = 21, 70% (of 20 in analysis) Age: 41.5 (±11.5).	Inactive adults	One group e-bike	4 weeks	Instructed to ride e-bike at least 3 days per week for at least 40-min for commuting

T trained (engage in endurance sport at least 4 times per week), *UT* untrained (moderately active but less than 4× per week), *Inactive* <150 min/week of moderate to vigorous physical activity, *Active* ≥150 min/week of moderate to vigorous physical activity [a] report as sedentary but do not specifically measure moderate to vigorous physical activity, *F* female, *M* male, *NA* no assistance, *LA* low assistance, *HA* high assistance, *CB* conventional bike

Energy expenditure per minute

Four studies assessed energy expenditure per minute [13, 23, 24, 27]. On an indoor trainer, energy expenditure per minute was lower on an e-bike with assistance (high or low) compared to an e-bike without assistance in physically active adults [27]. In outdoor trials two studies reported no difference in energy expenditure per minute between e-cycling and conventional cycling, though mean values were consistently lower for e-cycling [23, 24]. Absolute energy expenditure per minute while riding an e-bike ranged from 4.9 to 6.5 kcal/min.

Heart rate

Twelve studies reported heart rate while e-cycling [13, 18–20, 23–28, 30, 32]. During e-cycling the percentage of maximum heart rate ranged from 67.1 to 79.1. Overall, mean heart rate while riding an e-bike was lower than riding a conventional bike or an e-bike with no

Table 2 Physical activity intensity outcomes of interest measured during rides*

Study	Outcomes	Results; mean (SD)				
		E-bike	Comparison 1	Comparison 2	Comparison 3	Significance testing, *p value*
Bernsten, 2017 [22] [a]	*(Median, IQR)*	E-bike	CB			
	Percentage VO_{2max}	51 (27)	58 (28)			NC
	Measured METs	8.5 (3.1)	10.9 (2.7)			NC
	Estimated METs	6.9 (2.1)	8.4 (1.8)			NC
Cooper, 2018 [32]		E-bike	Walking			
	Mean HR	125.2 (18.1)	107.6 (15.8)			NC
	Men	121.2 (17.2)	103.2 (14.1)			NC
	Women	132.6 (18.9)	116.5 (16.9)			NC
	Percentage HR max	74.7	64.3			NC
Gojanovic, 2011 [18]		E-bike HA	E-bike LA	CB	Walking	
	Mean absolute VO_{2peak}	1.50 (.038)	1.79 (0.46)	2.00 (0.44)	1.6 (0.34)	< 0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
	Percentage VO_{2peak}	54.9 (11)	65.7 (8.1)	72.8 (6.4)	59 (9.1)	< 0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
	Mean estimated METs	6.1 (1.4)	7.3 (1.0)	8.2 (1.3)	6.5 (0.8)	< 0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
	Mean HR	138.4 (18)	149 (17.7)	157.0 (11.2)	132.7 (17.4)	< 0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
	Percentage HR max	74.5 (8.7)	80.3 (8.7)	84.6 (5.2)	71.5 (9.2)	< 0.001 overall, <.05, all comparisons except HA vs. Walk (>.05)
Hansen, 2017 [21]		E-bike HA	E-Bike LA	CB		
	Mean absolute VO_2	1.72 (0.54)	1.89 (0.62)	1.85 (0.52)		.02 overall, .04 LA vs. HA, > .05 CB vs. LA, CB vs. HA
	Percentage VO_{2peak}	68 (7.1)	74 (6.2)	73 (4.6)		.01 overall, .03 LA vs. HA, > .05 CB vs. LA, CB vs. HA
	Mean estimated METs	6 (1.8)	6.6 (2)	6.4 (1.6)		.02 overall; .027 HA vs. LA; >.05, CB vs LA, CB vs. HA
Hochsmann, 2017 [30]	*(Median, IQR)*	E-bike	CB			
	Percentage HR max[+]	74.9 (67.4, 82.8)	73.3 (67.7, 78.2)			NC
Langford, 2017 [23] [a,c]		E-bike	CB	Walking		
	Mean relative VO_2	16.95 (5.17)	19.32 (5.47)	15.12 (5.35)		NC
	Mean relative EE per minute	0.08 (0.03)	0.10 (0.02)	0.07 (0.03)		NC
	Mean estimated METs	5.1	5.8	4.5		NC
	Mean HR	121.35 (17.04)	127.45 (18.17)	115.25 (14.41)		NC
	Mean power output	63.28 (22.89)	73.13 (35.79)	NA		NC
La Salle, 2017 [26] [a]		E-bike	CB			
	Mean absolute VO_2	2.3 (0.1)	2.5 (0.1)			.45
	Percentage VO_{2max}	66.4 (2.6)	68 (2.8)			NR
	Mean estimated METs	8.3 (0.5)	8.5 (0.6)			.65
	Mean HR	147 (5)	149 (5)			.064
	Percentage HR max	79.1 (2.4)	80.4 (2.6)			NR
	Mean power output	115 (11)	128 (11)			.38
Louis, 2012 [27] [b]	*Trained*	E-bike HA	E-bike LA	E-bike NA		
	Mean relative VO_2	14.7 (2.0)	19.5 (2.4)	22.9 (2.2)		< .05, all comparisons
	Mean estimated METs	4.2 (0.6)	5.6 (0.7)	6.5 (0.6)		< .05, all comparisons
	Mean absolute EE per minute	5.1 (0.8)	7.6 (0.8)	7.8 (0.5)		< .05, all comparisons

Table 2 Physical activity intensity outcomes of interest measured during rides* *(Continued)*

Study	Outcomes	Results; mean (SD)				
		E-bike	Comparison 1	Comparison 2	Comparison 3	Significance testing, *p value*
	Mean HR	77.7 (11)	89.4 (10.2)	92.8 (11.6)		< .05, all comparisons
	Mean power output	47.3 (9.1)	83.6 (4.0)	104.2 (4.2)		< .05, all comparisons
	Untrained	E-bike HA	E-bike LA	E-bike NA		
	Mean relative VO_2	15.0 (2.0)	21.7 (4.2)	23.4 (3.6)		< .05, all comparisons
	Mean estimated METs	4.3(0.6)	6.2 (1.2)	6.7 (1.0)		< .05, all comparisons
	Mean absolute EE per minute	4.9 (0.8)	6.7 (0.8)	7.5 (0.9)		< .05, all comparisons
	Mean HR	96.8 (16.8)	116.8 (21.7)	116.7 (16.2)		< .05, all comparisons
	Mean power output	40.0 (7.1)	79.8 (4.8)	99.9 (6.9)		< .05, all comparisons
Meyer 2014 [28] [a]		E-bike	E-bike NA			
	Mean HR	94.71	131.31			NC
Peterman, 2016 [13]		E-bike				
	Mean estimate METs	4.9 (1.2				
	Mean absolute EE per minute	6.5 (1.9)				
	Percentage HR max	72.1 (5.4)				
Simons, 2009 [20]		E-bike HA	E-bike LA	E-bike NA		
	Mean estimated METs	5.2 (1.4)	5.7 (1.2)	6.1 (1.6)		<.05 HA and NA, >.05 HA vs. LA, LA vs. NA
	Mean HR	112.4 (22.9)	116.2 (22.4)	123.8 (23.2)		<.05 NA vs. HA; NA vs. LA, >.05 HA vs. LA
	Percentage HR max	6 7.1 (14.1)	69.3 (13.5)	73.9 (14.5)		<.05 NA vs. HA; NA vs. LA, >.05 HA vs. LA
	Mean absolute power	94.2 (29.2)	101.8 (24.8)	118.2 (30.9)		<.05 All comparisons
Sperlich, 2012 [19] [a]		E-bike	CB			
	Mean relative VO_2	18 (3.8)	25.5 (4.8)			<.05, ES = 1.73
	Mean absolute VO_2	1.33 (0.35)	1.77 (0.43)			< .05, ES = 1.12
	Mean estimated METs	5.2 (1.7)	7.1 (1.4)			<.05, ES = 1.22
	Mean HR	105 (20)	133 (19)			<.05, ES = 1.53
	Mean absolute power	363 (23)	415 (28)			<.05, ES = 2.02
Theurel, 2011 [24]		E-bike	CB			
	Mean absolute EE per minute	5.6 (1.3)	5.9 (1.8)			NR
	Mean HR	NR	NR			.02, 3% lower with e-bike
Theurel, 2012 [25]		E-bike	CB			
	Mean relative VO_2	29 (5)	37 (5)			< .001
	Mean HR	136 (23)	167 (17)			<.001

*Given the difference in the cycle routes conducted mean values or percentage of maximum for outcomes related to physical activity intensity are reported (e.g., Mean VO_{2peak}, mean heart rate, mean energy expenditure). For additional physical activity related outcomes reported in the studies see Additional file 4

+reported for only a subsample of the group ($n = 5$ e-bikes, $n = 4$ conventional bike)

EE energy expenditure, *HR* heart rate, *METs* metabolic equivalent, VO_2 volume of oxygen, VO_2 oxygen intake value; VO_{2max} highest oxygen intake value attainable for an individual, VO_{2peak} the highest oxygen intake value obtained on a specific test, *CB* conventional bike, *HA* high assistance, *LA* low assistance, *NA* no assistance

ES effect size measured as Cohen's d, *NC* not conducted, *NR* not reported

Relative VO_2, VO_{2max} and VO_{2peak} measured as ml/min/kg; *Absolute* VO_2, VO_{2max} and VO_{2peak} measured in l/min; *Mean absolute energy expenditure* measured in kcal/min; *Mean relative energy expenditure* measured in kcal/kg/min; *Mean heart rate* measured in beats per minute (bpm); *Mean power output* measured in Watts, *Estimated METs* measured using assumption that resting energy expenditure (i.e.,1 MET) = 3.5 ml/kg/min; *Measured METs* measured through assessed individual resting energy expenditure

[a]Results are reported to total cycle routes. Studies separated results for different route topography. See Additional file 3 for details on different cycling topography; [b] Participants completed same activity at three different speeds, self-selected speed reported; [c] Total sample analyses not conducted, see Additional file 3 for analyses between ride segments

assistance. Heart rate showed a trend towards being lower while walking compared to e-cycling [18, 23, 32].

Power output

Five studies assessed power output during conditions [19, 20, 23, 26, 27]. Mean power output was lower while riding an e-bike compared to a conventional bike or e-cycling with no assistance. Riding an e-bike on high assistance compared to low assistance led to significantly lower power outputs.

Overall, e-cycling was performed at a moderate intensity, but the intensity was lower than during conventional cycling. Most studies reported significant differences in the associated outcomes between e-cycling and conventional cycling. However, one study found no differences in physiological markers of intensity between e-cycling and conventional cycling [26]. While the evidence is limited, e-cycling appears to be performed at a greater intensity than walking.

Impact of topography

Five studies directly compared the impact of e-cycling in varying topographies (Additional file 3). The energy cost during e-cycling and conventional cycling uphill ranged from 5.2 to 6.8 and 7.2 to 8.5 METs respectively. This difference was statistically significant in the three studies that conducted hypothesis testing. Examination of means and medians suggested that energy expenditure (METs) during downhill and flat sections were lower while e-cycling compared to conventional cycling, but that this difference in energy cost was less distinct than during uphill sections. Across all studies, greater elevation gains in routes led to higher energy cost for both e-cycling and conventional cycling compared to flat routes or those conducted indoors. Differences in heart rate between e-cycling and conventional cycling appear to be greater during uphill sections, except for one study [19] that reported similar differences in heart rate between cycling conditions across all topographies.

Physical fitness

A pilot randomized control trial of physically inactive individuals reported an increase in peak oxygen uptake (VO_{2peak}) of 10% following 4-weeks of e-cycling compared to a 6% increase following 4-weeks of conventional cycling [30] (Table 3). In a similar population, using a single-group quasi-experimental design, one study reported an 8% increase in VO_{2peak} following 4-weeks of e-cyling [13] and another reported a 7.7% increase in VO_{2peak} following 3-months of e-cycling [31]. When separated into low and high fitness groups a significant increase in VO_{2peak} was reported only in individuals with low levels of fitness, with a 9.6% increase compared to a 1.5% increase in high fitness individuals [31]. Gender differences were reported in one study following 6-weeks of e-cycling with a 2 and 7% increase in VO_{2peak} in physically inactive men and women respectively [29]. Gender differences were also reported in maximum power output with women reporting lower increases in maximum power than men following a 6-week and 5-month intervention [29, 32].

Health outcomes

Three studies examined the impact of e-cycling on health outcomes beyond fitness (Table 3), for which the outcomes assessed were heterogeneous. After 4-weeks of e-cycling there were no changes in systolic or diastolic blood pressure at rest [13, 30]. There was no evidence of a difference in blood pressure whilst cycling between conventional cycling and e-cycling [30]. Peterman and colleagues [13] reported no changes in insulin resistance or lipid profiles following 4-weeks of e-cycling. However, a significant reduction in 2-h post plasma glucose concentration was reported. No changes were reported in the one study examining quality of life following 8 weeks of e-cycling [33].

Quality assessment and quality of the evidence

The global rating of acute studies yielded six moderate and five weak ratings according to the EPHPP tool (Table 4). Ten studies were rated as weak for representativeness of the target population, often due to a failure to report how participants were recruited. Methods of assessment were rated as strong. The repeated nature of conditions ensured the control of confounders, therefore yielding a strong rating. Overall there was moderate evidence that e-cycling could lead to physical activity at an intensity associated with beneficial health outcomes [14]. A global rating of strong was given to one longitudinal study, moderate was given to four studies and weak to one study. There was moderate evidence that e-cycling could lead to increased fitness. The evidence related to the impact of e-cycling on additional health outcomes was inconclusive.

Discussion

The aim of the current review was to assess the intensity of physical activity when riding an e-bike, and to examine the physiological and psychological outcomes associated with e-cycling. Where possible these outcomes were compared to traditional methods of active travel (i.e., walking and cycling). Eleven acute and six longitudinal studies were identified. There was moderate evidence that e-cycling provides moderate intensity physical activity in both physically active and inactive individuals. Furthermore, there was moderate evidence that e-cycling positively impacted cardiorespiratory fitness in physically inactive individuals. The impact of e-cycling on health outcomes beyond physical fitness was inconclusive given the sparsity of current research.

Quality of the evidence

The quality of all studies, bar one [30], was weak to moderate. These ratings should be viewed with caution

Table 3 Results of longitudinal intervention studies

Study	Outcomes	Results, mean, SD (*95% CI*)				
		Intervention		Control		Significance, *p-value*
		Pre	Post	Pre	Post	
		E-bike				
Cooper, 2018 [32]	Max absolute power	157.5 (55.7)	174.3 (70.8)			NC
	Men	182.1 (51.5)	206.2 (64.9)			NC
	Women	118.9 (38.9)	124.3 (49.0)			NC
		E-bike		NE		*Within groups*
De Geus, 2013 [29]	Absolute VO_{2peak}					
	Men	2.56 (0.35)	2.61 (0.38)	2.62 (0.46)	2.56 (0.35)	>.0.025 E-bike, NE
	Women	1.94 (0.37)	2.07 (0.41)	1.91 (0.35)	1.94 (0.37)	>.0.025 E-bike, NE
	Relative VO_{2peak}					
	Men	30.2 (4.3)	30.7 (5.6)	30.8 (4.9)	30.2 (4.3)	>.0.025 E-bike, NE
	Women	30.0 (6.0)	32.3 (6.5)	29.4 (5.1)	30.0 (6.0)	>.0.025 E-bike, NE
	Absolute max power					
	Men	169.5 (19.9)	192.1 (28.7)	173.8 (27.1)	169.5 (19.9)	<.0.025 E-bike, >.0.025 NE
	Women	130.9 (21.6)	145.9 (24.8)	131.1 (21.7)	130.9 (21.6)	<.0.025 E-bike, >.0.025 NE
	Relative max power					
	Men	2.00 (0.28)	2.30 (0.40)	2.05 (0.35)	2.00 (0.28)	<.0.025 E-bike, >.0.025 NE
	Women	2.03 (0.41)	2.30 (0.55)	2.04 (0.43)	2.03 (0.41)	<.0.025 E-bike, >.0.025 NE
		E-bike		CB		
Hochsmann, 2017 [30]	Relative VO_{2peak}	35.7 (5.8)	39.3 (8.3)	36.4 (7.3)	38.6 (6.2)	0.327, 1.4 (– 1.4–4.1)$^{+}$
	Relative power output	2.9 (0.6)	3.2 (0.6)	3 (0.5)	3.3 (0.5)	0.995, 0.0 (– 0.1–0.1)$^{+}$
	Resting HR	64.7 (6.5)	65.1 (7.6)	68.8 (8.8)	65.5 (10.6)	0.505, 2.0 (−4.2–8.2) $^{+}$
	HR at 100 W max text	113.4 (9.2)	111.5 (7.7)	113.4 (15.9)	109.2 (14.2)	0.219, 2.4 (– 1.5–6.2) $^{+}$
	SBP at rest	125.9 (13.8)	124.1 (11.3)	127.3 (10.6)	123.1 (12.4)	0.538, 2.0 (−4.5–8.5) $^{+}$
	DBP at rest	82.4 (8.5)	82.1 (8.2)	87.7 (8)	84.5 (8.8)	0.625, 1.2 (−3.9–6.3) $^{+}$
	SBP @ 100 W	174.1 (22.9)	160.3 (21.2)	160.8 (20)	150.4 (18.5)	0.93, −0.4 (−9.4–8.7) $^{+}$
	DBP @ 100 W	86.2 (8.3)	81.9 (6.5)	88 (7.1)	84 (8.1)	0.709, −1.1 (−7.5–5.2) $^{+}$
		E-bike				
Malnes, 2016 [31]	Relative VO_{2peak}	34.1 *(31.6, 36.7)*	36.5 *(34.4, 38.6)*			<.001
	Relative $VO_{2peak,}$ % gain		7.7 *(4.3, 11.1)*			
	High Fitness		1.5 (−5.6, 8.6)			0.626
	Low Fitness		9.6 *(5.9, 13.3)*			<.05
	Peak HR	181 *(175, 187)*	180 *(174, 186)*			0.429
		E-bike commute		Passive commute		
Page, 2017 [33]	QOL (baseline and week 8)	38.00 (3.86)	39.67 (4.47)	29.63 (6.57)	35.71 (5.59)	>.05 E-bike, Passive commute
	OQL (week 4)		38.84 (4.16)		32.67 (6.08)	<.01, ES = 0.28
		E-bike				
Peterman, 2016 [13]	Absolute VO_{2max}	2.21 (0.48)	2.39 (0.52)			<.05
	MVPA	28.1 (17.5)	29.0 (20.2)			>.05
	MVPA10+	11.7 (14.3)	13.0 (15.2)			>.05
	Absolute max power	165.1 (37.1)	189.3 (38.3)			<.05
	Fasting glucose	4.99 (0.52)	5.02 (0.47)			>.05
	2 h post plasma glucose	5.53 (1.18)	5.03 (0.91)			<.05

Table 3 Results of longitudinal intervention studies *(Continued)*

Study	Outcomes	Results, mean, SD *(95% CI)*				
		Intervention		Control		Significance, *p-value*
		Pre	Post	Pre	Post	
	HOMA	2.46 (0.95)	2.55 (0.82)			>.05
	Total cholesterol	3.90 (0.87)	3.92 (0.79)			>.05
	LDL	2.33 (0.8)	2.34 (0.71)			>.05
	HDL	1.21 (0.24)	1.18 (0.22)			>.05
	Triglycerides	0.95 (0.42)	0.91 (0.27)			>.05
	MAP	84.6 (10.5)	83.2 (9.4)			>.05
	SBP	110.0 (12.4)	109.1 (10.9)			>.05
	DBP	67.7 (8.8)	67.0 (8.0)			>.05

[+]difference between groups, 95% CI, ES = effect size
Distance (total and weekly) measured in kilometres; *Duration* (total and weekly) measured in minutes
NE no activity, *CB* conventional bike
SBP systolic blood pressure, *DBP* diastolic blood pressure, *MAP* mean arterial blood pressure, *QOL* quality of life, *LDL* low density lipo-protein, *HDL* high density lipo-protein, *HOMA* measure of insulin sensitivity using homeostatic model assessment, *MVPA* moderate to vigorous physical activity, *MVPA*10+ moderate to vigorous physical activity of bout of 10-min or greater, *W* watts
VO_{2max} = highest oxygen value attainable for an individual, VO_{2peak} = the highest oxygen intake value obtained on a specific test
Relative VO_{2max} and VO_{2peak} measured as ml/min/kg; *Absolute* VO_{2max} and VO_{2peak} measured in l/min *Mean energy expenditure* measured in kcal/min; *Mean heart rate or peak heart rate* measured in beats per minute (bpm); *Mean absolute max power* measured in Watts, *Mean relative power* measured in watts/kg*; glucose, cholesterol, LDL, HDL, Triglycerides* measured in mmol/L; *blood pressure* measured in millimeter of mercury (mmHg), *MVPA* and *MVPA10+* measured in minutes per day

Table 4 Quality assessment of included studies according to the Effective Public Health Practice Project tool

Study	Component rating						Global rating[a]
	Selection Bias	Design	Confounders	Blinding	Methods	Drop-outs	
Acute studies							
Bernsten [22]	Weak	Strong	Strong	Weak	Strong	Strong	Moderate
Gojanovic [18]	Weak	Moderate	Strong	Weak	Strong	Strong	Moderate
Hansen [21]	Moderate	Strong	Strong	Weak	Strong	Strong	Moderate
Langford [23]	Weak	Moderate	Strong	Weak	Strong	Moderate	Moderate
La Salle [26]	Weak	Strong	Strong	Weak	Strong	Strong	Moderate
Louis [27]	Weak	Strong	Strong	Weak	Strong	Weak	Weak
Meyer [28]	Weak	Weak	Strong	Weak	Strong	Weak	Weak
Simons [20]	Weak	Moderate	Strong	Weak	Strong	Strong	Moderate
Sperlich	Weak	Strong	Strong	Weak	Strong	Weak	Weak
Theurel, 2011 [24]	Weak	Weak	Strong	Weak	Strong	Weak	Weak
Theurel, 2012 [25]	Weak	Weak	Strong	Weak	Strong	Weak	Weak
Longitudinal studies							
Cooper [32]	Moderate	Moderate	Strong	Weak	Strong	Moderate	Moderate
De Geus [29]	Weak	Moderate	Strong	Weak	Strong	Moderate	Moderate
Hochsmann [30]	Moderate	Strong	Strong	Weak	Strong	Strong	Strong
Malnes [31]	Weak	Moderate	Strong	Weak	Strong	Strong	Moderate
Page [33]	Moderate	Weak	Weak	Weak	Strong	Weak	Weak
Peterman [13]	Weak	Moderate	Strong	Weak	Strong	Moderate	Moderate

[a]Strong = no weak component rating; moderate = one weak component rating; weak = two or more weak component ratings
Note: blinding was not included in the overall global rating calculation

as the purpose of physiological studies, such as the acute experiments reported here, is to explore a specific event in a controlled environment with less focus on obtaining representative samples. As such, many studies did not report how participants were recruited, leading to a weak rating for the selection bias component of the assessment. Study design, control of confounders and methods of assessment are often considered more crucial in these designs, all of which were strong in the acute studies reported here. Furthermore, while blinding is often unachievable in physical activity interventions, the use of objective methodology limits the impact of research bias on the outcomes.

Regarding longitudinal studies, methods of data collection were consistently strong, but with large variation in representativeness, design and reporting of withdrawals and dropouts. Confounders were considered in the context of differences between groups and were therefore rated as strong if studies used a single-group design. One pilot randomized control trial was conducted and was rated as strong [30]. Overall, there was a lack of high-quality longitudinal intervention-based research including pre-post measures examining the impact of e-cycling on physiological and psychological health outcomes.

The impact of e-cycling on physical activity intensity

To accrue health benefits, The American College of Sports Medicine recommend healthy adults engage in moderate-to-vigorous physical activity for 150-min per week [14]. Moderate intensity activity is classified as three to six metabolic equivalents (METs) and vigorous intensity activity at six METs or above. The current review suggests that e-cycling, even while using a high assistance mode, provides physical activity of at least moderate intensity on a variety of terrain, including downhill. Furthermore, e-cycling can elicit vigorous activity during uphill riding [18] and during rides with highly varied terrain [18, 26]. Interestingly, Bernsten and colleagues [22] reported that mean *estimated* METs were lower than mean *measured* METs during e-cycling. Estimated METs have been suggested to overestimate resting energy expenditure, thereby underestimating activity energy expenditure [34]. As such, the mean estimated METs reported in this review provide a conservative estimate of exercise intensity.

Relative physiological outcomes further suggest that e-cycling is performed at a moderate intensity with the percent of maximum heart rate ranging from 67.1 to 79.1 and the percent of $VO_{2peak/max}$ ranging from 51 to 75. These values exceed the hypothesised minimum intensity thresholds required for improvements in cardiorespiratory fitness in healthy adults [14, 35, 36].

E-cycling vs. traditional active transportation

Three studies compared e-cycling to walking [18, 23, 32] of which one compared the two modes on the same route [23]. In this study walking led to lower oxygen uptake than e-cycling across all topographies, though significant MET differences were only reported during uphill sections, with e-cycling expending more energy than walking. The few studies conducted suggest e-cycling is performed at a higher intensity than walking, however, more studies are needed to confirm these trends.

In relation to conventional cycling, this review suggests that e-cycling elicits lower physiological markers of intensity than conventional cycling, however the strength of this finding depends on the physiological assessment measure and route topography. Overall, mean percent of $VO_{2max/peak}$ is similar between conventional cycling and e-cycling ranging from 58 to 74% and 51 to 73% respectively. Studies examining active commuting on conventional bikes have reported similar mean percent of VO_{2max} in healthy adults ranging from 57 to 79% [6, 37]. However, mean relative oxygen uptake is lower during e-cycling compared to conventional cycling or e-cycling without assistance. Similarly, means and medians of estimated METs are consistently higher during conventional cycling or e-cycling without assistance compared to assisted e-cycling, with values ranging from 6.1 to 8.5 and 4.9 to 8.3 respectively, though the significance of the differences varied across studies.

La Salle and colleagues [26] reported similar MET values between e-cycling and conventional cycling. However, the values reported were substantially higher than those reported in other studies, with mean estimated METs of 8.3 and 8.5 for e-cycling and conventional cycling respectively. Participant demographics may have accounted for these differences, since participants were younger and had previous cycling experience. These participants may have had higher aerobic capacity and therefore self-selected a higher intensity activity level at which to complete the conditions. This is likely given that the relative intensity of activity is similar in studies of e-cycling in physically inactive individuals [13, 18–20, 30, 32]. When given the choice to self-select pace and intensity individuals may select a similar physiological intensity across activities regardless of the mechanical assistance, thereby resulting in similar physiological outcomes. In support of this, when individuals were required to maintain a cycling cadence of 60 revolutions per minute throughout a condition, there were significant differences in oxygen uptake and heart rate between e-bikes and conventional bikes [18] compared to studies in which individuals were able to self-selected their intensity [21, 22, 26]. Similarly, when instructed to complete 60-meters of riding in 10-sec for a total of 30-min the reported relative VO_{2max} was 29 ml/min/kg for e-cycling and 37 ml/min/kg for conventional cycling [25]. This suggests that performing the same amount of work requires more effort on a conventional bike than an e-bike, but that human beings reduce the amount of work conducted on a conventional bike, through choosing a slower speed, to account for the increase in expended effort.

In hilly terrain, where there is less opportunity to adjust effort levels to produce comparable intensity levels, the differences between conventional cycling and e-cycling may become more pronounced, with e-cycling requiring lower intensity activity, as found in studies comprised of routes with hilly features [18, 23]. This suggests that e-bikes are less sensitive to environmental factors such as topography. Therefore, physiological measures of intensity are lower on the e-bike than those reported on a conventional bike during uphill riding. The reduced intensity required during uphill riding when using an e-bike is one of the leading arguments for the promotion of e-bikes as an alternative mode of active transportation.

E-cycling and health

In the current review three studies provided weekly e-cycling goals for physically inactive individuals in the context of active commuting [13, 29, 30]. Two of these studies reported increases in VO_{2peak} and maximum power output following 4-weeks of e-cycling [13, 30]. In contrast de Geus and colleagues [10] reported no changes in VO_{2peak} following a 6-week intervention, though differences in maximum power output were seen. Differences between studies could be due to distance cycled. Specifically, both Hochsmann [30] and Peterman and colleagues [13] reported cycling distances of 70 km and 69.4 km per week respectively, compared to 54.3 km per week reported by de Geus [10]. The two studies reporting significant increases in fitness also described self-selected riding intensities of between 72.1 and 74.9% of maximum heart rate (within the moderate intensity zone [13, 30] with an average of 205 min (±43.3) of e-cycling per week [13]. This suggests that e-cycling can contribute to meeting weekly physical activity guidelines.

Without the provision of e-cycling goals, single group studies with physically inactive individuals reported increases in maximal power output of 7 to 10% over 3–8 months, despite lower average distance travelled than other studies [31, 32]. Fitness benefits were greatest in individuals classified as having low fitness [31], similar to findings with conventional cycling [6]. These results suggest that in the absence of specific goals (i.e., under free living conditions), participants engage in e-cycling and this e-cycling can contribute to improvements in fitness.

Beyond cardiorespiratory fitness, there is a lack of research examining the impact of e-cycling on physiological or psychological health outcomes, limiting our ability to draw conclusions. Peterman and colleagues [13] reported a decrease in 2-h plasma glucose during an oral glucose tolerance test after 4-weeks of e-cycling. This finding is in line with studies that have examined the impact of exercise on 2-h post exercise glucose concentrations in obese individuals [38, 39] but is novel in the context of e-cycling and conventional cycling. In the same study, no other metabolic changes were reported. Similar null effects on metabolic outcomes were reported in two systematic reviews on conventional cycling [37, 40].

E-cycling for public health?

Overall e-cycling can elicit at least moderate intensity physical activity. However, total energy expenditure when riding an e-bike is lower than when riding a conventional bike or walking over the same distance, given the reduced amount of time taken to complete a ride on an e-bike. Consequently, if e-cycling were to replace journeys made by walking or conventional cycling, individuals would have to ride for longer for comparable weekly energy expenditure. However, e-cycling is associated with lower ratings of perceived exertion than conventional cycling [23, 26], potentially enabling people to ride more frequently or for a longer duration. This possibility is supported by Hendriksen and colleagues [41], who reported that individuals in the Netherlands commuted 50% further with an e-bike than on a conventional bike.

Findings reported here suggest that e-cycling may be suitable for individuals with compromised health. Hansen and colleagues [21] showed that e-cycling elicited moderate intensity activity in older, obese individuals recovering from surgery due to coronary artery disease, while Cooper and colleagues [32] reported that e-cycling was feasible for middle-aged, overweight individuals with type 2 diabetes mellitus.

Overall, while there is a trend towards increased fitness following engagement in e-cycling interventions, more intervention research of a longer duration is required before the long-term impact of e-cycling on health can be determined. Fifty percent of the longitudinal studies in this review were approximately 1-month in length. This may not be enough time to see changes in body composition and some metabolic outcomes. Longer trials with larger samples sizes should be conducted with a focus on including a range of health outcomes in addition to cardiorespiratory fitness. These trials should utilize randomized controlled designs and clearly report their target population, recruitment process and dropouts and/or withdrawals. Interventions should also be conducted in clinical populations where physical activity is compromised. In addition, more research is needed to understand the impact of e-cycling on health based on sex or fitness level.

It is also important to consider the negative outcomes associated with e-cycling when assessing their potential utilization for health promotion. In the USA, e-bike users reported feeling safer riding their e-bike than a conventional bike, stating that the e-bike helped them to avoid crashes due to their stability, powerful brakes and the acceleration to avoid incidents and keep up with traffic. However, riders reported cycling faster on an e-bike than a conventional bike and felt that other road users misjudged their speed leading to potentially dangerous situations [42]. In the Netherlands data suggest that, after controlling for age, gender and amount of cycling, use of an e-bike was associated with an increased risk of being involved in a crash compared to conventional cycling [43]. The severity of these crashes was not significantly different from conventional cycling [43]. More context specific research is required to enable a risk-benefit assessment of engaging specifically in e-cycling. Nevertheless, e-cyclists would be well advised to be appropriately trained and use safety equipment to minimize risk.

Strengths and limitations

This is the first review to examine the physical activity intensity, cardiorespiratory, metabolic and psychological outcomes associated with e-cycling. This review used two pragmatic tools to assess the quality of studies and to provide an overall rating of the evidence. These tools provided an overall representation of the strength of research evidence related to e-cycling and health. Limitations of this review include the fact that some published studies may not have been identified. However, our systematic and broad search strategy makes this unlikely. It is more likely that we did not identify eligible unpublished studies or those published in an alternative language to English. Sample sizes used in studies were small and sample size calculations were rarely reported. Therefore, caution should be taken when interpreting the statistical significance of evidence. Given the heterogeneity in outcome measurement we were unable to quantify the effects of e-cycling on outcomes of interest using meta-analyses. In addition, focus on quality of life as a psychological outcome may have meant studies examining psychological outcomes such as depression or anxiety were excluded.

Conclusion

The composite results of the 17 studies included in this novel systematic review provide moderate evidence that e-cycling elicits activity at an intensity high enough to promote some positive health outcomes. E-cycling leads to reduced activity volume and intensity over the same distance compared to conventional cycling. Therefore, e-cycling requires more frequent and longer rides to accrue comparable health benefits. However, given that most individuals travel by car to work [44] e-cycling offers a physically active alternative to the largely sedentary behaviour associated with motorized commuting. Furthermore, longitudinal studies suggest, with moderate confidence, that e-cycling can lead to increases in cardiorespiratory fitness. Longer and higher-quality intervention studies, with transparent reporting, are needed to develop a strong evidence-based understanding of the impact of e-cycling on cardiorespiratory health and to explore the impact of e-cycling on metabolic and psychological outcomes. This will extend the current body of knowledge and provide guidance on public health initiatives to promote e-cycling to improve population health.

Endnote

[1]The MET is an expression of energy cost and is calculated from rest where 1 MET is estimated to equal 3.5 ml/kg/min

Additional files

Additional file 1: Example search strategy. (DOCX 12 kb)

Additional file 2: Description of overall strength of evidence criteria. (DOCX 12 kb)

Additional file 3: Outcomes of interest by route topography for acute experimental and quasi-experimental studies. (DOCX 23 kb)

Additional file 4: Additional physical activity outcomes measured in acute studies. (DOCX 28 kb)

Additional file 5: Additional physical activity outcomes measured in longitudinal studies. (DOCX 22 kb)

Acknowledgements
The authors would like to thank Sarah Koch and Kylie Gobereau for their help in translating study manuscripts.

Funding
This review was supported by the NIHR Bristol Nutrition Biomedical Research Centre.

Availability of data and materials
Not applicable.

Authors' contributions
JEB conceptualized the review. JEB, RP, ARC and AP contributed to design and search strategy. JEB, SST, ARC and RP contribute to screening, data extraction and quality assessment. JEB drafted the full manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Publisher's Note

Received: 8 August 2018 Accepted: 8 November 2018
Published online: 21 November 2018

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Appendix 3.3 Example search strategy used in the systematic review

EBIKE MEDLINE, EMBASE AND PSCHINFO

1. pedelec*.ti,ab.
2. (electric* adj1 (assist* adj1 bicyc*)).ti,ab.
3. (electric* adj1 (assist* adj1 cyc*)).ti,ab.
4. (electric* adj1 (assist* adj1 bike*)).ti,ab.
5. e-bike*.ti,ab.
6. (electric* adj1 bike*).ti,ab.
7. (electric* adj1 bicyc*).ti,ab.
8. (electric* adj1 cyc*).ti,ab.
9. (pedal-assist* adj1 electric* adj1 bike*).ti,ab.
10. (pedal-assist*).ti,ab.
11. (electrically-assist* adj1 bike*).ti,ab.
12. (electrically-assist* adj1 bicyc*).ti,ab.
13. (electrically-assist* adj1 cyc*).ti,ab.
14. (electric adj1 mobil*).ti,ab.
15. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14

No subject headings

Appendix 3.4 Description of overall strength of evidence criteria

Strong evidence: 1) at least two RCTs (included randomized cross over studies) of high quality or 2) one RCT of high quality and at least two RCTs of medium quality. Effects must be consistent in both cases.

Moderate evidence: 1) one RCT of medium quality and at least one RCT of low quality or 2) one RCT of medium quality and at least one controlled trial (CT) of high quality or 3) at least three CTs of high quality or 4) one CT of high quality and at least three CTs of medium quality. Effects must be consistent in all cases.

Limited evidence: 1) more than one RCT of low quality or 2) one CT of medium quality and two CTs of low quality or 3) two CTs of low quality and at least two before-after, cohort or longitudinal studies. Effect must be consistent in all cases.

Inconclusive evidence: 1) only one study or 2) multiple before-after, cohort, or longitudinal studies, or 3) contradictory effects.

No evidence: more than one study with consistent non-significant effects

Based on previously utilised method (De Bourdeaudhuij I, Van Cauwenberghe E, Spittaels H, et al. School-based interventions promoting both physical activity and healthy eating in Europe: a systematic review within the HOPE project. *Obesity Reviews* 2011;12(3):205-16. doi: 10.1111/j.1467-789X.2009.00711.x)

Appendix 3.5 Outcomes of interest by route topography for acute studies

Study	**Physical activity outcomes of interest measured**	**Results, mean, SD**										
		Route 1: Flat			**Route 2: Hilly**							
	(Median, IQR)	**E-bike**	**CB**		**E-bike**	**CB**						
Bernsten, 2017[a]	Percentage VO_2max	52(19)	55 (12)		50 (18)	60 (22)						
	Measured METs	8.5 (3.1)	10.3 (2.8)		8.4 (3.2)	10.8 (3.1)						
	Estimated METs	6.9 (1.9)	8.1 (2.5)		6.8 (2.5)	8.5 (2.1)						
		Section 1: 0.885km			**Section 2: 0.885km**			**Section 3: 0.885km**			**Section 4: 0.885km**	
		E-bike	**CB**		**E-bike**	**CB**		**E-bike**	**CB**		**E-bike**	**CB**
La Salle, 2017	Mean absolute VO_2	NR	NR*		NR	NR*		NR	NR*		NR	NR*
	Percentage VO_2 max	NR	NR		NR	NR		NR	NR		NR	NR
	Mean estimated METs	NR	NR*		NR	NR*		NR	NR*		NR	NR*
	Mean Hr	NR	NR		NR	NR		NR	NR		NR	NR*
	Percentage Hr max	NR	NR		NR	NR		NR	NR		NR	NR
	Mean power output	NR	NR		NR	NR		NR	NR		NR	NR
		Section 1: Downhill			**Section 2: Flat**			**Section 3: Uphill**				
		E-bike	**CB**	**Walking**	**E-bike**	**CB**	**Walking**	**E-bike**	**CB**	**Walking**		
Langford, 2017	Mean relative VO_2	13.0 (4.81)	13.8 (5.18)*	13.4 (5.25)*	15.9 (6.05)	18.2 (7.57)*	14.6 (5.56)*	23.2 (5.10)	26.6 (4.72)*	18.5 (5.42)*		
	Mean EE per minute	0.06 (0.2)	0.07 (0.03)	0.07 (0.03)	0.08 (0.03)	0.09 (0.04)	0.07 (0.03)	0.12 (0.03)	0.13 (0.02)*	0.09 (0.03)*		
	Mean estimated METs	3.7	3.9	3.8	4.5	5.2	4.1	6.6	7.6*	5.3*		
	Mean Hr	109.5 (13.1)	111.3 (12.9)	109.5 (13.1)	118.2 (19.5)	121.3 (30.1)	114.0 (14.7)	140.3 (20.5)	152.1 (17.0)*	126.5 (16.6)*		
	Mean power output	36.3 (18.9)	52.4 (16.5)*		62.4 (28.2)	93.0 (22.4)*		98.3 (25.8)	117.4 (27.7)			
		Section 1: small asphalt uphill			**Section 2: long gravel uphill**			**Section 3: short uphill on gravel**			**Section 4: downhill gravel**	
		E-bike	**CB**		**E-bike**	**CB**		**E-bike**	**CB**		**E-bike**	**CB**
Meyer, 2014[a]	Mean Hr	89.37 (3.92)	115.77 (10.57)		91.81 (5.60)	137.48 (8.13)		95.34 (3.31)	154.24 (9.59)		102.31 (1.75)	117.76 (13.90)
		Section 1: Uphill			**Section 2: Downhill**			**Section 3: Uphill**			**Section 4: Flat**	
		E-bike	**CB**		**E-bike**	**CB**		**E-bike**	**CB**		**E-bike**	**CB**
Sperlich, 2012	Mean relative VO_2	18.3 (4.6)	25.7 (4.8)*		16.9 (3.2)	23.2 (4.6)*		18.9 (4.3)	27.4 (5.3)*		18.0 (3.3)	25.7 (5.3*)
	Mean absolute VO_2	1340 (373)	1824 (450)*		1271 (356)	1656 (418)*		1390 (358)	1942 (439)*		1330 (380)	1839 (356)*
	Mean estimated METs	5.2 (1.2)	7.2 (1.5)*		4.8 (0.9)	6.5 (1.3)*		5.8 (2.8)	7.7 (1.6)*		5.1 (1.2)	7.3 (1.2)*
	Mean Hr	108 (18)	136 (17)*		104 (20)	133 (21)*		105 (17)	137 (16)*		100 (20)	140 (19)*
	Mean absolute power	89 (35)	105 (49)*		72 (37)	116 (32)*		84 (27)	122 (39)*		76 (33)	120 (33)*

[a] no significant testing conducted; *significantly different from e-biking

CB=conventional bicycle; EE=energy expenditure; Hr=heart rate; IQR=interquartile range; METs=metabolic equivalent; NR=not reported; SD=standard deviation; VO_2=volume of oxygen *Relative VO_2, VO_{2max}* and *VO_{2peak}* measured as ml/min/kg; *Absolute VO_2, VO_{2max}* and *VO_{2peak}* measured in l/min *Mean energy expenditure per minute* measured in kcal/min; *Heart rate* measured in beats per minute (bpm); *Mean absolute max power* measured in Watts, *Mean relative power* measured in watts/kg, *Estimated METs* measured using assumption that resting energy expenditure (i.e.,1 MET) = 3.5ml/kg/min; *Measured METs* measured through assessed individual resting energy expenditure

Appendix 3.6. Additional physical activity outcomes measured in acute studies

Study	Physical activity outcomes of interest measured	Results, mean, SD				
		E-biking	**Comparison 1**	**Comparison 2**	**Comparison 3**	**p value**
	Total Route	**E-bike**	**CB**			
Bernsten, 2017[a]	Time to completion	19.9 (3.1)	25.1 (3.9)			NC
		E-bike HA	**E-bike LA**	**CB**	**Walking**	
Gojanovic, 2011, Switzerland	Time to completion	18:48 (2:16)	20:45 (3:12)	29:36 (1:34)	22:06 (1:34)	<.001 all comparisons except Walk vs. LA (>0.5)
	Absolute VO_2 peak	1.99 (0.57)	2.36 (0.62)	2.65 (0.62)	2.22 (0.49)	<.001 overall, individual comparisons NR
	MET-minutes	114.1 (13.7)	145.8 (22.4)	252.8 (42.1)	144.1 (13.7)	<.001 overall, individual comparisons NR
	Peak Hr	157.9 (17.4)	168.1 (16.2)	175.6 (9.6)	149.1 (19.8)	<.001 overall, individual comparisons NR
		E-bike HA	**E-Bike LA**	**CB**		
Hansen, 2017, Belgium	Time to completion	31 (4.7)	35 (5.3)	37 (6.5)		<.001 overall, NA vs. HA, LA vs. HA, .301 NA vs. LA
	Estimated total EE	249 (53)	301 (57)	312 (45)		>.05 NA vs LA, <.001 NA vs HA; LA vs HA
	MET-minutes	183 (36)	222 (36)	230 (24)		<.001 overall, NA vs. HA, LA vs. HA, >.05 NA vs. LA
	Mean VCO_2	1542 (496)	1734 (569)	1742 (531)		.003 overall, 1.0 NA vs. LA, .03 NA vs. HA, .03 LA vs HA
	Ventilation*	55 (16.8)	63.9 (20.9)	60.7 (16)		.01 overall, 018 LA vs. HA, >.05 NA vs. LA, NA vs. HA
	Respiratory exchange ratio	0.9 (0.1)	0.9 (0.1)	0.9 (0.1)		0.095 overall
		E-bike	**CB**			
La Salle, 2017	Time to completion	12.5 (0.3)	13.8 (0.3)			.01
	Total Route	**E-bike**	**CB**	**Walking**		**mode x segment**
Langford, 2017	Time to completion	15.77 (1.57)	17.64 (1.45)	48.87 (3.99)		<.001 overall, all segments <.05 e-bike vs CB, e-bike vs walk
	Relative total EE	1.30 (0.37)	1.71 (0.51)	3.61 (1.31)		<.001 overall, all segments <.05 e-bike vs CB, e-bike vs walk
	Mean relative EE per trip	0.30 (0.08)	0.39 (0.12)	0.83 (0.30)		Overall NR, <.05 CB vs E-bike, Walk vs. E-bike
	Absolute VO_2	0.26 (0.07)	0.34 (0.10)	0.73 (0.26)		Overall NR, <.05 CB vs E-bike, Walk vs. E-bike
	Trained	**E-bike HA**	**E-bike LA**	**E-bike NA**		
Louis, 2012, France[b]	Ventilation	24.1 (3.5)	31.7 (3.4)	35.0 (4.0)		<.05 all comparisons
	Gross efficiency	13.8 (1.5)	18.7 (2.5)	19.6 (1.2)		<.05 NA vs. HA, LA vs HA, >.05 NA vs. LA
	Untrained	**E-bike HA**	**E-bike LA**	**E-bike NA**		
	Ventilation	24.9 (3.6)	35.1 (4.8)	37.3 (5.3)		< .05 NA vs. HA, LA vs HA, >0.5 NA vs. LA
	Gross efficiency	12.3 (2.2)	17.1 (2.6)	19.5 (1.9)		< .05 all comparisons
		E-bike	**E-bike NA**			
Meyer, 2014, Germany	Blood lactate	0.93 (0.13)	3.65 (1.29)			NC
		E-bike HA	**E-bike LA**	**E-bike NA**		
Simons, 2009	Time to completion	11:33 (0:58)	12:45 (1:26)	13:38 (1:49)		< .05 all comparisons
	Total absolute EE	77.5 (20)	94.3 (14.9)	108.1 (18.4)		< .05 all comparisons
	MET-minutes	60.3 (13.6)	71.6 (12.2)	81.4 (15.4)		< .05 all comparisons
	Maximum Hr	125.5 (23.2)	130.5 (23.3)	135.8 (23.6)		< .05 NA vs. HA, > .05 HA vs LA, LA vs. NA

	Maximum power output	253.8 (92.4)	266.6 (104.2)	259.1 (79.5)		>.05 all comparisons
	Total Route	**E-bike**	**CB**			
Sperlich, 2012[a]	MET-minutes	192 (62)	291 (57)			<.05, ES=1.66
	Oxygen cost of exercise	16.6 (4.8)	15.7 (6.8)			>.05, ES=0.15
	Respiratory exchange ratio	0.86 (0.06)	0.94 (0.10)			< .05, ES=0.97
	Breathing frequency	31 (4)	33 (5)			>.05, ES=0.44
	Ventilation	37.6 (6.7)	52.6 (12)			< .05, ES=1.54
	Blood lactate					
	Pre	0.6 (0.1)	0.6 (0.1)			
	Post	1.4 (0.8)	3.9 (3.0)			<.05, ES=1.13
	EMG amplitude					
	Biceps femoris	16.3 (15.7)	31.8 (23.3)			< .05, ES=0.78
	Vastus lateralis	28.9 (26.8)	43.1 (40)			< .05, ES=0.41
	Vastus medialis	35 (32.2)	54.8 (50.2)			<.05, ES=0.46
	Gastrocnemius medialis	27.3 (15.4)	37.6 (32.6)			< .05, ES=0.36
		E-bike	**CB**			
Theurel, 2011, France	Time to completion	160 (27)	166 (40)			.37
	Absolute total EE	923 (324)	933 (267)			.91
	Heart rate greater than 5% total work time	NR	NR			<.001, 17% lower when using e-bike compared to CB
	Time with EE greater than 6METs	23 (23)	28 (25)			.46
		E-bike	**CB**			
Theurel, 2012, France	Respiratory exchange ratio	0.86 (0.03)	0.9 (0.05)			<.05
	Mean Hr	136 (23)	167 (17)			<.001
	EMG amplitude					
	Rectus femoris	49 (4)	69 (12)			<.001
	Vastus lateralis	50 (4)	64(11)			<.001
	Gastrocnemius medialis	47 (26)	66 (18)			<.001

[a] no significant testing conducted; CB=conventional bicycle; EE=energy expenditure; ES=effect size; EMG=electromyography; Hr=heart rate; MET=metabolic equivalent; NC=not conducted; NR=not reported; T=trained; UT=untrained; VO_2=volume of oxygen; VCO_2=carbon dioxide output; VO_{2peak}=the highest oxygen intake value obtained on a specific test
Time to completion measured in minutes; *Absolute VO_2, VO_{2max}* and *VO_{2peak}* measured in l/min; *Relative VO_2, VO_{2max}* and *VO_{2peak}* measured as ml/min/kg; *oxygen cost of exercise* measured as ml/min/Watts VCO_2 measured in ml/min; *ventilation and breathing frequency* measured in l/min (**ventilation* measured in ml/min); *respiratory exchange ratio* = ratio between amount of carbon dioxide produced and oxygen used; *Power output* measured in Watts; *Gross efficiency* measured as a percent (Gross efficiency is the percentage ratio of external work achieved compared to total energy expended); *EMG amplitude* measured in µV; *Total EE* measured in kcal; *Total absolute EE* measured as kcal; *Estimated total EE* measured as METscore/kg/cycling hrs; *Relative EE per trip* measured as kcal/kg/km; *Total relative total EE* measured as kcal/kg; *Working time with EE greater than 6METs* measured as minutes; *MET-minutes* measured as METscore/mins; *Hr* measured in beats per minute (bpm); *Blood lactate* measured in mmol/l.

Appendix 3.7. Additional physical activity outcomes measured in longitudinal studies

Study	Outcomes	Results, mean, SD, (*95% CI)*						
		Intervention			Control			
		During intervention	Pre	Post	During Intervention	Pre	Post	p-value
	Median (IQR)	E-bike			Walking			
Cooper, 2018	Total distance	383.5 (103.0, 738.3)						NC
	Men	456.0 (379.0, 1395.0)						
	Women	111.0 (73.0, 252.0)						
	Weekly distance	21.4 (5.5, 37.7)						NC
	Men	23.1 (21.3, 72.9)						
	Women	6.2 (5.5, 14.9)						
	Mean number journeys per week testing week	4.5 (3.3)			1.0 (1.1)			
	Mean ride distance on testing week	7.5 (4.2)			1.0 (1.1)			NA
	Mean ride duration testing week	26.6 (12.6)			16.0 (17.2)			NA
		E-bike			No activity			
De Geus, 2013	Average distance per day[a]	15.5 (4.6)						
	Total distance[a]							
	Men	405.1 (156)						
	Women	246 (116.3)						0.019
	Mean ride frequency per week							
	Men	4.1 (1.7)						
	Women	2.9 (1.0						0.065
	Absolute power at blood lactate 2mmol/l							
	Men		94.6 (28.2)	121.6 (35.4)		96.4 (43.1)	94.6 (28.2)	.0604, >.0.025 No activity
	Women		80.7 (22.3)	106.1 (29.7)		72.7 (20.9)	80.7 (22.3)	0.001 e-bike, >.0.025 No activity
	Absolute power at blood lactate 4mmol/l							
	Men		151.1 (27.1)	174.0 (30.7)		149.1 (35.3)	151.1 (27.1)	<.0.025 e-bike >.0.025 No activity
	Women		117.2 (19.6)	135.1 (22.6)		113.4 (17.1)	117.2 (19.6)	<.0.025 e-bike >.0.025 No activity
		E-bike			CB			

Hochsmann, 2017	Total distance[a]	280.8 (101.6)			289.6 (131.5)			0.843
	Additional PA[a]	67.1 (66.8)			87.9 (78.7)			0.452
		E-bike						
Malnes, 2016	Average weekly distance	37.1 (21.0)						
	High Fitness	43.8 (16.4)						
	Low Fitness	36.1 (25.6)						0.472 H vs. L
	Average weekly duration	107.0 (62.0)						
	Time to exhaustion		11.4, (10.5, 12.4)	12.5, (11.4, 13.6)				0.069
	% gain - time to exhaustion							
	High Fitness			-2.5 (-22.3, 17.3)				0.561
	Low Fitness			14.3, (4.1, 24.5)				0.028
	Respiratory exchange ratio		1.3, (1.2, 1.3)	1.3, (1.2, 1.3)				0.272
	Ventilation		119.2, (106.2, 132.2)	119.8, (104.5, 134.7)				0.755
	Mean (Range)	**E-bike commute**			**Passive commute**			
Page, 2017	Average distance[a]	10.3 (5.6, 20.9)			17.1 (5.6, 29.1)			
	Average ride time[a]	6 (3, 8)			NA			
	Average frequency	1, 2			NA			
		E-bike						
Peterman, 2016[b]	Average ride time	58.5 (15.2)						
	Average distance	19.7 (8.8)						
	Average METh	5.2 (2.1)						
	Absolute mean EE per ride	420.1 (221.8)						

[a]self-report measures of activity, included to provide indication of activity level reported; [b] results reported for days in which cycling was prescribed (i.e., 3 days a week for at least 40-minutes)

CB=conventional bicycle; CI=confidence interval; EE=energy expenditure (measured in kcal); IQR=interquartile range; METh=metabolic equivalent hours; NA=not applicable; NC=not conducted; PA=physical activity measured in minutes per week; respiratory exchange ratio=ratio between amount of carbon dioxide produced and oxygen used; *Distance* (total and weekly) measured in kilometers; *Duration* (total and weekly) measured in minutes; *additional PA* measured in minutes; *time to exhaustion* measured in minutes; *MET-hours* measured as METscore/mins expressed in hours; *Absolute power* measured as Watts; *ventilation* measured in l/min; *Absolute mean EE per ride* measured as kcal.

Appendix 4.1

Journal of Transport & Health 19 (2020) 100910

Contents lists available at ScienceDirect

Journal of Transport & Health

journal homepage: http://www.elsevier.com/locate/jth

The impact of e-cycling on travel behaviour: A scoping review

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ARTICLE INFO

Keywords:
e-cycling
e-bikes
Active travel
Travel behaviour

ABSTRACT

Introduction: Electrically assisted bicycles (e-bikes) have become increasingly popular in the past decade. This review aimed to scope the literature to identify what is known about the frequency and duration of e-bike use, their impact on travel behaviour, the purposes for which e-bikes are used and factors associated with e-bike use. In addition, the review aimed to identify gaps in the literature and highlight future research priorities.
Methods: A scoping review of published and unpublished literature in any language. Relevant articles were identified through searching six databases, two grey literature platforms and reference lists. Searches were conducted until August 2019. Data were extracted using a standardised extraction form and descriptive and narrative results are provided.
Results: Seventy-six studies met the inclusion criteria. The volume of research has increased since 2017 and primarily examines personal e-bike use, as opposed to e-bike share/rental schemes or organizational e-bike initiatives. The use of e-bikes increased the frequency and duration of cycling compared to conventional cycling and may help overcome barriers associated with conventional cycling. The uptake in e-cycling largely substitutes for conventional cycling or private car journeys, though the degree of substitution depends on the primary transport mode prior to e-bike acquisition. E-bikes are primarily used for utilitarian reasons, though older adults also engage in recreational e-cycling. Research priorities include quantitatively examining e-bike use, their impact on overall transport behaviour and identifying determinants of e-cycling to inform intervention and policy.
Conclusions: This review suggests that the personal use of e-bikes is associated with a reduction in motorized vehicle use, which has potential positive impacts on the environment and health. The impacts of e-bike share schemes and workplace initiatives are less well understood. Evidence describing the purposes for which e-bikes are used, and the factors associated with usage, are useful to inform e-cycling promotion policy.

1. Introduction

Travel is an essential part of everyday life for most people. Motorized road travel is a major use of energy, creating air pollution and

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https://doi.org/10.1016/j.jth.2020.100910
Received 27 October 2019; Received in revised form 23 June 2020; Accepted 8 July 2020
Available online 29 August 2020

contributing to global warming (Fuglestvedt et al., 2008). Vehicles in congestion emit more pollution than free-flowing traffic (Zhang et al., 2011), which is of concern given that traffic levels, and associated congestion, are expected to rise in many developed countries including the UK (Department for Transport, 2018a), Europe (European Commission, 2019), Australia (Bitre, 2015b) and the United States (Federal Highways Administration, 2020).

Adoption of active travel, such as walking and cycling, may contribute to reducing congestion, greenhouse gas emissions and air pollution, while also having a positive impact on health through increased physical activity (Woodcock et al., 2009; Neves and Brand, 2019). Consequently, understanding ways to increase active travel is important to transport policy makers, urban planners and health care professionals (Laird et al., 2018). Furthermore, active travel has been highlighted as a means of reducing public transport use and the associated potential transmission of covid-19 and is being actively encouraged by the UK government (Department for Transport, 2020).

However, public engagement in active travel, in particular cycling, is often low (Cavill et al., 2019; Strain et al., 2016; Buehler and Pucher, 2012). In Europe 12% of 27,680 individuals across 28 member states reported cycling every day (European Commission, 2013). However, large variations in reported cycling exist in Europe with Spain (4%), Luxembourg (4%), and England (2%) reporting the lowest rates of daily cycling while the Netherlands (43%), Denmark (30%) and Finland (28%) reported the highest rates of daily cycling (European Commission, 2013). Specifically, in England in 2017 26% of yearly trips were made on foot and 2% on bicycle, accounting for 3% of total distance travelled (Department for Transport, 2018b). In the United States fewer than 3% and 1% of the population commuted to work on foot or by bike respectively (League of Amercian Bicyclists, 2019). Commonly reported barriers to active travel include the distance people must travel, lack of time, hilly terrain, and the undesirability of being out of breath or sweaty when arriving at a destination (De Geus et al., 2018; Van Cauwenberg et al., 2018a).

Electrically assisted bicycles (e-bikes) are a more environmentally friendly and sustainable mode of transportation than motorized vehicles, while providing at least moderate intensity physical activity (Bourne et al., 2018). The term e-bike includes a range of designs including solely throttle-controlled bikes, which do not require the rider to pedal or those which provide electrical assistance only when the rider is pedalling. E-bikes which require the user to pedal have lower motor power and maximum speeds compared to throttle-controlled bikes and are therefore legally classified as bicycles (Fishman and Cherry, 2016). Such bikes enable the user to maintain speed with less effort, overcoming some of the barriers to traditional cycling (Fishman and Cherry, 2016) and may encourage individuals to participate in active travel in place of motorized travel. For this review we consider only e-bikes that require the user to pedal for assistance to be provided.

E-cycling is increasingly popular, with 40.3 million e-bikes expected to be sold globally in 2023 (Statista, 2015). With this rise in popularity it is important for authorities to understand where e-cycling fits within current mobility patterns. This will assist in decision-making regarding investment in e-cycling infrastructure and help determine whether strategies to promote e-cycling are appropriate. It is also important to ascertain whether adoption of e-cycling impacts the sedentary behaviour of motorized vehicle use by replacing some car journeys, potentially reducing both motor vehicle congestion and pollution. In contrast, if e-cycling replaces conventional cycling and walking therefore representing a distraction from the improvement of current cycling and walking infrastructure and initiatives that may increase active travel.

An individual's transport mode choice depends on the travel need (e.g., commuting, shopping, escorting children) and specific trip attributes (including distance, location and time requirements (Götschi et al., 2017)). It is therefore important to understand how e-bikes are used (regarding distances travelled and duration of rides) and the purpose of their use to understand the contexts in which e-bikes could be incorporated into current travel systems.

In addition to objective travel choices, the decision to engage in e-cycling is likely to be determined by a series of perceptions regarding the individual and the environment. As such studies have begun to explore motivation for e-cycling and experiences of engaging in e-cycling to understand why individuals engage in this activity (Fishman and Cherry, 2016). To date, however, review evidence exploring the factors associated with e-cycling, and how engaging in e-cycling impacts travel behaviour, has not been conducted. Collectively, this information is important to guide future planning initiatives and health promotion campaigns.

A review of the literature will help to map the available evidence to document our current knowledge of how e-bikes are used (i.e., frequency and duration of e-cycling), the purposes for which e-bikes are used, their impact on travel behaviour and to identify potential determinants of e-bike use. In addition, a review will help identify gaps in the literature and highlight future research priorities.

2. Methods

A scoping review was selected as the most appropriate review method for addressing the research aims (Peterson et al., 2017, Grant and Booth, 2009). The 5-stage methodological framework proposed by Arksey and O'malley (2005) and developed by Levac, Colquhoun & O'Brien (2010) was adopted to guide this scoping review. Reporting of the scoping review followed the PRISMA Extension for Scoping Reviews guidelines (Tricco et al., 2018).

2.1. Stage 1: identifying the research question

A number of research questions were formulated to summarise the evidence. From the existing literature this review will determine:

- What is known about the frequency and duration of journeys made by e-bike?
- What is known about the purpose of e-bike use?

- What is known about the impact of e-bike use on overall travel behaviour?
- What is known about individual's motivation for e-cycling, experiences of engaging in e-cycling (specifically barriers and benefits to engaging in e-cycling) and general attitudes towards e-bikes and e-cycling?
- What are the current evidence gaps and research priorities?

2.2. Stage 2: identifying relevant studies

2.2.1. Identify relevant outcomes

The review included studies that provided data/results relevant to any of the research aims or questions. This included self-report or objective measures of the impact of having access to an e-bike on the use of the e-bike, and alternative modes of transport and the purpose of e-bike trips (e.g., recreation, commuting, errands etc.). In addition, outcomes related to the motives for e-cycling, experiences of engaging in e-cycling and general attitudes towards e-bikes and e-cycling were included. Studies that reported future preferences for e-cycling, without having had access to an e-bike were not included as these data would not assess actual impact.

2.2.2. Types of sources

Peer-reviewed primary research including both experimental and non-experimental studies, including cross-sectional and longitudinal quantitative and qualitative studies were considered for inclusion. Theses (PhD, MSc, MPhil or BSc), project reports or presentations and conference proceedings were considered for inclusion. Review articles were screened for appropriate references but not included in the review. Studies published in any language were considered. Editorials, opinion pieces and commentaries were not included.

2.2.3. Types of participants

Studies with adults over 18 years of age, healthy or with long-term health conditions were included. Eligible adult participants were owners of an e-bike or had regular access to an e-bike (e.g., were part of an e-bike sharing scheme, rented an e-bike or were provided with an e-bike as part of an intervention).

2.2.4. Context

Only studies of e-bikes that had pedals and were operated in part by the individual (i.e., some amount of energy, above resting metabolic rate, must be expended when cycling) were included. Studies including e-bikes operated solely by a motor, not requiring pedalling, were excluded.

2.2.5. Search strategy

The following databases were searched from 1989 (the date the first e-bike was produced) to the present day: Elsevier ScienceDirect, ISS Web of Science, ProQuest, EMBASE, MEDLINE (via Ovid) and Scopus. Search terms pertained to e-bikes only to keep the search as broad as possible. A list of search terms is provided in supplementary file 1. OpenGrey and Google Scholar (first 20-pages) were searched using the term '*electrically-assisted bicycle*'. The reference lists from all selected articles were hand-searched for relevant studies. Searches were run up to August 2019.

2.3. Stage 3: study selection

All identified records were uploaded to the online software Covidence (https://www.covidence.org). Duplicate publications were removed, and two reviewers (JEB and ARC) then independently conducted title and abstract screening. These reviewers met following completion of 20% and 50% of screening to assess agreement. Full texts were sourced, and when required, translation was conducted by individuals fluent in reading and speaking the required language in addition to English. Full-text screening was conducted independently by two reviewers (JEB and CE) who met at 25% and 50% of full text screening to assess agreement. Where findings from conference proceedings were superseded by a project report or published literature data from the earlier conference proceeding was not reported.

Scoping reviews are typically iterative given the increased familiarity of the researchers with the evidence as the review progresses (Arksey and O'malley, 2005). In the current review much of the evidence failed to report on the characteristics of the e-bikes being investigated. In North America and Europe, the predominant e-bike design has pedals and the rider must pedal for power to be provided. In China, however, e-bikes are predominantly throttle powered and do not require pedalling (Fishman and Cherry, 2016). As such, unless specifically stating the type of e-bike used, studies conducted in Europe and North America were included, while those conducted in China were excluded.

2.4. Stage 4: charting the data

A data extraction chart was created and reviewed by all authors prior to data extraction. The following data were extracted from each article: author(s), year and type of publication, location, study aims, study design, study methodology, sample size and characteristics, outcomes measured and key findings. Data extraction was conducted by two reviewers in a stepwise fashion. Specifically, JEB extracted data from 100% of included studies and FJK then extracted data from 25% of these studies to check for accuracy. Any discrepancies were discussed and resolved.

2.5. Stage 5: collating, summarizing, and reporting the results

A descriptive analysis was conducted to provide information on the volume of included studies by year of publication, location of study, study methodology and outcomes examined. Where behavioural outcomes were examined using qualitative methods these results were incorporated into a descriptive summary. For motivation, experience and attitude outcomes examined using qualitative methods, information was characterised by identifying the main themes reported by authors. Common themes across studies are presented. The review of qualitative research to identify the main themes was conducted by two reviewers (JEB and FJK), and a narrative summary is provided for each outcome reviewed. The meaning of the findings in relation to the overall research question and the broader implications for research, policy and practice is discussed, including identification of relevant evidence gaps and priorities.

3. Results

3.1. Articles retrieved

In total 4043 records were identified from database and grey literature searches. After duplicates were removed 2841 records remained and underwent title and abstract screening (see Fig. 1 for review flow diagram). A total of 181 articles underwent full test screening. Of these, 61 articles were considered relevant to the aims and were included in the review. Reference lists of eligible studies were searched, and an additional 16 articles were identified for inclusion in the review. Of the 77 articles for inclusion in the review one could not be sourced (Wright, 2013), leaving 76 for inclusion in the analysis.

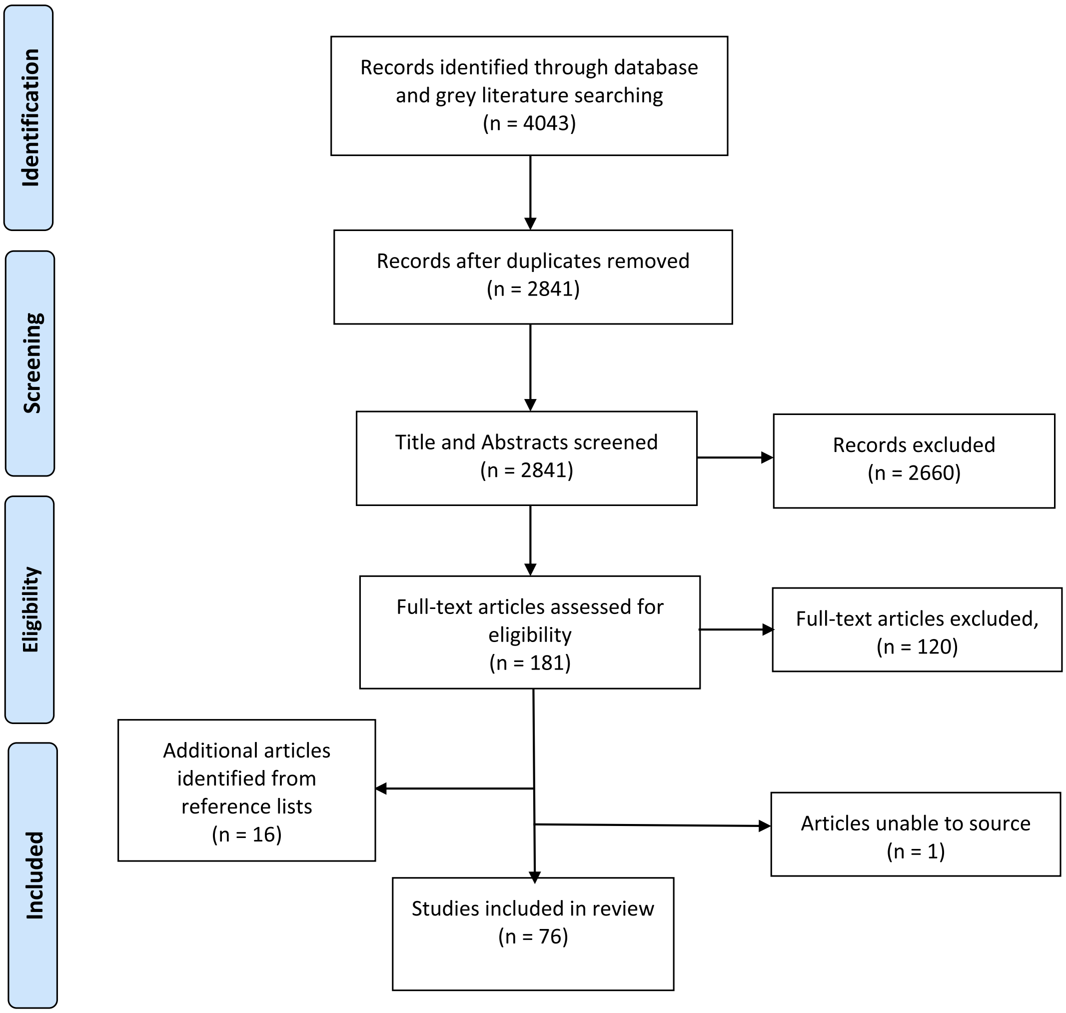

Fig. 1. Flow diagram of scoping review article identification.

3.2. Article characteristics

Articles were identified from 17 countries. A total of 80.3% of the articles originated from Europe (n = 61), 17.1% from North America (n = 13) and 2.6% from Australia and New Zealand (n = 2). Five articles (6.6%) were published between 2003 and 2010, all of which originated from Europe, with the remaining articles (93.4%) published from 2011 onwards. Fig. 2 shows the chronological increase in papers reporting relevant outcomes from 2003 to August 2019.

Of the 76 articles, 48 were peer-reviewed research papers, drawn from 40 studies and 28 were from grey literature. Most of the peer-reviewed research has been published in transport related journals (see Table 1) and has increased substantially since 2017 (see Fig. 2). The grey literature comprised five published conference proceedings, four theses, 17 project reports and two project presentations. Of the 68 unique studies identified 40 had a non-experimental design (30 cross-sectional, 10 longitudinal) and 28 were experimental. Most studies (n = 65) examined outcomes associated with personal e-bike use. Eight studies examined the impact of e-bike share or rental schemes and three studies examined workplace e-bike initiatives.

Non-experimental studies: Findings from non-experimental studies on personal e-bike use (n = 31) are reported in supplementary file 2. One study examined the experiences of students' use of e-bikes and two explored e-cycling in older adults. The remaining studies did not specify participants age; however, demographic data showed that most e-bike users were ≥40 years of age. The percentage of female e-bike users in the studies ranged from 15 to 56%. A 2014 survey of e-bike owners in USA reported 15% of the sample were female (MacArthur et al., 2014). When the survey was repeated in 2018, 28% of the sample were female (MacArthur et al., 2018). Samples sizes ranged from 11 to 1796. Nine studies compared e-bike use to conventional bike use. Non-experimental studies from e-bike rental/share schemes (n = 8) and workplace e-bike initiatives (n = 1) are reported in supplementary files 3 and 4, respectively.

Experimental studies: The populations targeted by experimental studies examining personal e-bike use (n = 26) were highly heterogenous (see supplementary file 5). Populations studied included university staff and students (n = 3), university students exclusively (n = 1), older adults (n = 1), inactive adults (n = 4), individuals with type 2 diabetes mellitus (n = 1), stroke survivors (n = 1), company employees (n = 4), commuters (n = 4) and parents (n = 1). Two studies provided families with electric vehicles on loan with the inclusion of e-bikes (Cellina et al., 2016; Kroyer and Johansson, 2013). One study required participants to hand over the keys to their motor vehicle in exchange for an e-bike (Moser et al., 2018). E-bike loan periods varied in length from one day to three years. The percentage of females in experimental studies ranged from 0 to 80% and sample sizes ranged from three to 1854. Experimental studies from workplace e-bike initiatives (n = 2) are reported in supplementary file 4.

3.3. What is known about the frequency and duration of e-bike use?

Sixty-one studies (80%) reported e-bike use following the acquisition of an e-bike. E-bike use was primarily measured using self-report online or paper questionnaires. Four non-experimental studies recorded e-bike use using GPS tracking and three with travel logs. Ten experimental studies used GPS tracking or bicycle odometer measurements and eight used travel logs including smartphone applications. The types of e-bike use outcomes reported were highly heterogenous with varying time scales and distance measurements reported.

Reported mean daily distances travelled on the e-bike ranged from 2.7 km to 24.0 km, with the majority of studies (n = 20) reporting mean daily distances between 3 km and 11.5 km. Frequency of e-bike use ranged from 1.9 to 5.1 days per week. Haustein and Møller (2016a) reported that recreational riders cycled further distances per trip compared to those that used the e-bike for utilitarian purposes (e.g., commuting, shopping, running errands). While Winslott Hiselius and Svensson (2017) reported that e-bikes were used for commuting on 3.6 days per week and for leisure on 1.4 days per week.

Participants cycled longer distances on an e-bike compared to a conventional bike. In a randomized controlled trial in which adults had access to an e-bike or conventional bike for 3-months the median distance cycled per week on the e-bike was 20.2 km compared to 11.9 km on the conventional bike, with individuals spending longer on the e-bike (62.7 min) compared to the conventional bike (51.1 min (Bjørnarå et al., 2019)). Similarly, in a study conducted in seven European countries, Castro et al. (2019) reported that e-cyclists average daily travel distance was 8.0 km compared to 5.3 km for conventional bike commuters. In addition, individual trip distances and duration of rides on e-bikes were longer than those on a conventional bike (Castro et al., 2019, Mobiel 21, 2014). In a number of studies participants also self-reported increases in cycling frequency and/or duration following the acquisition of an e-bike (Dill and Rose, 2012; Hendriksen et al., 2008; Kroyer and Johansson, 2013; Fyhri et al., 2017, MacArthur et al., 2018).

The majority of evidence suggested that men ride an e-bike more frequently and further than women (Cooper et al., 2018; Bundesamt für Umwelt, 2004; Van Cauwenberg et al., 2018; De Geus et al., 2013; De Kruijf et al., 2018; Jahre et al., 2019). However, Cappelle (2003) found that women (mean age = 46 years) cycled more frequently than men, while Castro et al. (2019) reported that more women were e-bike and conventional bike users than men in a sample of similar age.

Few studies have compared e-cycling between different age groups, of those that have the evidence suggested that younger adults cycled longer distances than older adults (Bundesamt für Umwelt, 2004) and that as age increases there is a decrease in e-bike use (Kroesen, 2017).

In the workplace, e-bikes were used for work travel by employees in the two studies that provided e-bikes as company transport (Prill, 2015; Kroyer and Johansson, 2013). When e-cargo bikes were introduced as a replacement for conventional bikes or cars/vans in a 2-year trial, 147 of 362 messengers rejected the adoption of the bike, with 48.3% reporting a preference to use the car or van (Gruber and Kihm, 2016).

Six of the eight studies examining e-bike rental/share schemes reported e-bike use. Distances covered on the e-bikes ranged from 2 to 10 km. In the two studies that compared e-bike to conventional bike share, the authors reported that individuals travelled further on

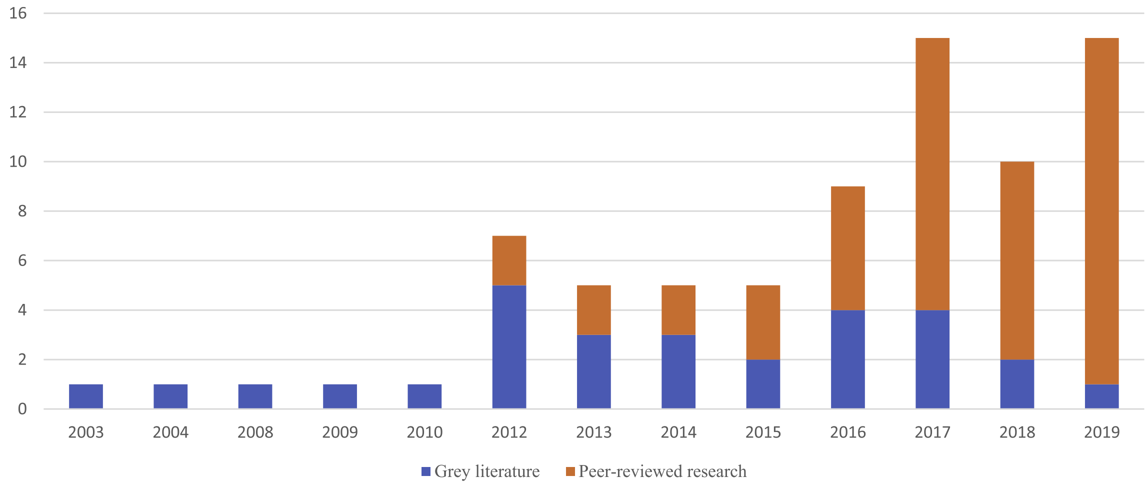

Fig. 2. Included studies by year of publication and article type.

Table 1
List of journals in which primary literature has been published.

Journal	Number of articles published
Acta Kinesiologiae Universitatis Tartuenis	1
British Journal of General Practice Open	1
BMC Public Health	1
Clinical Journal of Sport Medicine	1
Diabetic Medicine	1
Environmental Research Letters	1
European Journal of Applied Physiology	1
European Journal of Sport Science	1
Frontiers in Psychology	1
International Journal of Sustainable Transportation	3
International Transportation	1
Journal of Advanced Transportation	2
Journal of Adventure Education and Outdoor Learning	1
Journal of Cleaner Production	1
Journal of Transport and Health	3
Journal of Transport Geography	2
Medicine and Science in Sport and Exercise	1
Mobilities	1
PLOSone	2
Preventive Medicine Reports	1
Sustainability	2
The Canadian Geographer	1
Transportation Research Record	1
Transportation	1
Transportation Research Interdisciplinary Perspective	1
Transportation Research Part A	3
Transportation Research Part D	3
Transportation Research Part F	1
Transportation Research Procedia	1
Transportation Research Record, Journal of the Transportation Research Board	4
Travel Behaviour and Society	3

the e-bike than they did on a conventional bike (Langford et al., 2013; Bikeplus, 2016).

3.4. What is known about the purpose of e-bike use?

Forty-one studies (54%) reported on the purpose of e-bike use using mostly self-reported retrospective measures including questionnaires and travel diaries. E-bikes were used for a wide range of purposes including commuting, shopping, visiting friends and family and recreation. However, e-bikes appear to be used more frequently as a utilitarian mode of transport rather than for a leisure activity. Studies with samples aged ≤55years reported the e-bike being used primarily for commuting (Dill and Rose, 2012; Winslott Hiselius and Svensson, 2017; MacArthur et al., 2014; Plazier et al., 2017a; Popovich et al., 2014; Schleinitz et al., 2014; Cappelle et al., 2003; Kairos, 2010; MacArthur et al., 2018; Lobben et al., 2019; Behrendt, 2018; Sundfør and Fyhri, 2017) whilst older adults used the e-bike for shopping and visiting friends but rarely for commuting. In addition, older adults used the e-bike for recreational purposes. Whether e-bikes were primarily used for recreation or running errands in older adults varied across studies (Hendriksen et al., 2008; Van Cauwenberg et al., 2018; Johnson and Rose, 2015; Leyland et al., 2019; Wolf and Seebauer, 2014). Few studies have examined how the purpose of e-bike use differs between genders. Among older adults Van Cauwenberg et al. (2018) reported that women used the e-bike for more social visits than men.

In the workplace e-bikes were used for commuting, travelling between offices and to meet customers (Kroyer and Johansson, 2013; Prill, 2015). Of the three studies that examined the purpose of using an e-bike share scheme uses varied and included shopping, running errands, commuting to work or school or for recreation (Munkacsy and Monzon, 2017; Langford et al., 2013; He et al., 2019).

3.5. What is known about the impact of e-bikes on travel behaviour?

Forty-two studies (55%) examined the impact of e-bike use on other travel modes. The degree to which e-bikes replaced alternative transport modes varied across studies. However, the evidence suggests that the car and conventional bicycle were the most substituted modes of transport following acquisition of the e-bike.

The proportion of e-bike trips previously conducted by conventional bicycles ranged from 23% to 72% of total trips. Among older adults Van Cauwenberg et al. (2018) reported that 72% of conventional bike trips were replaced by the e-bike, with those who were conventional cyclists prior to acquisition of an e-bike reporting greater e-bike substitution than non-cyclists (Johnson and Rose, 2015).

The proportion of car journeys substituted following acquisition of an e-bike ranged from 20% to 86%, with three studies reporting the substitution of short car journeys with the e-bike[1] (Lee et al., 2015; Edge et al., 2018; Kroyer and Johansson, 2013). E-bikes also substituted for public transport with the proportion of journey substitution ranging from 3% to 45%. Few studies have found e-cycling to impact walking with the exception of one study conducted in the UK in which low levels of driving and high levels of walking were reported prior to the provision of e-bikes compared to the rest of the country (Cairns et al., 2017). In this study 38% of the sample reported a reduction in walking following the acquisition of an e-bike. Castro et al. (2019) note that the impact of the e-bike on travel behaviour is largely influenced by the primary mode of travel prior to the introduction of the e-bike. Specifically, in Antwerp e-bikes primarily substituted for conventional bike journeys (34%) and private car journeys (38%), while in Zurich, the e-bike primarily substituted for public transport journeys (22%). Across the 7 cities the authors reported that the degree of substitution of car, conventional bike or public transport journeys was 2–49%, 5–60% and 6–35% respectively. The mode of transport being substituted was still used extensively in addition to the e-bike. Winslott Hiselius and Svensson (2017) reported that the impact of e-bikes on travel behaviour differed between rural and urban areas of Sweden. In rural areas the e-bike substituted 71–86% of car trips compared to 42–60% of car trips in urban areas. In urban areas the e-bike also substituted for conventional cycling and public transport. No studies have examined the differential impact of e-bike use on travel behaviour based on gender.

In the workplace e-bikes replaced car journeys or conventional cycling (Prill, 2015; Kroyer and Johansson, 2013). Regarding e-bike share or rental schemes on university campus 57% of walking trips were substituted with the e-bike (Langford et al., 2013), while in Madrid e-bikes substituted similarly for public transport and walking, the primary modes of city travel (Munkacsy and Monzon, 2017). In the UK 11 bike share projects, Bikeplus (2016) reported that e-bike trips primarily substituted for car trips, the primary mode of transport in UK cities (Department for Transport, 2019b).

3.6. What is known about e-cyclists motivation for e-cycling?

Twenty-eight studies (37%) examined participants' motivation for riding or purchasing an e-bike. Motivation for using or purchasing an e-bike was commonly reported in relation to overcoming barriers to conventional cycling. These included the ability to overcome hilly terrain, to ride with less effort and to complete longer and/or faster trips. The ability to reduce travel time was an important motivational factor for younger adults. In addition, younger adults were more motivated to use an e-bike due to environmental concerns, to reduce car use and to save money compared to older adults. Older adults were motivated to e-cycle as it provided them with the ability to continue to ride despite physical limitations and the potential to maintain or increase physical activity and fitness. Few studies examined differences in motivational factors between genders. However, MacArthur and colleagues (2014, 2018) reported that females were more likely to buy an e-bike to overcome hilly terrain and to ride with friends and family compared to men.

In the workplace, motivation for e-cycling included sustainability and better mobility around the city (Prill, 2015) and a preference for e-cycling over using the car or conventional bicycle (Kroyer and Johansson, 2013). Of the two studies that reported on motivation for using e-bike share schemes, the primary motivation for use was that e-cycling was faster than alternative transport modes, thereby reducing travel time and being more convenient (Langford et al., 2013; Bikeplus, 2016).

[1] These studies do not provide a definition of what constitutes a short car journey.

3.7. What is known about the experience of engaging in e-cycling?

3.7.1. Benefits of e-cycling

Forty-three studies (57%) explored participants reported benefits of e-cycling. Table 2 provides an overview of the reported individual, social and physical benefits of e-cycling. Participants discussed the benefits of e-cycling in comparison to other transport modes. Specifically, e-cycling required less physical effort than conventional cycling due to the assistance provided and was associated with reduced perspiration. The extra assistance, and reduced effort, enabled participants to travel longer distances and/or decrease their travel time in comparison to conventional cycling. E-bike users were able to ride hilly terrain and take more direct routes to their destination. E-cyclists felt safer and more confident riding an e-bike on busier streets in comparison to a conventional bike due to the ability to keep up with traffic and accelerate faster at traffic lights. E-cycling saved time compared to the car or conventional bike and was perceived as being less restricted by parking or congestion compared to motorized transport.

The e-bike enabled individuals who cannot ride a conventional bicycle to begin riding or who were considering giving up conventional cycling to continue riding. The only reported social benefit of riding an e-bike was the ability to ride with friends and family. Specifically, e-bikes removed differences in riding abilities due to fitness or physical limitations between riders enabling unfit individuals to keep up with fitter individuals riding a conventional bike. The enjoyment and fun associated with e-cycling was the most consistently reported benefit across all studies.

Few studies examined differences in perceived benefits of e-cycling based on age or gender. Van Cauwenberg et al. (2018) found no differences in reported benefits of e-cycling between older men and women. Regarding age, in three studies that focused exclusively on older adults (Van Cauwenberg et al., 2018; Johnson and Rose, 2015; Leger et al., 2019) the ability to cycle longer distances was a consistently reported benefit. In studies with younger samples (i.e., 40–60 years of age) the time savings accrued from e-cycling, in comparison to conventional cycling and a car was a common benefit, with e-cycling providing more predictable journey times.

Similar benefits of e-cycling were reported in workplace initiatives. In addition, participants reported greater autonomy in comparison to travelling by public transport or carpooling and the e-bike enabled easier access around the city, avoiding parking problems (Prill, 2015; Kroyer and Johansson, 2013). In Madrid, the e-bike share scheme provided a faster and more economical mode of transport in comparison to walking or public transport (Munkacsy and Monzon, 2017). In a rental scheme in the UK, e-bikes provided participants the opportunity to ride with friends and family and those of higher fitness levels than themselves (Sustrans, 2013).

3.7.2. Barriers to e-cycling

Thirty-seven studies (49%) explored participants barriers to e-cycling. Most of the barriers reported related to the e-bike itself or the

Table 2
Benefits of e-cycling, (the number in brackets represents the number of studies reporting that specific benefit).

Individual	Social	Physical	
Fun/enjoyment (21)	Ability to ride with friends and family (12)	Ability to ride longer distances than conventional bicycle (20)	Most commonly reported
Reduced perspiration in comparison to conventional cycling (15)		Faster journeys compared to conventional cycling, walking and sometimes cars (18)	
Reduced overall effort in comparison to conventional cycling (12)		Ability to ride hilly terrain (12)	
Improved health (physical and mental) (9)		Time saving in comparison to conventional bicycle or car (8)	
Ability to continue to cycle despite physical limitations (8)		Ability to ride new routes and to new destinations due to speed and less impact from terrain (9)	
Increased feelings of safety in comparison to conventional cycling (6)		Ability to carry heavier loads (17)	
Increased physical activity (6)		Lower environmental impact (9)	
Increased confidence riding in traffic compared to conventional cycling (5)		Ability to combat weather conditions compared to conventional cycling; less impact from wind (7)	
Increased feelings of autonomy over travel in comparison to public transport or car (2)		Cost savings (6)	
		Less concern regarding parking or traffic (3)	Least commonly reported
		Ease of use (3)	

environment (see Table 3). Regarding the environment e-bike users felt unsafe riding with motor vehicles due to risk of accidents. In addition, users were concerned about riding alongside conventional cyclists and pedestrians due to potential conflict. Lack of, or poorly maintained, cycling infrastructure exacerbated these safety concerns. For individuals commuting into the city, lack of charging or parking facilities were barriers to riding. The weather, particularly rain, was a commonly reported barrier to e-cycling.

Regarding the e-bike, users felt anxious about the distance they could travel before the battery ran out of charge. Cycling the e-bike without power was not seen as favourable due to the weight of the bike that made it difficult to lift onto cars or public transport and to make repairs. Weight of the e-bike was a greater concern for older adults and women. E-bike users also reported that technical problems were hard to repair themselves or expensive if requiring a mechanic. Maintenance was the most commonly reported barrier to e-cycling for individuals who rode to commute or run errands, while issues with battery life were the greatest concern for recreational cyclists (Haustein and Møller, 2016a). The cost of buying an e-bike and replacing batteries was a barrier to some users, particularly younger adults. Due to the high value of e-bikes users were concerned about theft and therefore carried their e-bike batteries with them when not on the bike.

E-bike users highlighted a general perception of e-bikes being for lazy or overweight individuals and were worried about being judged by others. Younger adults, of working age and who were accustomed to conventional cycling were more likely to report this barrier than older adults. Similarly, the reduced physical activity when e-cycling, compared to conventional cycling, was a barrier for younger individuals.

Some differences in e-cycling barriers were reported across countries. Specifically, in the Netherlands conflict with other cyclists was a barrier to e-cycling, while in the UK the lack of cycling infrastructure and poor parking facilities were commonly reported barriers (Jones et al., 2016).

Prill (2015) reported similar barriers to e-bike use in their workplace e-bike initiative. In addition, if participants had multiple appointments to attend the e-bike was not seen as appropriate. Participants in Malmo, Sweden reported that e-bikes were not well maintained by the organization and batteries were left uncharged (Kroyer and Johansson, 2013). Regarding e-bike share schemes, barriers were similar to those reported for personal e-bike use. In Madrid, uses believed that the geographical coverage of the e-bike share scheme was a barrier to use (Munkacsy and Monzon, 2017). For some users the cost of the schemes were prohibitive to use (Munkacsy and Monzon, 2017; Sustrans, 2013).

3.7.3. *What is known about general attitudes towards e-bikes and e-cycling?*

Overall participants were satisfied with the experience of e-cycling. de Kruijf and colleagues (2019) reported that when e-cycling is perceived as less strenuous it is associated with greater satisfaction, which relates to greater frequency of e-cycling. Dissatisfaction with e-cycling derived from environmental concerns due to poor cycling infrastructure and parking facilities and factors related to the e-bike itself which included poor range and the weight of the e-bike.

Prior to riding an e-bike there was a degree of scepticism associated with e-cycling and a judgement regarding the members of the

Table 3
Barriers to e-cycling, (the number in brackets represents the number of studies reporting that specific barrier).2

Individual	Social	Physical		
		Environmental	E-bike specific	
Less physical effort and activity than conventional cycling (5)	Theft concerns (15)	**Safety concerns** • riding in car traffic (17) • riding with conventional bicycles and pedestrians (6)	**Battery concerns** • Range anxiety (19) • Charging issues: Remembering to charge, not practical, time (5) • Heavy/awkward to carry (3) • Battery life not as long as proposed by manufacturer (2)	Most commonly reported ↑
Getting too sweaty (2)	Social stigma, e-bikes as cheating (8)	**Cycling infrastructure** • Lack of/poor maintenance of cycle lanes (11) • lack of charging stations (2) • lack of parking facilities (3)	**Cost** • E-bike itself (14) • Replacing battery (3)	
Fear of falling (1)	Regulation over where e-bike can be used (3) – North America specific	Weather (especially rain) (13)	**Weight** • Of e-bike (17) • Riding when battery dead (5)	
Unable to ride due to health (1)		Hard to integrate with public transport (2)	Hard and expensive to repair and maintain, technical difficulties (14)	
		Hard to integrate multiple destinations, easier and faster by car (2)	**Design of e-bikes** • Limited load capacity (4) • Too few gears (2) • Gear box issues (1) • Not designed to carry children (1)	↓
		Time constraints, faster by car (2)	Too slow (5)	Least commonly reported
			Uncomfortable (4)	

population for whom e-bikes were designed for. Specifically, e-bikes were perceived as being for older, overweight or lazy adults. However, in one study elderly individuals perceived e-bikes as being for young, active individuals (Cappelle et al., 2003). These perceptions are dynamic with experimental studies reporting that attitudes towards e-bikes become more positive with increased use (Drage, 2012; Edge et al., 2018; Plazier et al., 2017b). Stromberg and colleagues (2016) report that their sample of previous conventional cyclists saw the e-bike as a mode of transportation and not a form of exercise. Similarly, Haustein and Møller (2016a) report that utilitarian e-cyclists appreciate the practically of e-cycling for daily transport and picking up children and shopping. Among e-bike share/rental schemes and workplace initiatives similar attitudes to e-bikes were reported.

4. Discussion

The current review aimed to understand what is known about how electrically assisted bicycles are used, the purpose of their use and their impact on travel behaviour. In addition, the review aimed to provide insight into the motivation for e-cycling, experiences of e-cycling and attitudes towards e-cycling to identify the potential mechanisms that promote or inhibit e-bike use.

4.1. E-cycling and travel behaviour

The evidence suggests that e-bikes increase the total frequency and distance travelled by bicycle and promote longer individual cycle trips, compared to a conventional bicycle. E-bikes appear to substitute for 23–72% of conventional bike journeys and 20%–86% of private cars journeys. While previous research has suggested that conventional bicycles can substitute for private car journeys (Brand et al., 2013; Goodman et al., 2013), the degree of substitution may not be as high as that seen for e-bikes, with Hatfield and Boufous (2016) reporting that recent conventional bicycle trips replaced 33% of car travel in a sample of Australian adults.

The degree to which e-bikes substitute for alternative transport modes largely depends on the primary mode of transport prior to the introduction of the e-bike (Castro et al., 2019; Cairns et al., 2017). Findings of the current review suggest that participants in cities with high levels of cycling often report a shift from conventional cycling, as well as car use, to e-cycling (Astegiano et al., 2017; Haustein and Møller, 2016a; Hendriksen et al., 2008; Lee et al., 2015; Paetz et al., 2012) while in cities or countries with low levels of cycling the primary transport shift is from car to e-bike (Johnson and Rose, 2015; Popovich et al., 2014, MacArthur et al., 2018). As such, interventions should be directed towards areas of high car use to have the most potent impact of population health and road traffic reduction. In many countries, including the UK, the USA, and Australia the majority of journeys are made by car and for relatively short distances (Department for Transport, 2019b; BITRE, 2015a; McGuckin N. and Fucci, 2018). In England, for example, 61% of all journeys are completed by car, of which 68% of these are less than 5 miles in length (Department for Transport, 2019b). These short car journeys have a higher impact on air pollution and carbon dioxide emissions per mile than longer journeys (De Nazelle et al., 2010). Given that most e-bike users travel approximately 7 miles per day, longer than the distance individuals report being willing to travel by conventional bicycle (Pooley et al., 2011), e-cycling could positively impact the environment through the replacement of motorized vehicle use to a greater extent than conventional cycling. For individuals substituting private motorized transport or public transport trips for e-bikes there is a significant increase in weekly energy expenditure, which could positively impact health (Castro et al., 2019).

While e-cycling substitutes for conventional cycling, individuals switching from conventional cycling to e-cycling still accrue enough physical activity to meet the current guidelines for significant health benefits, due to increased frequency and duration of e-cycling (Castro et al., 2019). Furthermore, individuals switching from conventional cycling to e-bikes may be prolonging their cycling engagement as physical limitations or health concerns mean these individuals consider replacing conventional cycling with car journeys. This is commonly reported among older adults (Johnson and Rose, 2015; Leger et al., 2019).

In the workplace, the evidence suggest that e-bikes hold potential to substitute for conventional bicycles or cars, however the decision to adopt an e-bike is highly dependent on work requirements and corporate support of maintenance. Research into the impact of e-bike share or rental schemes is increasing as more e-bikes are integrated into bikeshare systems (Fishman, 2016). Similar to the findings from conventional bike share schemes (Fishman, 2016), e-bikes substitute for a range of transport modes, including walking, public transport and cars, depending on the primary mode of transport in that city. The distance travelled with shared e-bikes is slightly lower than that for private e-bike use. This is not surprising given the bike share systems are introduced in prespecified geographical areas to reduce use of motorized vehicles and enable quick access from one area to another within this location. Therefore, they are bound by the constraints of the prespecified range in which the e-bikes can be used and serve a different purpose to private e-bike use.

4.2. What influences e-cycling?

Individuals engage in e-cycling due to a range of benefits that make e-bikes more appealing than conventional bicycles. These benefits also motivate individuals to purchase an e-bike and serve a specific travel demand, such as carrying more cargo, reducing travel times, or travelling further. Younger adults are largely motivated to ride e-bikes due to the environmental benefits and to reduce outgoings through decreased car use, while older adults are motivated to ride e-bikes due to potential health benefits. As such, future e-bike promotion campaigns should aim to target these populations with different messages, specific to these benefits. In countries with both high and low levels of cycling there was a social stigma associated with e-cycling (Behrendt, 2018; Boland, 2019; Jones et al., 2016; Leger et al., 2019; Dill and Rose, 2012; Paetz et al., 2012). This suggests even in areas with a positive cycling culture such as Portland (USA) and the Netherlands this positive perception may not currently extend to e-bikes which are perceived as being for lazy and/or overweight individuals. Given that social and cultural norms impact levels of cycling (Haustein et al., 2020), it is important that local authorities engage in initiatives to promote e-cycling as a 'normal' mode of transport. This could be achieved through the provision of e-bikes to individuals on trial periods as this review suggests that the negative perceptions of e-cycling often dissipate following engagement with e-cycling (Paetz et al., 2012; Drage, 2012; Edge et al., 2018; Plazier et al., 2017b). This strategy could help to normalise e-cycling and encourage e-bike sales.

The most frequently reported environmental barrier to e-cycling was concern regarding safety specifically when riding in motorized traffic or with vulnerable road users (i.e., pedestrians or conventional cyclists). In the current review there are contradictory results of how the speed associated with e-cycling impacts safety perceptions. Specifically, in some studies participants reported feeling safer riding an e-bike than a conventional bike due to an ability to keep up with traffic and avoid potential accidents (MacArthur and Kobel, 2017; Edge et al., 2018; Dill and Rose, 2012) while in other studies participants reported that the e-bikes speed created dangerous situations, therefore, negatively impacting safety perceptions (Jones et al., 2016; Gordon, 2012; Popovich et al., 2014; Plazier et al., 2018; Haustein and Møller, 2016b). Interestingly, it is the speed associated with e-cycling that contributes to increased excitement and confidence on an e-bike (Haustein and Møller, 2016b, MacArthur et al., 2018).

The speed, and use of infrastructure designed for motorized vehicles as opposed to shared pedestrian paths or cycles ways, has been reported to lead to more conflict between e-bikes and motorized vehicles than conventional bicycles (Dozza and Werneke, 2014; Dozza et al., 2016; Haustein and Møller, 2016b). Interviews with e-bike users in USA showed that e-cyclists were concerned that motor vehicles underestimated the speed of the e-bike due to an inability to distinguish the e-bike from a conventional bike (Popovich et al., 2014), this is supported by video analysis by Dozza et al. (2016) who suggest that while e-bikes look like conventional bicycles their increased speed means drivers have less time to see them or react to them. However, a recent study suggested that after controlling for the amount of cycling (therefore exposure to potential incidents) and age there is no difference in crash risks between conventional bicycles and e-bikes (Schepers et al., 2018).

Interestingly, regular e-bike users are less likely to report traffic incidents than individuals who use an e-bike for a limited period or have less experience (Haustein and Møller, 2016b). This suggests that experience may reduce likelihood of traffic incidents. In the current review e-bike owners tended to report fewer safety concerns than non-users (Simsekoglu and Klöckner, 2019b). Furthermore, countries with low levels of cycling such as Canada, the UK and, USA had more frequent reporting of barriers associated with safety due to poor infrastructure and riding with traffic than countries with high levels of cycling (Gordon, 2012; Haustein and Møller, 2016a; Jones et al., 2016; Leger et al., 2019; MacArthur et al., 2018; Popovich et al., 2014). It is therefore important that potential e-bike users are provided with training on how to safely ride and manoeuvre an e-bike in a low traffic environment to help build confidence and to reduce the likelihood of traffic incidents. Furthermore, local authorities should examine how they can best invest in e-cycling infrastructure to help reduce conflict between different road users.

Additional environmental barriers to e-cycling include poor cycling infrastructure, difficultly integrating bicycles with public transport and limited end of trip facilities. These are similar to the environmental barriers reported for conventional cycling (Heinen et al., 2010) and require collaboration between local authorities and organizations to help improve cycling infrastructure. Barriers specific to the e-bike, including the weight and battery life should be addressed through the provision of suitable e-cycling infrastructure such as charging stations and adapting public transport to incorporate e-bikes. E-bike manufacturers have an important role in streamlining e-bike technology and continuing to reduce the weight of e-bikes.

Overall, e-cycling was more common in men than women, a similar pattern to conventional cycling (Heinen et al., 2010). However, in the current review women were more likely to be e-bike owners than men (Kroesen, 2017). It is possible that women are encouraged to purchase an e-bike due to the anticipated benefits but are more fearful to ride it due to the lack of cycling infrastructure. In countries with high levels of cycling and good cycling infrastructure, such as the Netherlands and Denmark, the mode share of cycling is higher in women than men (Fishman et al., 2015; Haustein et al., 2020; Aldred et al., 2016). This was seen in one experimental study conducted

Table 4
Future research priorities for understanding e-bike use and travel behaviour.

Research priority	Why required
Objective measures of e-bike use and travel behaviour using GPS or smartphone tracking prior to and during e-bike access to quantify the impact of e-bikes on travel behaviour	Current evidence relies primarily on self-report, retrospective measures of travel behaviour
Longitudinal research to examine the causal impact of individual, social and physical determinants associated with e-bike use and travel behaviour	Current evidence provides a qualitative understanding of potential determinants of e-cycling. No studies have examined the individual, social and physical factors directly associated with e-bike use and travel behaviour through quantitative estimates
Research to examine the effect of e-bike availability on travel behaviour by age, sex and socio-economic status	Few studies have examined the impact of demographic outcomes on e-bike use, travel behaviour or the purpose of use
Experimental research to examine effects of e-bike availability on travel behaviour in individuals less familiar with e-cycling	Most of the research to date has been conducted with e-bike owners or those familiar with cycling. Individuals unaccustomed to e-cycling will likely display different patterns of use and possess different attitudes and experiences of e-cycling
Research to examine the potential of e-bikes to serve as company vehicles and replace cars or light goods vehicles for deliveries	Limited research in this area. This is an important area of research as 36% of all car journeys made in England in 2017 were for commuting or business purposes and light commercial vehicles were the faster growing motor vehicle in the UK in the last 25 years
Evaluation of the addition of e-bikes to bike share systems and their impact on alternative transport	Limited research in this area. It is important to ascertain whether the provision of these, more expensive products, is a valuable strategy to increase bike use

in Belgium in which women e-cycled 13% more than men (Cappelle et al., 2003). As such, with the provision of appropriate cycling infrastructure more women may be encouraged to ride an e-bike. E-bike use findings suggest that e-bikes are used more frequently for commuting to work compared to leisure use. However, the distance of commuting journeys is less than during leisure rides (Winslott Hiselius and Svensson, 2017; Haustein and Møller, 2016a). As such, the total distance ridden across a week maybe similar between leisure riders and commuters, but the pattern of use is different which may vary by life stage. For example, Hendriksen (2008) reported that individuals > 65years, mostly leisure riders, rode on average 25.3 km per week, while commuters rode 39.4 km per week. Interestingly, there were no differences in the purpose of e-bike use between countries with high or low levels of cycling. Understanding the purpose for which e-bikes are used is important for local and/or national policy decisions regarding active travel, including e-bike promotion campaigns and for the provision of e-bikes particularly where individuals do not own the e-bikes.

4.3. Research gaps and priorities

The study has identified several gaps in the current literature and provided future research priorities. These are outlined in detail in Table 4. Specifically, research priorities include a) conduct experimental research to examine the impact of adopting e-cycling on travel behaviour in non-cyclists; b) use objective measures to collect data on e-bike use and travel behaviour; c) conduct longitudinal research to examine the causal impact of individual, social and physical factors on e-bike use and travel behaviour; d) examine the extent to which e-bike availability impacts travel behaviour; e) examine the potential for e-bikes to serve as company vehicles and f) evaluate whether e-bike sharing systems impact alternative travel behaviour.

4.4. Implications for policy

The evidence presented suggests that e-cycling has the potential to positively impact the environment, through reduced motorized vehicle use, and individual health, through increased or prolonged cycling. As such, further discussion is required among local and national authorities and researchers to discuss whether the current evidence is strong enough to encourage the promotion of e-cycling as an alternative to motorized transport and to identify what further evidence maybe required to direct and inform policy. Experts should review the psychological factors associated with e-cycling reported here to prioritize schemes that can help to promote e-cycling and reduce motorized vehicle use in areas where motorized vehicle use is currently high.

4.5. Study strengths and limitations

This is the first review to comprehensively explore how e-bikes are used, their purpose of use and impact of travel behaviour and to identify the volume of this evidence. In addition, the review has documented the factors associated with e-cycling and identified key future research priorities. A key strength is the appropriateness of our methods to the research aims, allowing a broad and informative scope of a wide field of literature. In addition, we applied rigorous methods to (e.g. searching, screening, data extractions) and followed the established PRIMSA-ScR checklist.

There are, however, some limitations to consider. Scoping reviews are broad in nature and while they provide an overview of existing literature formal assessment of study quality is not conducted in a scoping review (Arksey and O'malley, 2005; Levac et al., 2010). This can make it difficult to determine the strength of the evidence being reported. In addition, while our search terms were broad it is possible that we missed some relevant articles. The authors decided to exclude studies conducted in China as most e-bikes in China do not require pedalling for assistance to be provided. This exclusion could have meant that some relevant studies were omitted.

Given the heterogeneity of outcomes reported it was not possible to quantitatively synthesize the literature, making comparisons between studies difficult. The authors have attempted to report the results in an objective way and provide sufficient detail for readers to draw conclusions regarding the evidence. Furthermore, when reviewing qualitative research, extraction of common themes was largely guided by the authors' interpretation of the findings and their identified themes. The themes may have been different to those identified by other qualitative researchers.

5. Conclusion

This scoping review identified 76 studies that examined the role of e-cycling on a variety of behavioural and psychological outcomes. The research consistently demonstrated that e-bikes serve to increase cycling frequency and duration and can substitute for motorized transportation particularly short car journeys. With half of all car journeys in the UK being between 1 and 5 miles in length (Department for Transport, 2019a) e-bikes represent a viable sustainable alternative means of transport for a large proportion of car journeys.

Funding information

This study is funded by the National Institute for Health Research Bristol Biomedical Research Centre (Nutrition theme) at University Hospitals Bristol and Weston NHS Foundation Trust and The University of Bristol.

Disclaimer: The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Declaration of competing interest

The authors declare that they have no competing interests.

Acknowledgements

The authors would like to thank Emma La Fontaine and Caroline Linnemann for their assistance in translating documents.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jth.2020.100910.

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Appendix 4.2 Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	62
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	N/A
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	62-63
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	64
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	N/A
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	65-66
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	66
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Appendix 4.3
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	66-67
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	67
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	67
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	N/A
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	67

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	Figure 4.1
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	68-70
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	Appendix 4.4 to 4.7
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	71-80
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	80-86
Limitations	20	Discuss the limitations of the scoping review process.	86-87
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	87
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	see Appendix 4.1

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document)

Appendix 4.3 Example search strategy used in the scoping review

1. pedelec*
2. electric* assist* bicyc*
3. electric* assist* bike*
4. electric* assist* cyc*
5. e-bike*
6. electric* bike*
7. electric* bicyc*
8. electric cyc*
9. pedal-assist electric* bike*
10. pedal-assist*
11. pedal-assist electric* bike
12. electrically-assist* bicyc*
13. electrically-assist* cyc*
14. electrically-assist* bike*
15. pedal-assist cyc*
16. electric mobil*

Appendix 4.4 Data extracted for each article reporting personal e-bike use for non-experimental studies

First author, year	Country, location	Participants	gender (%female); Age, years	Study design and methodology	Outcomes examined	Key findings
Arsenio (2017) CP	Portugal, Agueda	248 students **15 had used e-bikes**	**Total sample:** 51.2% Female Age range:15-21	**Cross-sectional** *Paper Qu*	Experiences Barriers	Weather, infrastructure (pavement conditions), car traffic, traffic noise, accident risk (with pedestrians and other road users), traffic speed
Astegiano, (2017) PR	Belgium, Ghent/ Leuven	**60 e-bike owners**	50% Female ≤ 40 = 50% 40-60 = 23% ≥ 60 = 8%	**Longitudinal** *Online Qu* *GPS tracking*	E-bike use	83% of e-bike trips performed in week, 17% of trips on weekends. Mean trip distance=6.8km, Mean trip duration=23.8mins. Longer distances ridden on weekdays vs. weekend days. More trips performed in summer months.
					Purpose	E-bike primarily used for commuting and recreation. Car is preferred for shopping and non-recurrent activities.
					AT	Modal shift for commuting; CB to e-bike = 100%; car to e-bike = 64%; PT to e-bike = 50%. Modal shift for shopping, no change in car use; PT to e-bike = 50%; CB to e-bike = 67%. Modal shift for habitual leisure: car to e-bike = 45%; PT to e-bike = 100%, CB to e-bike = 61%. Modal shift for non-recurrent leisure; car to e-bike = 13%; PT to e-bike = 67%; CB to e-bike = 45%
					Attitudes	Dissatisfied with presence of recharge sports, borderline satisfied with storage facilities for e-bikes and infrastructure
BUWAL (2004) PR	Switzerland, Italian (Ticino; TI) & German speaking part of Switzerland (DS)	**~139 e-bike owners**	**TI** % Female unclear $Mean_{age}$ = 51 **DS** 44% Female >50% = <45yrs	**Longitudinal** *Mobility log* *Qu* *Interviews* Before and 1yr after e-bike purchase	E-bike use	**TI:** 13.8% of journeys made on e-bike on weekdays, 4.9% on weekend days. Weekdays: Mean daily duration = 20 mins; daily distance = ~ 3.3km. Weekends: Mean daily duration = 15 mins; daily distance = ~2.7km **DS:** 37.9% of journeys made on e-bikes on weekdays, 15.3% on weekend days; Weekdays: Mean daily duration = 46 mins; daily distance = ~ 11km; (Males travel longer distances than women, younger adults [26-45] travel longer distances than older adults [46-65]). Weekends: mean daily duration = 19 mins; daily distance = ~4.4km covered. 13% of annual mileage covered on e-bikes
					Purpose	**TI:** Mainly used for commuting followed by shopping **DS:** 61% of e-bike journeys for commuting, 11% shopping, 15% leisure, 13% other business
					AT	**TI:** Weekdays; e-bikes replace 1.6km of car km; 1.4km of CB km. Weekends e-bikes replace 0.8km car km, 1.3 km of CB km **DS:** Weekdays e-bikes replace 3.1km of car km, 4.5km of CB km, 3km of PT km. Weekends e-bikes replace 0.8km of car km, 2.8km of CB km, 0.4km of PT km; 5.2% ↓ in miles travelled with car; % modal share on weekdays before e-bike purchase: 48.8% car, 2.1% e-bike, 32.1% PT, 16.8% slow traffic; % modal share on weekdays after e-bike purchase: 28.1% car, 37.9% e-bike, 29.6% PT, 4.4% slow traffic; % modal share on weekends before e-bike purchase: 57.6% car, 1.3% e-bike, 33.1% PT, 8% slow traffic; % modal share on weekends after e-bike purchase: 50.2% car, 15.3% e-bike, 25.1% PT, 9.5% slow traffic
Castro (2019) PL	7 European cities	9335 respondents **365 e-bike owners** (112	**E-bike owners:** 49% Female $Mean_{age}$ (CI)= 48.1 (47-49.3)	**Longitudinal** *Online Qu* *Travel diaries*	E-bike use	E-bikers used e-bike on 14.5 dpm and CB on 7.9 dpm. Cyclists used CB on 14 dpm; average trip duration, mins (CI) for e-bikers on e-bike = 35 (31.7, 38.3) and CB = 41.9 (34.2, 49.5); for cyclists on CB = 25.6 (25.1, 26.1); daily average travel duration, mins (CI) for e-bikers on e-bike = 32.2 (24, 40.4) and CB = 13.4 (8.6, 18.2); for cyclists on CB = 30.3 (28.8, 31.7); average trip distance, km (CI) for e-bikers on e-bike = 9.4 (8.6, 10.2) and CB = 8.4 (7.2, 9.7); for cyclists on CB = 4.8 (4.7, 4.8); daily average travel distance, km (CI) for e-bikers on e-bike

		in Antwerp; 107 in Zurich) 7212 CB owners 1758 non-cyclists	**CB owners:** 52% Female $Mean_{age}$ (CI)= 41.4 (41.1-41.7) **Non-cyclists** 62% Female $Mean_{age}$ (CI)= 42 (41.4 – 42.7)			= 8.0 (6.2, 9.7) and CB = 2.5 (1.5, 3.5); for cyclists on CB = 5.3 (5.0, 5.5). E-bike owners significantly older than cyclists, had greater access to a car. No differences in sex, level of education or income. More women were e-bikers and cyclists.
					AT	25% of private vehicle trips (car or motorbike) substituted by e-bike; 23% of CB trips and 15% of PT trips. In Antwerp e-bikes substituted for CB (34%) and private motorized vehicles (38%); in Zurich e-bikes substituted mainly for PT (22%); Substitution of car trips ranged from 2-49% across 7 cities; 6-35% for PT; 5-60% for CB. Whatever the primary mode of transport being substituted with the e-bike, the respondent still reports high levels of use of this mode of transport (e.g., if respondent primarily substitutes PT for e-bike, respondent will still report high levels of PT)
					Motivation Riding	Reduced physical effort (26%); time saving due to faster trips (24%); ride further (24%); environmental concerns (5%); health considerations (10%)
Dill (2012) [PL]	USA, Portland	**28 e-bike owners**	43% Female $Median_{age}$ = 48 (range 24-64)	**Cross-sectional** *Interviews*	E-bike use	23 participants ↑ amount of cycling since purchasing e-bike; Participants ride to different destinations and take new routes
					Purpose	E-bike primarily used for commuting; ~2/3 used e-bike for errands and shopping. 6 participants used e-bike for leisure
					AT	E-bikes substituted primarily for CB or cars. E-bike substitutes for CB when owner experiences some change (e.g., aging, injury, change in travel distance) that reduces ability to use CB
					Motivation purchasing	Greater riding capabilities than CB (n=20); enables individuals who can't ride CB to cycle (due to health or age); alternative to a car (n=20); environmental concerns (~1/3 owners)
					Experiences Benefits	Travel longer distances; commute to work instead of car, in areas they wouldn't be able to commute with CB due to hills; take more direct routes than CB as can ride on routes with more traffic and hilly terrain; less perspiration than CB; reduced effort so feel more energized; increased speed, faster than CB, can keep up with traffic; carry more/heavier loads; ability to ride with friends and family; ability to keep up with other cyclists (more commonly reported by women); increased perception of safety compared to CB due to weight of e-bike; increased PA
					Experiences Barriers	Weight - difficult to lift in general and on car or PT racks; theft concern; difficult to make repairs; anxiety about battery range; feeling judged or self-conscious about using e-bike (negative reactions to e-bikes from regular cyclists, e-bike seen as 'cheating', for lazy/overweight people); fear of government regulation over where e-bikes can be used
Eddeger (2012) [PR [2]c]	Italy, Pescara	**258 employees bought e-bike**	*Not reported*	**Cross-sectional** *Paper Qu*	AT	80.3% used car less since buying the e-bike
					Experiences Benefits	No traffic; easy parking; increased physical activity (benefits reported by 53% of participants)
					Attitudes	96% completely satisfied with e-bike
Gordon (2012) [TH]	USA, Davis & Sacramento California	**37 e-bike owners**	37% Female; 22.2% ≥65	**Cross-sectional** *Interviews*	E-bike use	Mean frequency of e-bike use = 4.26 dpw (SD=1.89). Mean milage per week = 44.04 (SD=34.18)
					Purpose	Mainly transportation (77.8%); Exclusively for transportation (37%). Participants commented e-bike originally purchased for recreation but started using for transportation
					AT	40.7% drive a lot less since getting e-bike, 37.5% drive a little less since getting e-bike, 20.8% drive the same amount; many participants used CB prior to e-bike. E-bike used for trips that were considered too long or hilly or involved too much cargo for CB but too short for car
					Motivation purchasing	Reduce environmental impact - for people who cycled a lot bought e-bike to further reduce remaining car use and reduce parking costs

					Experiences Benefits	↑ speed compared to CB = reduced travel time so can commute more regularly as less time constraints; acceleration = ↑ confidence to cycle on roads as can keep up with traffic; more suitable than CB for roads designed for cars; environmentally friendly - some participants able to reduce # cars due to different types of trips that could be made on e-bike; enjoyable; enabling individuals with physical limitations to ride; decrease physical effort which increased riding for individuals who found CB increasingly difficult; less perspiration (reduced need for shower)
					Experiences Barriers	High cost; theft concerns; weight of bikes (esp. for women and older participants) = hard to ride with no power or lock; range anxiety; for participants living outside the city - poor infrastructure (lack of access to charging facilities leading to range anxiety); concerns about safety riding in traffic
					Attitudes	E-bike seen as fitting with people's environmental values - best option for low environmental impact transport
Haustein (2016) [PL]	Denmark	**427 e-bike users** 76% owners 24% regular access	51% Female 18-39 = 10.4% 40-49 = 13.6% 50-59 = 26.8% 60-69 = 36.9% 70+ = 12.2%	**Cross-sectional** *Online Qu*	E-bike use	74% used e-bike several times a week. 2% used e-bike < monthly. Recreational riders cycle the longest distances, compared to utilitarian cyclists, with 47.5% of this group cycling 10km or greater; Frequency of e-bike use was higher than frequency of CB use before e-bike access; Significantly more distance was covered on the e-bike than on the CB before e-bike access ($p <.001$)
					AT	Significant ↓ in % of recreation and utilitarian riders who cycled a CB daily after access to an e-bike (~50%, $p <.001$). Utilitarian riders still rode CB, in addition to e-bike; younger adults used CB and e-bike after getting access to the e-bike, older adults reduced CB use after gaining access to the e-bike.; Modal shift from CB to e-bike = 64%; from car to e-bike = 49%; from bus to e-bike = 48%; from walking to e-bike = 33%; from PT to e-bike = 26%
					Motivation purchasing	Cycle longer distance; cycle more frequently; less exhaustion; start cycling; 32% of utilitarian e-bikers bought e-bike to replace car, 23% for recreational riders; younger adults more likely to be motivated by replacement of car than older people
					Motivation riding	Enjoyment of cycling; ↑ PA; cheaper than other modes; environmentally friendly
					Experiences Barriers	battery range/life (34%); weight of e-bike (hard to cycle when battery dead, 19%); maintenance of e-bike too much effort or expensive (19%); battery range/life biggest problem for recreational riders (6%), maintenance was biggest problem for utilitarian riders (4%); weight is the biggest problem for the older age group (4%); battery for the middle age group (4%) and low speed for the youngest age group (3%)
					Attitudes	Those that bought e-bike to increase cycling frequency and distance appreciated the increased speed and fun compared to CB; recreational e-bikers appreciate being able to ride more frequently and longer; utilitarian e-bikers appreciated e-bike for practical reasons such as daily transport, picking up children and shopping
Helms (2015) [PP]	Germany, 4 regions	**312 e-bike users**	*Not reported*	**Longitudinal** *Online Qu* *Field tests (n = 70)*	E-bike use	Median journey length = 4km, 50% of all journeys under 9km, Mean distance on e-bike = 11.4km (on CB = 7.1km)
					Purpose	Commuting, leisure and everyday life
					AT	E-bike largely replaced cars (41% of journeys and 45% of the distance) and CB (38% journeys, 32% of distance); 62% of car commute journeys replaced with e-bikes, 18% of CB commute trips and 10% of PT commute trips; 36% of car and 36% of CB trips for everyday life replaced by e-bike; 61% of leisure CB trips are replaced by e-bike and 15% of car trips for leisure are replaced by the e-bike
					Motivation riding	↑ PA; health; greater autonomy; ↑ mobility; simplicity; less effort; comfort; faster; ability to ride further
					Experiences	↑ daily mobility; improved fitness; can ride more challenging routes; can go further; can use on holidays

					Benefits	
					Experiences Barriers	Technical difficulties; battery concerns; weight; other road users; poor infrastructure; maintenance
Hendriksen (2008) [PR]	Netherlands	**285 e-bike owners** 1163 non-e-bike owners	*Not reported*	**Cross-sectional** *Online Qu*	E-bike use	Mean km per week on e-bike = 30.5; CB = 24.9; road/mountain bike = 28.6; Mean km per week for over 65s on e-bike = 25.3, CB = 20.7; Mean km per week for commuters on e-bike = 39.4, CB = 22.5, road/mountain bike = 29.8. 77% of e-bike users cycling longer distances since purchasing e-bike; 73% of over 65s made more frequent cycling trips since purchasing e-bikes; Commuters travelled 9.3km on e-bike, 6.3km on CB;
					Purpose	77% used e-bikes for leisure; 68% for shopping; 47% to visit friends/family. Over 65s specifically: 89% used e-bike for leisure, 68% for shopping. Commuters specifically: 64% for commuting to work; 64% for leisure; 60% for shopping
					AT	E-bikes substitute for 34.3% of CB trips; 18.3% car trips, 2.1% walking, 2.5% moped/scooter, 3.1% PT; Over 65s e-bikes substitute for 43.3% of CB trips; 19.1% car tips, 1.2% bus trips, 1.2% walking and 0.2% taxi; For commuters e-bikes substitute for 33.3% of CB trips, 15.9% car, 8.1% PT, 5% motorbike/scooter trips. 34% of users no longer use CB since buying e-bike; 1% of e-bike users no longer use private car
					Motivation purchasing	Difficulty cycling CB (66%); ability to cycle in windy conditions (52%); cycle longer distances (46%); ability to cycle uphill (29%); ↑ physical activity (17%); cycle faster (11%); environmentally friends (10%); less perspiration (8%)
					Experiences Benefits	Cycle faster (75%); cycle further (77%); commute more often (22%); do more leisure rides (65%), cycle more for private purposes (57%), improved health (30%). Improved health more often stated by commuters (42%) than over 65s (37%)
					Attitudes	94% of e-bike owners were satisfied with e-bike. Dissatisfied with battery range (79%); charging time of batteries (63%), maintenance costs (60%), weight of e-bike (60%)
Jahre (2019) [PL]	Norway, Sogn og Fjorane & Agdar	1977 public employees **158 e-bike owners** 1610 CB owners 209 no bike	**E-bike owners:** 64% Female $Mean_{age}$ = 49.2 (SD = 10.9) **CB owners:** 63.2% Female $Mean_{age}$ = 48.4 (SD =10.9)	**Cross-sectional** *Online Qu*	E-bike use	E-bike owners: Mean distance travelled from home to work = 6.5km (SD = 5.2); frequency of cycling to work = 1.9 dpw (SD = 1.8); CB owners: Mean distance travelled from home to work = 5.5km (SD = 5.4); frequency of cycling to work = 0.9 dpw (SD = 1.5) E-bike owners were at significantly higher odds of cycling more often and a greater distance compared to those possessing a CB. Men were at higher odds of cycling a medium distance (vs. short distance) to work than women. E-bike owners reported lower levels of leisure PA than CB owners. No differences in bike ownership based on sex, ethnicity, age, educational level or income
Johnson (2015) [PL]	Australia	**69 e-bike owners**	21.7% Female $Mean_{age}$ = 71yrs 65-69 = 46.4% 70-79 = 43.5% 80+ = 10.1%	**Cross-sectional** *Online Qu*	E-bike use	87.5% of participants reported riding the e-bike weekly; 34.3% reported riding the e-bike daily. No difference in the e-bike use of those that had ridden CB prior to e-bike purchase and those who had not
					Purpose	69.6% of e-bike rides were for local trips, 31.9% for visiting friends; a few participants now rode e-bike for shopping; of the 14 employed people the majority rode e-bike to commute. Other trip purposes included PA (18.8%) and recreation (14.5%)
					AT	If the e-bike was not available the majority of trips would be made by car, followed by PT, then CB; for regular cyclists use of CB ↓ after acquisition of e-bike; daily CB use ↓ from 30.2% to 7.5%; weekly CB use ↓ from 45.3% to 16.9%; monthly CB use ↓ from 24.5% to 13.2%; 1/3 participants did not ride the CB at all since purchasing the e-bike

					Motivation purchasing	Less effort than CB (53.6%); replace car trips (50.7%); maintain or increase health and fitness (42%); to ride hills (406%); ride with a medical condition (34.8%); keep up with friends and family (27.5%); 5.8% other (5.8%; longer distance, for fun, environmental benefits or age)
					Motivation riding	Reasons for changing from CB to e-bike included ability to ride hills (23.3%); physical limitation that limited CB (injury, illness or disability (16.3%); age (11.6%); ability to keep up with friends (9.3%); for exercise/health benefits (8.1%) and as an additional cycling option (5.8%); other responses included easier than CB; didn't need to shower; likely to ride more frequently; to ride further; to commute; to carry luggage; for environmental benefits and to be faster
					Experiences Benefits	Ride to different destinations on e-bike compared to CB; 47.4% of participants rode greater distances; 31.6% included hills in journey; carry shopping; e-bike was more stable than CB (28.6%); power assistance or additional speed helped them get out the way of a potential crash (61.9%); 29% stated that e-bike helped to avoid crash
Jones (2016) [PL]	UK, Oxford & Netherlands, Randstad & Groningen	**22 e-bike owners**	55% Female Mean$_{age}$ = 56yrs	**Cross-sectional** *Interviews Online Qu*	E-bike use	13 participants used e-bike for many weekly journeys
					Purpose	E-bikes used for many commuting, leisure and accessing local shops
					AT	Since purchasing an e-bike 14 participants ↓ driving, 12 ↓ CB, 3 ↓ walking; and 8 ↓ use of PT; for those that ↓ CB they may have given up cycling completely and transferred to car prior to e-bike. Those who had never used CB prior to e-bike largely replaced car journeys
					Motivation purchasing	Reduced ability to cycle CB due to physical inability, health or other circumstances - e-bike was a solution that enabled continued cycling; seeing friends and family with e-bike
					Experiences Benefits	Travel greater distances than CB; can use for distances that are too long for CB; can fit in more activities than CB (e.g., escorting children, running errands); time saving compared to CB; less effort than CB; less perspiration compared to CB; ability to maintain or increase PA even if CB reduced; tool to continue to be able to cycle; enjoyment over other transport modes
					Experiences Barriers	High cost; weight (difficult to manoeuvre and lift in car and on PT); range anxiety (range less than proposed by manufacturer, worse in winter); remembering to charge battery; expense of battery replacement; social stigma; not designed to carry children; belief that people view e-bike as cheating and only for unfit/old people; safety concerns (accidents); Netherlands: safety concerns due to high level of cyclists. UK: safety concerns due to poor infrastructure and anticipating inattentive drivers; limited bike parking at PT locations
Kroesen (2017) [PL]	Netherlands	10,4239 participants completed survey (2013-15) e-bike and non-e-bike owners	*Not reported*	**Cross-sectional** *Online national mobility survey data* Model impact of e-bike ownership on travel behaviour	E-bike use	E-bike owners mean distance on e-bike = 3.04km. This is more than non-e-bike owners on a CB (2.63km; p<.001); E-bike ownership ↑ with being female, older, being retired and greater household income. E-bike use ↓ with age, occupation and is less for females than males.
					AT	E-bike owners travel less by CB than non-e-bike owners (p<.001). E-bike owners travel less by car as a driver and by PT than non-e-bike users (p's<.001); reduction in CB ownership from 81% to 49% among e-bike owners. No impact on car ownership; e-bike ownership reduces CB use, car as driver and PT use. CB ownership increase CB use and e-bike use, while reduces car and PT use, but to a smaller extent than e-bike ownership.
Lee (2015) [PL]	Netherlands	**217 e-bike owners**	56% Female Mean$_{age}$ = 59.9 (SD = 10.6)	**Cross-sectional** *Online and paper Qu*	Purpose	**Survey:** 77% of participants used e-bike for pleasure; 54% to visit friends and family; 53% for shopping; 42% for exercise; 42% for commuting; 14% access to PT; 4% to go to school **Travel diary:** 37% of participations used e-bike for recreation; 27% commuting; 25% shopping; 5% visiting friends and family; 5% other; 1% access to PT

				1-day travel diary	AT	**Survey:** 68% of participants stated e-bike replaces CB; 62% stated e-bike replaces short car trips; 45% stated e-bike replaces short PT trips; 25% stated e-bike replaces walking **Travel diary:** 41% of CB trips replaced by e-bike; 40% of car trips, 7% of PT trips, 6% of motorbike trips; 4% of walking trips; 2% would not have gone; e-bikes most likely to replace cars for work related trips than for other purposes, recreation is the most common trip but does not replace one mode of transport over another.
					Motivation riding	e-bike was more comfortable (71%); easier to ride (67%); longer trips (60%); faster (45%); difficult to ride CB (30%). Additional reasons for use included: combating windy conditions; riding without sweating; physical limitations that prohibit CB; exercise and recreation
Leger (2019) [PL]	Canada, Waterloo	37older adults (55+), **8 e-bike owners**, 12 CB owners, 17 non-cyclists	**Whole sample:** 50% Female Age range = 60-97	**Cross-sectional** *Focus groups*	Experiences Benefits	Ability to cycle despite physical limitations due to injury, health, surgery, transition between CB and cycling cessation; reduced physical exertion in comparison to CB, puts less stress on body; ability to maintain or increase mobility levels; increased convenience due to less physical strain and therefore the ability to cycle longer distance; ability to continue to ride with friends and family; reduced reliance on vehicle which saves money and is good for the environment; fun and enjoyable
					Experiences Barriers	**E-bike specific**: unaware of how e-bikes are regulated and where they can be use; social stigma, e-bikes are 'not-real' cyclists; **E-bike and CB**: poor cycling infrastructure; safety concerns regarding potential vehicle collisions; stigma that older adults should not be cycling in general
Ling (2017) [PL]	USA	750 participants **122 e-bike owners** **241 owners of e-bike & CB** 387 CB owners	**Whole sample:** 17% Female 18-34 = 55% 35-49 = 21% 50-69 = 61% 69+ = 11%	**Cross-sectional** *Online Qu*	E-bike use	E-bike only mean daily distance = 14.9 miles; E-bike + CB mean daily distance = 16 miles; CB mean daily distance of 12.3 miles; E-bike riders ride on average between 3.6-3.7 dpw, CB = 2.7 dpw; E-bike riders ride more frequently and greater distances than CB riders
					Purpose	E-bike only: 76% for recreation and exercise; 30% commuting; 29% errands; 17% trail/mountain biking; 23% general transport; 3% carrying goods/kids; 3% work related transport; E-bike & CB owners: 66% for recreation and exercise; 47% commuting; 41% errands; 18% trail/mountain biking; 18% general transport; 20% carrying goods/kids; 7% work related transport; The primary travel purpose of 15-40year olds is commuting, primary travel purpose of 50-69yr olds is recreation
					Motivation riding	For better health (82% of participants); for fun (77%); to get from one place to another (54.5%); environmentally friendly (46.5%); cost saving (38.5%); time saving (33%). Cost saving, environmentally friends and time saving were more motivating for younger (15-40) than older riders (50+)
					Experience Benefits	Ability to ride uphill (84.5% of participants); travel longer distances (66.5%); combat windy conditions (61%); enjoyment (50%); ability to go faster (54%); less perspiration (43.5%); ability to ride with friends and family (25%)
					Experiences Barriers	cost of the e-bike is a barrier to purchasing (78% of participants); cost to maintain the e-bike (15%). Barriers were greater for the younger population
MacArthur (2014) [PL]	USA & Canada	**553 e-bike owners or regular users**	15% Female 18-24 = 1% 25-34 = 10% 35-44 = 18% 45-54 = 26% 55-64 = 32% 65+ = 13%	**Cross-sectional** *Online Qu*	E-bike use	33% of respondents reported ≥61% of trips were made by e-bike; 93% rode e-bike daily or weekly (prior to e-bike, 55% of respondents rode CB weekly/daily); 73% rode e-bike to different destinations compared to CB; 45% rode different routes; 34% rode further distances; 33% rode to different destinations for errands or social events; 16% commute to different destination; 10% conduct recreational trip; 7% ride hillier routes; 35% do not avoid hills on e-bike compared to CB; 31% take more direct or higher traffic route, 30% take lower traffic or less direct route.
					Purpose	to commute (45% of participants); local trips (24%), recreation (20%), all purposes (11%); respondents with physical limitations used the e-bike more for recreation and less for commuting compared to those without a physical limitation; < 55yrs used e-bike more for commuting and less for recreation than over 55 yrs.

					Motivation purchasing	To replace some car trips (65%); limited ability to ride CB (21%); to increase fitness (52%); live/work in hilly area (60%); ride with less effort (55%); ride with friends and family (11%); other (28%: longer distances, faster, carry heavy cargo, cost saving, driving not an option and to keep up with traffic); Females more likely to buy e-bike to ride with friends and family or because they live/work in a hilly area compared to men (p's<.05). Respondents < 55yrs more likely to buy an e-bike to replace a car than those ≥55; Respondents ≥55 more likely to buy an e-bike for heath (reduced ability to ride CB and to ↑ fitness), to ride with less effort and keep up with friends and family
					Experiences Benefits	↑ speed and longer journeys (18%); ride with less effort/up hills (18%); improved health (16%); cost savings (12%); fun (11%); environmentally friendly (11%); ability to ride with friends and family (8%); carry more weight (5%); 60% felt safer on an e-bike than a CB
					Experiences Barriers	weight of bike (26%); weather conditions (14%); cost of e-bike (8%); limited range (8%); complexity of bike (more to go wrong, 6%); dealing with car users (6%**)**; theft concerns (4%); battery charging time (4%)
MacArthur (2018a) [PR]	USA & Canada	**1796 e-bike owners/regular users** 1663 USA, 133 Canada	28.5% Female 18-24 = 2.3% 25-34 = 10.6% 35-44 = 19.9% 45-54 = 20.1% 55-64 = 27.9% 65+ = 19.2%	**Cross-sectional** *Online Qu*	E-bike use	34.6% of all weekly trips are made by e-bike; overall cycling ↑ after e-bike purchase with 91.5% of participants frequently riding their e-bike; of 6.6% who didn't ride CB before, 93.5% rode e-bike daily or weekly
					Purpose	70% of participants ride e-bike to different destinations or for different reasons than they rode their CB (can commute, no need to avoid hills, can cycle further); to commute (34%); recreation/exercise (44.5%); personal errands (29.1%); visiting friends/family (18.4%); entertainment (16.4%). Older participants and those with physical limitation primarily ride e-bike for recreation and exercise; younger participants more likely to use e-bike for commuting but also for running personal errands and visiting friends/family (p's <.05).
					AT	↓ in daily & weekly riding of CB after purchasing e-bike (↑ in overall cycling); If e-bike not available the car would have been used for most trips; e-bikes used to replace PT (explore beyond PT routes) and car trips
					Motivation purchasing	To replace car trips (27.7%); to ride with less effort (27.7%); for recreation (27.6%); live /work in hilly area (26.9%); to increase fitness (25.3%); to increase cycling (22.5%); to ride longer distances (21.9%); cost effective (19%); due to a medical condition that limits CB (15.6%); to carry cargo or kids (14.6%); environmental concerns (13.8%); to avoid traffic (12.6%); to keep up with friends and family (8.2%); to avoid parking problems (6.2%); enjoyment. Younger adults (<55yrs) more likely to buy e-bike to replace car trips than older adults (≥55). Older adults more likely to buy e-bike for reaction and to increase fitness than younger adults. Females are more likely to buy e-bike because they live in a hilly area, need to carry cargo or kids and to keep up with friends/family compared to men.
					Experiences Benefits	↑ frequency and duration of cycling trips; reduced travel time; less effort; cycling to new destinations or routes; ability to ride hilly topography; ability for older adults, those with physical limitations to ride where CB not possible; ability to carry ↑ load (including children); ↑ safety perception compared to CB (78% vs. 64% respectively) ability to avoid dangerous situations, less perspiration; reduce car use; enjoyable; ability to ride with friends and family
					Experiences Barriers	e-bike technology issues (functionality/performance); hard to maintain (e.g., changing tires); weight; range anxiety (hard to ride without assistance); conflict with other road users (cars, buses, pedestrians and CB)
					Attitude	96.4% of respondents enjoyed the overall experience of e-cycling; 75.1% would rather e-bike than drive and 67% agreed it was important to reduce the amount of car trips they tool. The e-bike is considered more fun than a CB, largely due to the speed and acceleration. E-bikes allowed respondents to go further than on an CB without the need to shower at the destination.
				Cross-sectional	E-bike use	Mean trip length = 14.5km (range 1-84)

Mobiel 21 (2014) [PR]	Belgium, Flanders	**369 e-bike commuters**	Majority over 40yrs	*Online Qu*	AT	~½ of all respondents switched from car to e-bike for commuting to work
					Experience Benefits	85% of respondents report enjoying commuting by e-bike; 12% enjoy using the e-bike as a means of transport
Paetz (2012) [PL]	Germany	750 online posts from e-bike users	*Not reported*	**Netnography**	E-bike use	For commuters: 19% e-bike travel is under 10km; 57% 10-25km; 23% 25-50km; 1% >50km
					AT	Most users change from CB to e-bike; some changed from second car to e-bike
					Motivation purchase and riding	48% bought e-bike to commute (alternative to car, less physical effort and perspiration before work; to enjoy fresh air); 28% for health (physical limitations due to accident or illness or increased age; to stay/increase fitness); 15% for leisure (to ride with friends and family; to carry luggage); 9% for transport (to carry loads – children, dogs, groceries); car users primary reasons for purchasing e-bike include: increased fuel prices; desire for environmentally friendly mode of transport
					Experiences Benefits	Overcoming headwinds; overcoming hilly terrain; ↓ physical effort; fun
					Experiences Barriers	Reduced battery range in winter; expense of battery, desire to maintain lifespan of battery for longer; concerns about weight of loads e-bikes can carry; social stigma therefore desire of e-bike to look like CB
					Attitude	For many people the test drive and feeling they first experience sparks an interest in riding an e-bike; e-bikers want easy access to a competent e-bike dealer
Plazier (2017a) [PL]	Netherlands, Groningen	**24 e-bike owners** Commuted from outside to inside city	50% Female $Mean_{age}$ = 45 (SD = 9.3)	**Longitudinal** *2 wk GPS data Interviews*	E-bike use	34.5% (376/1090) of all single destination trips were made on the e-bike.
					Purpose	Of the 376 trips made on the e-bike 282 were for commuting to and from work; 50% of all school trips made on the e-bike; majority of commuting trips made by e-bike (63.3%) with average length of 14.1km. Longer commuting trips made by car, train or motorbike. When combining different destinations, e-bike used less
					AT	Car was the preferred method of transport for free-time (63.3%), going shopping (55.9%) and visiting friends and family (83.3%). E-bike mostly alternated with car use as opposed to walking or PT; e-bike does not replace CB for running errands as it is not a worthwhile use for such short distances
					Motivation purchase	13 participants were uncomfortable with their commuting patterns, buying an e-bike came from desire to change behaviour; 20 participants had life changes (e.g., changing jobs, moving work locations, having children, aging) that made them reconsider commuting habits; 19 participants previously commuted by car and CB was not a feasible alternative; commuting was the primary motive for purchasing an e-bike; health mentioned as a purchasing reason for 8 participants
					Experiences Benefits	↑ speed; ↓ travel time compared to CB; ↓ effort compared to CB; ability to select most direct route; wind did not affect decision to e-bike; ↑ PA; autonomy over PT or carpooling; well-being; being outside (green areas, tranquillity); ability to explore alternative routes
					Experiences Barriers	Weather – preference for car when windy or raining (especially when working); safety concerns when riding in city; low speeds and increased number of stops in urban areas; battery life; lack of time especially if travelling to multiple destinations - faster by car
Popovich (2014) [PL]	USA, Sacramento, California	**27 e-bike owners**	37% Female $Mean_{age}$ = 54	**Cross-sectional** *Interviews*	E-bike use	Mean weekly frequency = 4.3; Mean weekly distance = 44 miles (range = 2 to 140); E-bike used to commute up to 20 miles each way
					Purpose	>1/3 used e-bike primarily for transport (commuting, errands, visiting people); 10 used exclusively for transport. 1 participant used e-bike exclusively for recreation. Several participants shifted from using e-bike for recreation to using it also for transportation once they found it convenient, safe and fun to ride
					AT	20 participants drove car less now they had an e-bike; 5 drove the same amount; before getting e-bike participants spent ~$91 on gas per month, ~$60 on gas after the e-bike; e-bike replaces CB

					Motivation purchasing	Encouraged by friend/family; 7 participants stated environmental concerns (reduce driving and environmental footprint); to extend cycling behaviour as health declines
					Experiences Benefits	Speed (faster than CB); ↓ travel time required to travel certain distance or can cover greater distance, in comparison to CB; more frequent cycling compared to CB; ↓ effort to reach and maintain high speeds; reduced perspiration; greater acceleration (relative to CB); fun; ability to ride even with physical limitations or difficulty with CB due to age/health; carry more cargo; ability to ride uphill; ability to ride w friends and family; transition between car and CB for less fit; greater confidence due to acceleration and speed; less impacted by weather (wind); cheaper than car and more environmentally friendly
					Experiences Barriers	Cost to purchase compared to CB; weight - hard to manoeuvre (especially for women and older adults); extreme weather (heavy rain and very hot); theft concerns; safety concerns - interacting with other car users, ↑ speed greater crash concern; concerns about mixed use lanes (pedestrians, CB and e-bikes); concerns about drivers ability to distinguish an e-bike from CB; unable to use e-bike on some bike paths due to regulations; range anxiety; slower than using car
					Attitude	Participants believe that their peers see e-bikes as cheating
Rogiers (2016) [TH]	Netherlands	**264 e-bike owners**	56% Female	**Cross-sectional** *Online Qu*	E-bike use	Majority of journeys for EB25 between 5-20 km in length. 61% of journeys >20km for EB45; few journeys less than 5km; 36% used e-bike every day, 39% used e-bike several times per week
					Purpose	Respondents with a bike limited to 25km/hr used the e-bike for leisure (28%), shopping (21%), visiting friends (19%), errands (16%) and work (14%). Respondents with e-bikes limited to 45km/hr also used the e-bike for leisure (22%), shopping (18%), visiting people (12%), errands (18%) and work (29%)
					AT	45% of car journeys replaced by e-bike; 40% of CB trips; 8% of PT trips; 5% of walking trips
					Motivation Purchasing	to get more active after period of inactivity (primarily in ≥65yrs); due to physical limitations (↑ with age); to cover longer distances; overcome weather conditions (wind and rain); environmental concerns (strongest in youngest age group)
					Experiences Barriers	Weather conditions (greater in older adults); theft concerns; weight; range anxiety
Schleinitz (2014) [PR]	Germany	**59 e-bike owners**	36% Female $Mean_{age}$ EB25 = 53.5 $Mean_{age}$ EB45 = 41.7	**Longitudinal** *Pre-post qu 4wks GPS Travel Diaries*	E-bike use	Mean frequency of e-bike journeys (SD) in 4 weeks EB25 = 45.9 (22.2), EB45 = 42.4 (43.5). Mean trip distance (SD) EB25 = 4.7km (2.8), EB45 = 7.1 (4.2; p=.07). Mean trip duration (SD) for EB25 = 17.2 mins (7.3), EB45 = 19.4 mins (9.9); no difference in distance based on age; younger adults ride faster than older adults; 31.4% of all weekly journeys made by e-bike for EB25; 47.2% for EB45
					Purpose	E-bike primarily used for commuting (EB25=27.5%; EB45=53.6%), shopping (EB25=13.9%, EB45=14.4%), leisure (EB25=22.3%, EB45=16%). EB25 riders use e-bike for errands (17.6%); ≥64yrs used e-bike less for work and to childcare facilities than younger adults but more frequently for errands and recreation
					AT	Compared to representative data participants in study were more likely to ride a e-bike and travel less frequently by car as the driver (42.1%), by PT (14.2%) or on foot (25.9%); if e-bike not available car was most common alternative (40.4% and 50.4% respectively for EB25 and EB45). PT and walking rarely given as alternatives. CB is alternative to e-bike for those <65yrs for 2.8% and 5.2% of journeys for EB25 and EB45 respectively but not for older age group; when e-bike was available it was an alternative to over 60% of car journeys
					Motivation riding	Enjoyment of cycling; health aspects; environmental concerns; cost of petrol/diesel; ability to ride directly to destination
					Motivation purchasing	↓ effort (particularly on hills); health limitations and age reasons that limited CB (particularly in older adults); enjoyment; faster; less perspiration; lower cost than car; environmentally friendly

					Experiences Benefits	↓ effort (46.9% EB25, 30% EB45); easier to ride uphill (44.9% EB25, 10% EB45); ride longer distances (28.6% EB25, 0% EB45); faster compared to CB (22.4% EB25, 20% EB45); acceleration (16.4% EB25, 0% EB45); fun/enjoyment (26.5% EB25, 30% EB45); cost saving (10.2% EB25, 40% EB45); health & fitness (12.2% EB25, 10% EB45); less perspiration (6.1% EB25, 20% EB45); environmentally friends (8.2% EB25; 0% EB45); ability to take more direct routes (2% EB25, 10% EB45); no worry about parking (2% EB25, 20% EB45); reduced car use (2% EB25, 20% EB45); time saving (2% EB25; 20% EB45)
					Experiences Barriers	Weight (79.6% EB25, 50% EB45); range concerns (49% EB25, 80% EB45); battery charging concerns (20.4% EB25, 10% EB45); cost of e-bike (28.6% EB25, 40% EB45); cost of replacing battery (8.2% EB25, 10% EB45); complicated mechanics, increased breakdown risk (4.1% EB25, 10% EB45); underestimation of speed (6.1% EB25, 0% EB45); theft concern (4.1% EB25, 20% EB45); increased risk of dangerous riding (4.1% EB25, 10% EB45); exposure to bad weather (0% EB25, 40% EB45).
Simsekoglu (2019a) [PL, a]	Norway	**252 e-bike users** 658 non-e-bike users	**E-bike users** 45.2% Female $Mean_{age}$ = 54.07 (SD = 14.07)	**Cross-sectional** *Online Qu*	E-bike use predictors	Positive attitude towards e-bike was most important predictor of e-bike use; self-image, health and ease of use all contribute to having a positive attitude towards e-bikes. Environmental and personal beliefs contribute to having a positive e-bike attitude. Innovativeness (desire to adopt e-bike early on in technological development) second most important predictor of e-bike use (less innovative = less likely to own e-bike). Car users are more likely to use e-bikes than non-car users; CB users less likely to use e-bike; likelihood of e-bike use increases with age up to 60yrs, then reduces; e-bike use increases with income
Simsekoglu (2019b) [PL, a]					Experience Benefits	Mobility benefits (e.g., I can reach my destinations faster using e-bike than CB) were the most agreed benefit among e-bike users (5.86 out of 7); Health and other benefits (e.g., use of e-bike is good for my health) highly agreed upon (5.78 out of 7); Symbolic benefits (e.g., using an e-bike says something positive about me) least agreed upon (3.84 out of 7); users of e-bikes reported higher mobility, symbolic and health and other benefits compared to non e-bike users
					Experience Barrier	Environment and other barriers (e.g., poor weather conditions) are stronger barriers to e-cycling than usability (e.g., e-bike is heavy) and safety barriers (in case of an accident, there is a higher change of getting severely injured with an e-bike than a CB); Non users perceive the e-bike usability and safety to be greater barriers to use than e-bike users. No difference in perception of environmental barriers
Van Cauwenberg (2018a) [PL, b]	Belgium	1146 older adults **357 e-bike riders**	**E-bike users** 53.8% Female $Mean_{age}$ = 71.8 (SD 5.2)	**Cross-sectional** *Online Qu*	E-bike use predictors	Women: 75% higher odds of being e-bike user than men (*p*=.004); greater odds of being an e-bike user if have one motorized vehicle compared to not having one (*p*=.003); greater BMI associated with higher odds of having an e-bike (*p*=.003)
					E-bike use	E-bike use was related to higher odds of cycling in the past week. Among those that cycled in the past week, e-bike use was related to 45% more minutes of cycling in the past week independent of sex, BMI and cycling limitations. E-bike use related to higher odds of having cycled for transport in the past week. This relationship was stronger for those with a higher BMI. Among those that cycled for transport in past week, e-bike use was associated with 35% more mins of cycling for transport, independent of sex, BMI and cycling limitations. E-bike use was related to 183% higher odds of having bike for recreation in past week independent of sex, BMI and cycling limitations. Among women and those with cycling limitations, e-bike use was associated with 57% and 180% more minutes of cycling for recreation respectively.
					Purpose	For transport (71%), for recreation (59%); median volume of cycling for transport = 135 min/week, cycling for recreational = 175 mins/week
					E-bike use	Duration of e-biking in past week: Median (Q1-Q3) = 135mins (5-360); duration of e-biking for transport in past week: Median (Q1-Q3) = 60mins (0-150), duration of e-biking for recreation: Median (Q1-Q3) = 40mins (0-

Van Cauwenberg (2018b) [PL, b]						180). No differences in duration of e-biking due to gender. E-cycling frequency was lower in winter compared to autumn, summer and spring. Men cycled significantly more frequently than women (except in summer when there was no difference)
					Purpose	63.3% cycled alone for recreation (men cycled more for recreation alone than women, p=.04); 47.9% cycled for recreation in a group (no gender difference); 52.9% used e-bike for shopping (no gender difference); 47.3% cycled to visit someone and 46.2% for social activities (women conducted more social visits than men)
					AT	72% of CB trips were replaced by e-bike; 50.7% of car/motorbike trips replaced by e-bike; 22.1% of trips made on foot replaced by e-bike; 19.9% of PT trips replaced by e-bike; respondents made new trips on the e-bike (no gender difference in substitution)
					Motivation purchasing	↓ effort than CB (24.1%); to ride longer distances (23.5%); health limitations that restrict CB (14.8%); to ride hilly/windy conditions (9.2%); to improve fitness/health (8.2%); to keep up with friends (7.6%); to drive less (6.7%); no gender differences in purchase motivation
					Experiences Benefits	Ride longer distance compared to CB (35%); ability to continue to ride as can't ride CB (26.3%); environmentally friendly (9%); fun (7.8%); faster than CB (6.4%); to improve health (5.6%); cost saving compared to car (5.6%); 4.2% other (e.g., easier in windy conditions). No significant gender differences in e-cycling benefits
					Experiences Barriers	Weight (33.3%); theft concern (11.8%); cost of e-bike (8.4%); fear of falling/injuries (7%); range anxiety (5.9%); 4.5% other (e.g., conflicts with pedestrians or cyclists, technical issues, poor infrastructure, hard to replace batteries; knee problems; hard to ride without battery). Men were significantly more likely to report battery issues as important disadvantage compared to women. Women had more fear of falling and injuries than men.
VCD report (2013) [PR]	Germany	**506 e-bike users**	*Gender not reported* <20 = 0.2% 20-29 = 1% 30-39 = 8% 40-49 = 21% 50-59 = 29% 60-69 = 28% 69+ = 13%	**Cross-sectional** *Online Qu*	E-bike use	36% report daily use; 58% weekly use; 6% less frequently; 21% of journeys are between 5-10km; 29% 10-20km; 44% 20+ km; 93% travel 20+km/week, 61% travel 50+km/week, 25% travel 100+km/week
					Purpose	Leisure (76%); errands (69%); commuting (49%; over 75% if ≤59yrs); travel (17%); transport heavy loads (10%); transport children (5%)
					AT	74% report e-bike had replaced some car trips, 21% report e-bike has exclusively replaced car use
					Motivation purchasing	↓ effort; environmentally friendly, health issues; time savings over car and PT; uncomplicated mode of transport
					Experiences Benefits	time saving on short distance; health reasons; cost savings (all compared to car)
Wild (2019) [PL]	New Zealand, Auckland	**24 e-bikers**	54% Female Majority 35-44 years	**Cross-sectional** *Interviews*	Experiences Benefits	Fun/enjoyable; reduced impact of tiredness and weather; greater autonomy and reliability over commute time; ↑ well-being from being outdoors; gentle exercise (difference between participants in amount they thought they were exerted themselves on the e-bike); riding with friends and family
Winslott Hiselius (2016) [PL]	Sweden	**321 e-bike owners** 163 Urban, 155 Rural	24% Female $Mean_{age}$ urban = 52.5yrs $Mean_{age}$ rural = 55.7yrs	**Cross-sectional** *Online Qu*	E-bike use	In urban areas e-bike used: 3.62 dpw for work/school, 2.25 dpw for grocery shopping, 1.01 dpw for visiting friends, 1.44 dpw for leisure. In rural areas e-bike used: 2.93 dpw for work/school, 2.11 dpw for grocery shopping, 0.94 dpw for visiting friends and 1.4 dpw for leisure; participants rode ~70.87km per week
					Purpose	Used for work or school by 66% of urban participants, 52% of rural participants; used for grocery shopping by 55% of urban participants, 61% of rural participants, used for visiting friends by 58% of urban participants, 57% of rural participants, used for leisure by 44% of urban participants, 52% of rural participants.
					AT	In urban and rural areas, the e-bike largely replaced the car; e-bike replaced the car to a greater extent in rural areas (71-86% of car trips substituted) than urban areas (42-60%). In urban areas the e-bike also replaced the CB

						and PT; People living in urban areas use the e-bike on more dpw to replace the car for work and school (3.15 days (SD = 1.91) compared to those in rural areas (2.52 days (SD = 1.67). E-bike replaced 55.28 (SD = 58.32) car km in urban areas and 61.55 (SD = 77.05) car km in rural areas.
					Motivation purchasing	58% of participants bought e-bike to deal with weather conditions (wind and rain); 58% due to environmental reasons (no differences in age); 57% interested in technology (80% of 19-34yrs olds agreed with statement); 71% of participants 19-34% bought e-bike to reduce travel time compared to CB (not as important for older adults – 42%); for younger (19-34) and older adults (65+) the ability to carry heavy items was more important than for adults 35-64; 23% of adults aged 65+ bought an e-bike as CB was less feasible due to age or physical inability, not a motivation for younger adults
Wolf (2014) [PL]	Austria	**1398 e-bike owners** following government subsidy for e-bike	40.6% Female 16-29 = 1.6% 30-45 = 8.9% 46-60 = 27.9% >60 = 61.6%	**Cross-sectional** *Paper Qu*	E-bike use	Respondents travel ~794 km per year on the e-bike
					E-bike use predictors	E-bike use strongly associated with perceived usefulness of e-bike. Usefulness of e-bike is impacted by ease of use, appropriate infrastructure, and an individual's norms. Having a strong attitude towards PA makes e-bike seem easy to use. E-bike is perceived as less useful if there are longer destinations and a high level of car availability; High perceived usefulness and strong personal norms = ↑ e-bike commuting; long distances to work, high car availability and strong attitudes towards PA – ↓ e-bike commuting. Commuting is more impeded by distances of trip than by car availability. Similar predictors for shopping trips except distance to destination is less important. For leisure trips the impact of perceived usefulness is less important. For leisure e-bike use strong attitudes towards PA and long distances = ↑ e-bike use. Older adults are more likely to ride e-bike for shopping and leisure if they perceive e-bike as useful compared to younger adults. For shopping older adults will use the e-bike if they think the infrastructure is less favourable compared to younger adults. For leisure, longer distances ↑ e-bike use in older adults, but longer distances ↓ perceived usefulness in e-bikes among younger adults. Older adults find e-bike more useful if there is adequate infrastructure and if they enjoy PA they find the e-bike easy to use and uncomplicated.
					Purpose	In October 2011, 25.4% of all work trips made on e-bike; 24.5% of shopping trips and 39.1% of leisure trips
					AT	37% of respondents reduced car use on work trips since buying e-bike; 40% for shopping trips and 40% for leisure trips. Data from October 2011 suggest that commuters shifted from PT to e-bike; e-bike did not induce shift from car with 71.6% of all work trips being made in the car, which is higher than the national average of 46.4% of all work trips made in a car. This sample had further to travel to work than the national average (14.7km vs. 10.7km, respectively). For shopping respondents mainly switch from walking to e-bike. Some car trips for leisure purposes are replaced by e-bike.

[a, b,] studies that are from the same data set; [c] Eddeger et al (2012) report on a series of e-bike projects conducted across the European Union. Projects pertinent to this review have been included

[CP]=conference proceeding; [PL]=primary literature; [PP]=project presentation; [PR]=project report; [TH]=thesis

Outcomes: AT=impact of e-bike use on alternative modes of transportation; Purpose=The purpose of e-bike use

CB=conventional bicycle; CI=confidence interval; DL=drivers license; dpm=days per month; dpw=days per week; DS=German speaking part of Switzerland; EB25=e-bike limited to 25km/hr; EB45=e-bike limited to 45km/hr; EV=electric vehicles; IQR=interquartile range; km=kilometre; mins=minutes; PA=physical activity; PT=public transport; Qu=questionnaire; SD=standard deviation; TI=Ticino, Italian speaking part of Switzerland; wk=week; yr=year

Appendix 4.5 Data extracted for each article reporting e-bike share/rental schemes organized by study design

First author, year	**Country, location**	**Participants**	**gender (%female); Age, years**	**Study design and methodology**	**Outcomes examined**	**Key findings**
Non-experimental studies						
Berg (2019) PL	Sweden, Jonkoping	11 users of vehicle share system from one residential block (4 cars, 12 e-bikes)	Not reported	**Cross-sectional** *Interviews – presents 5 cases as examples of experiences*	Experiences Benefits	Married male, 2 children: Ability to ride hilly terrain Male 20s living with partner: reduced physical effort (good if not wanted to exert yourself) Married female, 1 child: enjoyment; convenient
					Experiences Barriers	Married male, 2 children; Inconvenient if have multiple locations to visit e.g., dropping off and collecting children; safety concerns with other vehicle users; inconvenient rental times; Young female: cost of rental compared to CB; reduced physical effort compared to CB; Married male, 1 child: get sweaty or wet; less comfortable than car Married female, 1 child: no seats to carry children; technical barriers including charging the battery and locks which was the responsibility of users; Young male: not as fast as CB; sceptical about activity associated with e-bike
Guidon (2018) PR	Switzerland, Zurich	Users of e-bike share system	Not reported	**Longitudinal** *GPS tracking*	E-bike use	Pool of 200 e-bikes. Total of 99,094 trips made between April 2017 – November 2017. Average of 305 trips made each day. Mean trip distance = 2.5km, mean trip duration = 10.3 minutes; 46% of trips were made between 7am – 10am and 2pm – 5pm with greater demand on weekdays compared to weekend days (37%). Demand for e-bikes was 17% lower during rainy periods. Using open source data the authors determined that demand was higher for e-bikes for social and economic activities compared to sporting or recreational activities. Neighbourhoods with higher income, a good cycling network and with good connection to public transport had higher demand for e-bikes
He (2019) PL	USA, Park City, Utah	Users of e-bike share system	*Not reported* Largest proportion of regular users between 50-55 Largest proportion of non-regular users = 15-35	**Longitudinal** *GPS tracking*	E-bike use	Total of 7921 trips made between July 2017 – November 2017. 84.51% of trips made by non-regular users (bought a single trip pass); 15.49% made by regular users (pass holders). Mean trip distance for regular users = 4.9miles; mean trip distance for non-regular users = 4.65 miles. Individuals were more likely to use e-bikes in the summer and on hotter days. For regular users, higher wind speeds negatively predicted e-bike use. Closer proximity to transit centre, recreational centre or bike trial also increased the likelihood of e-bike use.
					Purpose	Large proportion of trips recorded were looped trips (even for regular users) suggesting e-bikes are used for recreational activities to a greater extent than commuting
Hess (2019) PL	Switzerland, Basel	192 Active (153) and inactive (26) users of e-cargo bike share scheme	**Active members:** 40% Female, $Mean_{age}$ = 39.62 (SD = 10.44) **Inactive members:** 44% Female, $Mean_{age}$ = 38.32 (SD = 8.7)	**Cross-sectional** E-cargo bikes available for reservation at 24 locations across city *Online qu*	E-bike use predictors	↑ probability of being active member if cycle or walk for more purposes. Being older and female decreased the probability of being an active member. Inactive members have a higher probability of having a driver's licence, having a higher income and living in larger households
					Experiences Barriers	60.1% of active members and 34.6% of inactive members stated they didn't use the system regularly as the e-cargo bike was only required for specific activities such as carrying bulk and other transport often satisfied their needs; 27.5% and 23.1% of active and inactive members, respectively, stated that the sharing procedure was either not flexible in regard to when bike could be collect, you couldn't spontaneously rent the bike, the rental location was too far away, cost was too high and it required considerable effort; 11.8% and 30.8% of active and inactive members, respectively, had access to another e-cargo bike or e-bike with a trailer; 3.9% and 7.7% of active and inactive members,

						respectively, stated the size, weight and load safety of the bike was an issue; 2.6% of active members did not like the e-bikes and wanted to use their own power to cycle
Langford (2013) [PL]	USA, Washington	22 e-bike share users at University *24% of population enrolled in share scheme*	41% Female, 55% = 18-20 27% = 21-25 18% = 25+ 82% students 18% faculty/staff	**Longitudinal** 2 e-bike stations with 20 e-bikes on university campus 8mnth data collection *GPS tracking* *Qu*	E-bike use	Mean trip length = 2.03km (SD = 0.95). Mean trip time = 13.07mins (8.19); E-bike trips were 13% longer than CB share trips with longer active trip times, though e-bike trips involved in more stops
					Purpose	44% of all trips on e-bike were made to commute between class or to go to library to study; 16% for exercise/leisure; 16% for personal reasons; 14% for shopping
					AT	57% of walking trips substituted with e-bike; 11% of CB trips; 11% of bus trips and 11% of car trips. 11% of participants stated they would not have made the trip without the e-bike.
					Motivation riding	51% of participants chose to use an e-bike as it was faster than alternative mode; greater convenience (24%); less energy than alternative mode (19%); 3% chose e-bike as didn't have to worry about parking; provides exercise (3%). Men stated speed as a motivator for choosing an e-bike over AT modes
					Attitudes	59% strongly agreed that e-bikes are more attractive than CB as they remove terrain barriers; 64% strongly agreed they could travel farther; 41% strongly agreed they were light and manoeuvrable; 32% strongly agreed they were easier to start at stop signs and signals (more commonly perceived by males than females); 27% strongly agreed they provided exercise opportunities (greater for females than males); 18% strongly agreed they were better for the environment and 18% strongly agreed they didn't have to worry about battery range
Munkacsy (2017) [PL]	Spain, Madrid	205 respondents – 41.8% used city e-bike share (21.4% subscribers, 20.4% occasional users)	41% Female Mean_{age} = 37.6 (SD = 11.6)	**Longitudinal** *3 qu over 3 years*	E-bike use	Total of 65000 subscribers in 24 months; ¼ of people cycle more frequently than before starting to use bike-sharing; Av. total trip length is higher than before e-bike sharing
					Purpose	E-bikes used for shopping and running errands, largely replacing walking. Increase in modal distribution of cycling (CB and e-bike) for shopping and errands from 2% - 13% for e-bike share subscribers and 2% - 7% for occasional users. E-bikes also used for going to work or school with an increase in modal distribution of cycling (e-bike and CB) from 7% - 15% for occasional users and 15% - 17% for subscribers
					AT	Walking and PT = primary transport mode in city. Majority of e-bike trips replace walking or PT (around 50% for each). Participants use e-bike share when less convenient to use PT (due to transfer, costs more, congestion) or walk (late). 27% make fewer trips by car as a result of the e-bike share, 56% less trips by PT and 49% less trips on foot, 36% less trips by CB
					Experiences Benefits	E-bike is faster (38%); environmentally friendly (38%); e-bike sharing is more economical than other modes (26%); a form of exercise whilst travelling (26%)
					Experiences Barriers	Occasional users of the system stated e-bike share was not as convenient as other modes of transport (48.5% own CB, 23.7% e-bike doesn't fit travel itinerary, 23.5% faster by other transport); lack of geographical coverage of scheme; pricing policy; lack of cycling infrastructure; road safety (too fast and dangerous on road
Bikeplus (2016)[PR]	UK, 11 projects	*Not reported*	45% Female 3% = 16-24 17% = 25-34 29% = 35-44 25% = 45-54 19% = 55-64	**Longitudinal** 188 e-bikes installed across UK *Not clear how data collected*	E-bike use	Between late 2015 – September 2016, 2667 people tried the e-bike. 11702 journeys were made, travelling over 27000 miles; mean e-bike length = 5 miles (3 miles on CB); e-bike supported longer trips, with difficult topography and lead to shorter travel times
					AT	For 46% of regular users shared e-bike trips were previously made by private car or in taxi; 41% of trips previously made by car; 19% by CB; 16% by bus; 15% on foot, 4% by taxi; 4% by train and 1% by car club

			6% = 65-75		Motivation riding	Reasons for using the e-bike; 37% for PA; 34% enjoyable, 28% reduces journey time; 23% increased convenience compared to PT; 22% cost saving; 21% reduced effort; 17% easy to park; 16% longer journeys
					Experiences Benefits	58% of users reported feeling happier, 41% feeling healthier, participants also reported weight loss. 33% felt the e-bike enabled them to ride hilly topography that was not otherwise possible.
Sustrans (2013)[PR, a]	UK, Scotland	162 people hired e-bikes	65.2% Female 42.5% 55+yrs	**Longitudinal** Hiring out e-bikes *Surveys* *Case studies* *Mileage computer*	E-bike use	Av. Cycling distance for 36 users surveyed was 30km, median ride time 3.43hrs
					AT	Reduction in commuting to work via car with e-bike hire. 3 participants would have used car if e-bike not available; 12 would have used CB; 9 would have walked; 25 wouldn't have made journey
					Experiences Benefits	Enables individuals with lower fitness or reduce ability to ride compared to CB; ability to ride with friends and family; ability to continue riding with increased age
					Experiences Barriers	Cost of rental is prohibitive on longer term basis
					Attitudes	Initial negative perception of e-bike as 'cheating', once ridden have a 'eureka moment' when e-bike becomes a potential transport option

[a] Some data reported by Cairns et al (2017); [CP]=conference proceeding; [PL]=primary literature; [PP]=project presentation; [PR]=project report; [TH]=thesis

Outcomes: AT=impact of e-bike use on alternative modes of transportation; Purpose =The purpose of e-bike use

CB=conventional bicycle; PT=public transport

Appendix 4.6 Data extracted for each article reporting organisation-initiated e-cycling for employees

First author, year	Country, location	Participants	gender (%female); Age, years	Study design and methodology	Outcomes examined	Key findings
Non-experimental studies						
Prill (2015), TH	Germany, Frankfurt	30 users of company e-bikes	35% Female,	**Cross-sectional** E-bikes introduced as company vehicles *Interviews* *Focus groups*	E-bike use	70% used e-bike for work (only 28% permitted to use e-bike for work), 42% able to use e-bike for private purposes
					Purpose	Primary use was for commuting between home and work or home and PT. Some participants used for errands, passenger transport, exercise and leisure
					AT	E-bikes used to replace car journeys. Participants combined e-bike w PT to replace car; journeys by CB and PT also substituted. Riding e-bike can increase subsequent CB use
					Motivation riding	Sustainable mobility; reduce car use; good for health (easy to fit PA into routine); cost savings; better access around city
					Experiences: Benefits	Enjoyable and fun; sustainable mobility; speed (allows for greater acceleration and reduced travel time); time savings; reduce effort (compared to CB); ↓ perspiration; ability to ride hill topography; ↑ autonomy (less restrictive than PT or carpooling); ↑ self-esteem and well-being; ability to ride with friends and family; ↑ PA; can ↑ use of CB (↑fitness and confidence; ↑ personal mobility (for those with physical limitations restricting CB); extends cycling season (wear appropriate clothes without perspiration); cost savings
					Experiences: Barriers	Weight (difficult to manoeuvre and lift especially for women); range anxiety; technical problems with batteries and motors; equipment concerns (bike locks and folding e-bikes hard to transition); poor cycling infrastructure; poor e-bike facilities on PT; weather (rain and cold. Not a problem for regular cyclists); time pressure (to get to multiple appointments); other transport demands (kids to school, long travel distances); ability to carry load required; theft concerns; cost of bike
					Attitudes	Scepticism regarding who e-bike is for – old adults, physical disabilities. First experience of riding e-bike is formative as it is fun and enjoyable 'the e-bike grin'
Experimental studies						
Gruber (2016) CP	Germany	~600 messengers across 8 courier companies in 7 cities	7.2% Female, $Mean_{age}$= 42.6 (SD 11.6)	**Single group intervention** 2yr trial of e-cargo bikes *Pre, 21mnth surveys*	E-bike use	127000 shipments carried out on e-bikes = 8% of all shipments of participating companies. E-bikes used for ½ a million kms in operational business. 147 out of 362 respondents rejected long-term adoption of the e-cargo bike.
					Attitudes	85.2% of respondents believed e-cargo bikes made sense in the city; 83.1% believe e-cargo bikes contribute to environmental protection; 76.4% believe e-cargo bikes can take over tasks formerly own by car messengers
Kroyer (2013)PR	Sweden, Malmo	77 employees had access to e-bikes for business trips	38% Female	**Single group intervention** E-bikes available as service vehicles over 20 months *Post qu*	E-bike use	E-bike booked approximately 2 times a month and ridden over 5km. 53% of participants believed they cycled further on e-bike than CB and 53% believed they cycled more frequently
					Purpose	Primarily for going between offices, meeting or visiting customers
					AT	Previously participants booked CB and cycled approximately 3km 52% would have ridden CB if e-bike not available; 19% would have used car (carpool or private journey) or taxi; 22% would have chosen another e-vehicle (e-moped or electric car)
					Motivation riding	67% chose e-bike as they preferred it to CB or car; 21% curious to try e-bike; 6% no alternatives

					Experiences Benefits	Speed; comfortable; less perspiration; fun/enjoyable; avoid parking problems; environmentally friendly; less effort; fresh air
					Experiences Barriers	Problems with sizing and adjusting e-bikes; regular maintenance of e-bikes not conducted; batteries not charged; required greater carrying capacity
					Attitudes	73% battery had enough charge to cover needs others felt that had to consider charging; 2 people had accidents; 95% of respondents were happy with e-bike experience

[CP]=conference proceeding; [PL]=primary literature; [PP]=project presentation; [PR]=project report; [TH]=thesis

Outcomes: AT=impact of e-bike use on alternative modes of transportation; Purpose=The purpose of e-bike use

CB=conventional bike; km=kilometre ; PA=physical activity; PT=public transport; SD=standard deviation; qu=questionnaire

Appendix 4.7 Data extracted for each article reporting personal e-bike use for experimental studies

First author, year	Country, location	Participants	Gender(%female); Age, years;	Study design and methodology	Outcomes examined	Key findings
Behrendt (2018) [PL, c]	UK, Brighton	**80 commuters** from 2 companies	56% female; 20% = 20-29 31% = 30-39 24% = 40-49 20% = 50-59, 5% = 60+ 35% used car at least 1 day in previous week 10% used CB at least 1 day in previous week	**Single group intervention** 6-8wk e-bike loan *Pre - post Qu, GPS tracking, Interviews, Focus groups*	Experiences Benefits	Feelings of confidence compared to CB due to power; feel safer compared to CB due to assistance; ability to ride with friends and family due to increased speed; predictable journey times due to constant speed; enjoyment of the experience of e-cycling
					Experiences Barriers	Anxiety about battery running out and having to cycle home; battery life not as long as suggested by manufacturers; impractical to charge battery; feeling judged - by others (e-bikes are cheating or for lazy individuals) and themselves (as previous cyclists); high initial cost of purchasing e-bike
Cairns (2017) [PL, c]					E-bike use	Mean distance cycled during intervention = 82miles (range 1-456); Mean distance per week = 20.7miles (range 0-90); Mean duration per week = 150.5minutes (range 0-720).
					Purpose	72 participants used e-bike for commuting, 47 for pleasure, 37 for shopping, 34 for visiting friends, 30 for other personal business.
					AT	During intervention 34 participants reported ↓ in car use as driver; 20 ↓ use of CB; 30 ↓ in walking, 27 ↓is use of PT; 13 reported ↑ in CB use; 7 reported ↑ in walking; Mean car miles per week before trial = 75, during trial = 59; Mean minutes spent walking, before trial = 339 (range 0-1170), after trial = 264 (0-1200); Mean minutes spent CB, before trial = 47 (range 0-840), during trial = 19 (range 0-360)
Bjornara (2019) [PL]	Southern Norway	36 parents w child born between 2013-2016 18 exp. / 18 control	50% Female; Exp. $Mean_{age}$ = 35.8 (SD 5) Control $Mean_{age}$ = 35.5 (SD = 4.0)	**RCT (2-arm)** Exp: 3mnth loan of e-bike, longtail bike, CB in random order (total 9-mnth bike loan) Control: no bike *Pre, post Qu, Cycle odometer Travel diary*	E-bike use	E-bikes achieved the greatest cycling distance and time for the trial period, with the smallest sample variability; 3mnth e-bike loan: Median (IQR) distance per week = 20.2km (24.8), Median (IQR) cycling time per week = 62.7mins (68.5); CB Median (IQR) distance and time = 11.9km (21.2) & 51.1mins (84.7); Longtail median (IQR) distance and time = 9.3km (21.1) and 40mins (72.7)
					Purpose	At 9-month significantly more participants in the intervention were classified as cyclists (>50% of weekly trips conducted by that mode) for commuting purposes compared to the control condition (n=7 vs. n=1 respectively, *p*=0.04). No differences in the number of individuals classified as cyclists between intervention and control for kindergarten travel or grocery store travel (*p's*>.05)
					AT	At 9month, within the intervention group, there was a significant reduction in the number of participants using the car to travel to work and kindergarten across all seasons, but not to the grocery store. Control group showed no changes in driving or cycling frequency
Boland (2019) [TH]	UK	**3 stroke survivors** loaned adapted e-bikes (2 e-trikes, 1 e-bike)	0% Female $Mean_{age}$ = 63 (SD = 6)	**Single group intervention** 3-month e-bike or e-trike loan *Post interview*	Experiences Benefits	Positive impact on fatigue due to ↓ physical effort; ability to cycle for longer; ↑ confidence to ride longer and farther; ability to ride uphill; ability to overcome windy conditions; adaptations enabled participant to ride e-bike; enjoyment; form of physical activity that could improve health; positive impact on overall mobility
					Experiences Barriers	Effect of physical impairment on riding the bike; lack of confidence due to physical impairments; safety concerns riding in traffic; hot weather impacted motivation; assistance too powerful; anxiety about battery running out; weight of bike; seat discomfort; fear of being strapped in to bike; stigma attached to e-biking by conventional cyclists;
Cappelle (2003) [CP]	Belgium, Brussels	**250 participants** University of Brussels	45.5% female $Mean_{age}$ = 46.3	**Single group intervention** 6-8 wk e-bike loan *Daily logbook*	E-bike use	Mean total distance = 183km (172.9km for men; 194.6km for women); Mean daily distance = 4.2km; Women cycled 13% more than men
					Purpose	E-bike trips equally distributed between commuting, shopping and leisure. 66% used e-bike at least once for commuting; 60% for leisure; 57% for shopping; 43% made new trips on e-bike
					AT	Some e-bike trips replaced car journeys. E-bike alternative for PT; 36% rode CB more since finished e-bike loan

				Post Qu	Experiences Barriers	technical problems as a barrier to e-cycling (51.6%); weight of e-bike (46.7%); limited range (42.9%); lack of infrastructure in the city (25.8%); dangerous in busy traffic (22%); cost of e-bike (19.8%); theft concerns (19.8%); weather conditions (19.8%); parking concerns (18.7%); too few assistant levels (15.9%); inadequate gearbox (15.4%); extensive learning process for e-bike (13.7%). Additional barriers mentioned by fewer participants include: luggage problems, comfort concerns, greater assistance required, poor design
					Experiences Benefits	37% reported a time gain from e-cycling compared to car (approximately 10mins for each trip, 76 hours less time in traffic jams per year); 21.4% reported e-bike as enjoyable
					Attitudes	51% of women and 64% of men were dissatisfied with the range of the e-bike battery; 10% of women and 16% of men were dissatisfied with the charging aspect, found it difficult; 11% women and 12% of men were dissatisfied with the quality of the e-bike; 65% dissatisfied with public parking for e-bike; 79% reported lack of cycle tracks; E-bike seen as activity for elder, disabled and less sporty, by the young and sport. Elderly and less sporty believed e-bike was for young and active individuals.
Cellina (2016) [CP]	Switzerland, Luango	**9 families, 16 individuals given EVs to test, including e-bikes**	*Not reported*	**Single group intervention** 3mnth e-bike loan *Smartphone app* *Focus groups* *Interviews*	E-bike use	E-bikes rarely used
					Experiences Barriers	Physical effort required to ride in hilly terrain; general level of physical effort not appropriate if travelling for work; comfort problems due to weather: sweating when too hot and getting wet when raining; lack of cycle lanes (concerns about safety)
					Experience Benefits	Positive impact on health; reliability and performance of e-bike
Cooper et al (2018) [PL, d]	UK, Bristol	**18 T2DM**	39% Female Mean$_{age}$ = 58.1 (SD 7.9)	**Single group intervention** 5-mnth e-bike loan *Cycle odometer* *Interviews*	E-bike use	Median (IQR) total distance cycled = 383.5km (103-738.3). Median (IQR) total distance for men = 456km (379-1395), women = 111km (73-252); Median (IQR) weekly distance = 21.4km (5.5-37.7). Median (IQR) weekly distance for men = 23.1km (21.3-72.9); women = 6.2km (5.5-14.9)
					Purpose	E-bikes used for commuting, shopping and recreation
					Experience Benefits	Travel without perspiration; enjoyment from being outdoors; ability to cycle with friends and family
Searle et al (2019) [PL, d]					Experiences Benefits	↑ feelings of autonomy managing T2DM; enjoyable and easy way to be physically active; improved health (improvement in diabetes related outcomes and weight loss); ability to cycle with friends and family;
De Geus (2013) [PL]	Belgium, Brussels	**24 inactive adults**	46% Female Mean$_{age}$ Men = 45 (SD = 7) Mean$_{age}$ Men = 43 (SD = 6)	**Single group intervention** 6wk e-bike loan, instructed to ride 3 dpw *Log book*	E-bike use	Mean daily distance (SD) = 15.5 km (4.6); Mean total distance cycled by men was 405.1 (156) km; for women mean total distance cycled = 246.0km (116.3; p = .019). Mean weekly travel frequency was 4.1 (1.7) days for men and 2.9 (1.0) days per week for women, not significantly different
De Kruijf (2019) [PL, e]	Netherlands, North Brabant	**547 car commuters** (car & multi-modal)	52% Female 12% = 25-39 37% = 40-49 51% = 50-65	**Single group intervention** Financial compensation for riding e-bike *GPS data using smartphone* *Pre, mid, 6month qu*	Attitudes	Experienced satisfaction with e-cycling commute is higher at 6months than satisfaction with car commuting (p <.001). Degree of satisfaction associated with number of cars in household (if only one car there is a larger ↑ in satisfaction than if own >1 car) and urban context (those living in urbanized areas have lower satisfaction than those in non-urbanized areas); Individuals that use e-bike more frequently have greater increase in travel satisfaction after 6-months; If e-bike experienced as strenuous then there is lower satisfaction (p<.001); Greener landscape through which to cycle is associated with greater satisfaction (p = .002)
De Kruijf (2018) [PL, e]					E-bike use	At 6mnth men use e-bikes more than women (particularly multimodal commuters); those who report being in bad physical condition e-bike less than those who perceive their condition as neutral or good; multimodal commuters with one car in household e-bike more than those with more vehicles; car commuters on a lower

						income cycle more than those on a higher income; the further people have to travel to work the less they e-bike; higher number of commuting days is associated with greater frequency of e-cycling; Frequency of CB at baseline has positive effect of e-bike frequency at 6months
					AT	At baseline; 62% of all commuting trips made by car, 33% by regular bike and 5% by other modes. At 1month; 28% of commuting trips made by car, 1% by CB, 68% by e-bike and 3% by other. At 6month 24% of all commuting trips made by car, 1% by CB, 73% by e-bike and 3% by other. As commuting distance increases car use increases.
Drage (2012) [PR]	Austria, Andritz	**20 older adults**	30% Female Mean_{age} = 50.5yrs (range 40-70)	**Single group intervention** 1wk e-bike loan *Mobility log* *Qu* *Interviews*	E-bike use	Total of 1465.73km travelled on e-bike, over 222 trips
					Purpose	69 trips, covering 216.05km, made for shopping (66 under 10km); 58 trips, covering 720.32km, made for recreation (39 ≤10km); > 60yrs rarely use e-bike for shopping, used PT or foot; 40-60yrs use e-bike for shopping
					AT	Of the 222 trips completed on the e-bike, 122 trips would have been made in the car if the e-bike was not available; 860km of the 1465.73km travelled substituted for the car
					Experiences Benefits	Allows for longer journeys as shorter journey times; less time consuming and inconvenient than PT; less traffic holds ups and parking problems compared to car; ability to ride hilly terrain; enables people who would not use CB (due to overweight, illness or old age) to cycle; ability to ride with friends and family; ride new routes and to new destinations; less perspiration; positive reactions from friends and family
					Experiences Barriers	Cost to buy; weight (heavy to carry for short trips); theft concerns (from home and in public places); concerns over image of e-bike (not in line with sporty image)
					Attitudes	Sceptical to try e-bike - immediately changed after first ride with e-bike. Males dismiss e-bikes more than females
Eddeger (2012)[PR, [1]i]	Netherlands, Eindhoven	**330 employees** across 14 companies	*Not reported*	**Cross-sectional** *E-bike loaned for commuting* Qu	Experiences Benefits	Easy for longer distances; good for health; environmentally friendly; reduced travel time and costs due to not having to wait in congestion; feeling of having a constant tailwind
					Attitudes	80% said e-bike lived up to expectations; 70% would use e-bike for daily commute; 77% reported a very positive experience with the e-bike
Edge (2018) [PL, f]	Canada, Waterloo	**25 individuals** University of Waterloo		**Single group intervention** 3yr e-bike loan *Focus groups* *Interviews*	E-bike use	Increase in total number of utilitarian trips over time (commuting and errands). Used to commute between home and work (~6-10km)
					Purpose	Primarily used for commuting and running errands; Returning cyclists more likely to use for recreation than avid cyclists; some participants used e-bike for family commutes (day-care, farmers market, social gatherings)
					AT	All participants used e-bikes to commute to work, replacing use of cars, or for avid cyclists, CB. E-bike more likely to replace short car journeys; of 9 participants that used e-bike to commute 8 previously used car
					Motivation riding	Reduce car use due to environmental benefits of e-cycling; a physically active commute; try new technology
					Experiences Benefits	More enjoyable to commute by e-bike than car; avid cyclists stated e-bike increased areas in which individual was willing to ride (busier roads) due to ↑ perception of safety; ability to ride hilly topography; less perspiration (reduced need to shower); less overall effort; time savings; less conflict with motor vehicles due to speed; faster than walking, cycling or PT; can travel further than CB or on foot; ease of parking; lower carbon footprint; ↑ PA; being outdoor; perceptions of health and environment benefits depend on mode that was being replaced – more benefits when switching from sedentary car travel, less when switching from CB
					Experiences Barriers	Range anxiety (especially for riding new routes or with lots of hills); hard to pedal without battery due to weight; weight - heavy to life; theft concerns; awkward to carry battery; fear of doing repairs; less exercise than CB;

						hard to integrate with PT; weather (snow rain or extreme cold; avid cyclists more likely to ride e-bike in poor weather conditions than a CB); fear of using roads without cycling lanes and lack of cycling infrastructure; uncertainty about where e-bikes are allowed to be used; difficult to run errands vs. using the car
					Attitudes	Increasingly positive attitudes over time of us of e-bike.
Gorenflo (2017) [PL, f]		31 individuals University of Waterloo	42% Female	*GPS data* *Pre, mid, post qu*	E-bike use	Mean number trips over 3years = 241.9 (staff = 197.5; students = 290.1); $Mean_{trip\ duration}$ = 11.3mins (staff = 12; students = 10.7); lower e-bike use in winter compared to summer
					Purpose	E-bike primarily used between 8am – 10am and 4pm – 6pm suggesting e-bike used for commuting
					Attitudes	When considering travel modes participants valued independence, stress-free travel, reliability and safety. E-bikes perceived as healthier, eco-friendlier, less expensive, more stress-free than cars. However, cars are more independent and comfortable than e-bikes. Regarding safety, PT and walking are perceived as safest travel modes, followed by all others including e-bike and car.
Fyhri (2015) [PL, g]	Norway	**226 participants in trial** **Exp. = 66** Control = 160	**Exp**: 34% Female, $Mean_{age}$ =47 **Control** 27% Female $Mean_{age}$ =46	**Non-randomized trial (2-arm)** 2/4 wk e-bike loan *Pre-post survey and travel diary*	E-bike use	At baseline 30% of exp. group considered themselves cyclists, at post 52%; Mean (SD) distance cycled per wk (km) at baseline: control = 33.9 (45.1), exp. = 40.1 (58.6); post intervention: control = 29.8 (40.9), exp. = 68 (60.9); ↑ in cycling as a share as total transport kms in exp. group (p <.0001); 28% of all trips at baseline and 48% post intervention. No change in control group; 20% at baseline and post intervention. Women made more cycle trips than men but total distance covered was not significantly different between men and women. No differences in e-bike use based on age
					Purpose	↑ in cycling distance for transport in exp. group (km); baseline=26.5; post=48 and control, baseline=19.9, control=22.3. ↑ in cycling distance for exercise in exp. group (km) baseline=13.6, post=20.1; ↓ in control group baseline=14.1, post=7.5; significant ↑ in total commuting and non-commuting distance and km cycled as a share of total commute or non-commute km following the intervention for exp. (*p* < .005). No change in control group
Fyhri (2017) [PL, g]		Exp = 66 Control = 214			E-bike use	Mean daily cycling distance = ~6.9km; 77% cycled more often with the e-bike than before on CB. 56% made longer trips on the e-bike than before on CB
					Purpose	72% used e-bike primarily to commute
					Experiences Benefits	Participants use the additional power to - cycle faster on hilly topography; ride routes hilly routes; reduce perspiration; cycle longer distances; ↑ speed; carry luggage (although used to a less extent than the other factors)
					Experiences Barriers	Cost of purchasing e-bike; theft concerns
Hein (2017) [CP]	Germany, Hannover	**101 employees**	*Not reported*	**Randomized cross-over design** 2-wk e-bike or CB loan in random order *Smartphone app*	E-bike use	Frequency of e-bike trips = 5.3 dpw (SD 4.3), for CB frequency of trips = 3.2 dpw (SD = 4.0; *p* < .001); average duration of e-bike trips = 37.5mins (SD = 23.5), average duration of CB trips = 40.3 mins (SD = 27.8; *p* = .45)
Hochsmann (2017) [PL]	Switzerland, Basel	**32 inactive participants** E-bike = 17 CB = 15	**E-bike:** 17% Female $Mean_{age}$ = 37 **CB:** 13% Female $Mean_{age}$ = 43	**Pilot RCT** 4wk e-bike loan or CB Instructed to ride bike 3 x per week for commuting *GPS tracking*	E-bike use	Total distance of commuting to work during intervention: E-bike = 280.8km (101.6), CB = 289.6 (131.5; p =0.843); Daily elevation gain for e-bike users = 380.5m (275.4) and for CB = 244.9m (204; p = 0.132)

Kairos (2010) [PR]	Austria, Vorarlberg	**342 individuals** given e-bike subsidies; **93 organizations given subsidies for 158 bikes**	**Private customers:** 33% Female $Mean_{age}$ = 46yrs	**Single group intervention** 1yr data collection *Online Qu* *Interviews* *GPS tracking*	E-bike use	**Private customers:** Mean yearly distance = 1400km (range = 40 - 8000); 22% of distance in summer, 33% in autumn, 33% spring, 17% winter; 15% rode less often than planned, 27% more frequently than planned, 40% rode as much as planned. **Organizations:** Mean yearly distance of 1432km (range 111 – 4000). **Overall:** Mean distance per trip = 7km. 12.5% rode routes longer than 13km (private and organizations)
					Purpose	**Private customers:** 18% used e-bike for recreation; 39% for work; 18% for shopping; 25% other; 12% of riders were accompanied by children under 6 years; 5% carried heavy luggage
					AT	**Private customers:** 52% of CB trips replaced by e-bike, 35% car trips replaced by e-bike; 21% of purchasers made substantial changes to long term travel behaviour; No change in PT or walking. **Organizations:** In previous year 41% of car journeys replaced by e-bike, 35% of CB replaced by e-bike; estimate 230,000 car km replaced by e-bike project
					Motivation: purchasing	Less perspiration compared to CB; 60% of respondents stated it was environmentally friendly; 85% wanted to reduce car use
					Experiences Barriers	**Private customers:** 58% would ride more if cycle path network was present; 47% of individuals would ride more if bike infrastructure was in better condition
					Attitudes	Organization: 95% satisfied with e-bike
Kidd (2009) [PR]	UK, Brecon Beacons	**75 volunteers**	41% Female 18-30 = 2 31-45 = 15 46-60 = 20 60+ = 13 Unknown = 11	**Single group intervention** 1day e-bike loan *Pre – post paper Qu*	E-bike use	Mean distance travelled = 18 miles; median = 17miles
					Purpose	18 participants used e-bike to commute to work; 20 for shopping; 41 for leisure
					AT	Of total miles travelled, 67% of these replacing car miles (1818 car miles, ½ tonne of carbon).
					Motivation riding	Cycle with partner (n=3); replace 2nd car (n=4); health/age (n=7); technology interest (n= 9), reduce carbon footprint (n=9); help on hills (n=16); try commuting (n=20); reduced risk of buying one (n=4)
					Experiences Benefits	Ability to ride hilly topography (n = 24); fun/enjoyable; easy way to exercise; ability to cycle to new destinations (e.g., commuting [n = 23], leisure rides [n = 16]); taking quick trips into town (n = 33); reduced travel time; allows for longer journeys; less perspiration (n = 10); easy to carry shopping ability to ride with friends and family
					Experiences Barriers	High cost of e-bike; reduced exercise compared to CB; uncomfortable on bumpy roads (n = 7); no protection from weather (n = 7); carrying loads (n = 7); hard to manoeuvre due to weight (n = 15); concern about battery range on journeys over 15 miles (n = 27)
Kroyer (2013)[PR]	Sweden, Malmo	40 households in Malmo borrowed EVs **12 households tested e-bikes (17 individuals**)	**Total sample:** 65% Female $Mean_{age}$ = 41yrs (range = 16-75)	**Single group intervention** 2-month e-bike loan *Post qu online* *Interview*	E-bike use	All but one participant ↑ cycling with access to the e-bike; ↑ in spontaneous leisure trips
					AT	E-bike replaced car for 2 participants and PT for 3 participants; for 10 participants e-bike replaces short car journeys; several participants stopped driving to work and used e-bike
					Experiences Benefits	Fun/enjoyable; easy to ride; allowed people who would not be able to ride CB to cycle (due to physical limitations or age); less effort; ability to cycle with family; less perspiration; weather (rain and wind not as much of an issue); increased autonomy (not relying on PT); increased speed; comfortable
					Experiences Barriers	Theft concern (1 had e-bike stolen); lots of locks; battery heavy to carry; concerns over road safety; weight of e-bike; high initial cost
Leyland (2019) [PL, h]	UK, Reading & Oxford	**38 individuals given e-bikes,** 36 given CB 26 non-	**E-bikers:** 53% Female $Mean_{age}$ = 61.90 (SD = 7.00) **CB:**	**Non-randomized 3-group intervention** 8-week trial *Travel diaries*	E-bike use	E-bikers: average number of hours cycling per week = 2.39 (SD = .90); CB: average number of hours cycling per week = 2.07 (.59). E-bikers spent 26% of time in turbo, 7% in sport, 24% in tour, 28% in eco, 15% with motor off
Spencer (2019) [PL, h]					Purpose	Majority of participants used e-bikes (and CB) for recreation in green spaces away from traffic or on quiet roads; most rides started and ended at participants home or immediate surrounding areas

		cycling controls	55% Female Mean$_{age}$ = 63.03 (SD = 7.47) **Non-cyclists:** 73% Female Mean$_{age}$ = 66.04 (SD = 78.84)	*Focus groups* *Post online qu*	Experiences Benefits	**E-bike specific**: fun & enjoyment; enables those with physical limitations to ride when CB more challenging; ability to cycle further, in less time than CB; ↑ confidence to ride longer journeys; ability to ride with friends and family of higher fitness levels; **E-bike & CB**: discover new cycling routes; improved health & well-being
					Experience Barriers	**E-bike specific:** weight of bike and high centre of gravity makes it hard to manoeuvre and hard to lift into car or turn upside down for repairs. **E-bike and CB:** poor quality cycling infrastructure; negative experiences interaction with motor vehicles and sometimes pedestrians; lack of time; lots of 'paraphernalia' or organize
Lobbens (2018) [PL]	Norway	**25 inactive participants**	72% Female Mean$_{age}$ = 44 (Range = 33-57)	**Single group intervention** 3 or 8 month e-bike loan *GPS tracking*	E-bike use	Mean weekly distance (SD) = 37.6km (24); average weekly duration of e-cycling = 107.1mins (SD = 62); participants cycled significantly more in autumn (47.4km/week) compared to spring (32.1km/week); no differences in cycling distance in winter (36.4km/week) compared to autumn or spring.
					Purpose	Participants cycled significantly more on weekdays (7.1km/day) compared to weekend days (0.9km/day). Decline in cycling during holidays and vacation days.
MacArthur (2017) [PR]	USA, Portland	**150 employees** of 3 campuses	64% Female 18-24 = 4% 25-34 = 17% 35-44 = 34% 45-54 = 30% 55-64 = 13% 65+ = 1%	**Single group intervention** 10 wk e-bike loan *Pre, during, post online qu's*	E-bike use	10% of participants used e-bike 4-7 dpw; 43% used it 1-3 dpw; 47% used it 1-3 dpm; frequency of cycling ↑ after gaining access to an e-bike compared to CB for all journey purposes. The further a person lived from work the less frequently they reported using the e-bike
					Purpose	59% used e-bike at least 1x week for commuting; 19% used e-bike to commute 3+ times per week; 55% used it at least 1x week for errands; 55% used it at least 1x week for visiting friends and family; 40% used it at least 1x week for socializing; 51% used it at least 1x per week for recreation/exercise
					AT	After using e-bike 43% of participants said they were more likely to use a CB for exercise or recreation
					Experiences Barriers	Adverse weather conditions (55% of participants); cannot carry load required (50%); arriving sweaty or had no shower facilities (10%); destination was too far (23%); time constraints (10%); safety concerns when riding (14%); unable to e-bike for health reasons (10%); theft concern (17%); lack of comfort on e-bike (19%); not easy to connect with PT (9%); trouble with e-bike on PT due to crowding or weight of bike (26%). Barriers of arriving sweaty, destination too far, time constraints, hills were less pronounced/not relevant for e-cycling compared to CB
					Experiences Benefits	Comfortable (85%); fun (91%); easy to use (92%); ability to ride faster and further compared to CB (79%); feeling of safety riding e-bike (93%); more comfortable riding in traffic on e-bike than CB (69%); ability to ride with friends and family (76%)
Mercat (2013) [PP]	France, Chambery	**Over 900 participants**	Not reported	**Single group intervention** 1-2wk e-bike loan Given $250 to buy e-bike at end of trial *Post online Qu*	E-bike use	Mean trip distance = 7km (3.5km on CB); 30-55 age group most likely to buy e-bike after intervention; e-bike purchasers covered on average more than 2000km per year; 66% used e-bike daily; 80% used e-bike several times per week in good weather; 26% used several times per week in winter.
					AT	1.2 million km a year transferred from car to e-bike, 85% of people who bought e-bike reduced car use. This was mostly women
Moser (2018) [PL]	Switzerland, countrywide	1854 participated in Bike4Car **(144 completed**	28% Female Mean$_{age}$ = 43.6 (SD = 10.7)	**Single group intervention** 2 wk trial in exchange for car keys. E-bike subsidy	AT	1 yr after the trial participants had weaker associations with the car and motorbike use for a range of activities (e.g., going shopping; commuting to work) than they did before the trial (p's <.001). Participants had stronger associations with these activities and the e-bike (p<.001). No change in associations between traveling by foot or PT. For individuals that purchased the e-bike there were less habitual associations with car compared to those that didn't buy an e-bike

		pre & post measures)		*Pre,1yr online qu*		
Page (2017) [PL]	UK	**31 participants** University campus **12 Exp.** 19 Control	80% Female Age range 21-55yrs	**Non-randomized trial (2-arm)** Exp: Up to 5mnth e-bike loan Control: no loan *Online qu* *Travel diaries*	E-bike use	Median loan period was 6wks. Exp. group used e-bike 1-2 times per week. Mean daily distance = 10.31 km (range = 5.63-20.92); Median travel time = 21-30mins
					Attitudes	Prior to using e-bike: 68% of participants were concerned about road safety; 89% poor weather; 53% concerns about road conditions. Intervention significantly reduced concerns about road safety ($p<.01$) and road conditions ($p<.05$). Weather was still a significant barrier to riding. There was a decrease in concerns about riding up hills following the intervention ($p<.01$)
Peterman (2016) [PL]	USA, Boulder	**20 inactive commuters**	70% Female $Mean_{age}$ = 41.5 (SD 11.5)	**Single group intervention** 4wk e-bike loan. Instructed to ride bike 3x per week for commuting for at least 40mins each time *GPS* *Informal interview*	E-bike use	Mean duration per ride = 33.1mins (14.5), mean distance per ride = 11.2km (6.8); mean weekly ride duration = 205mins (43.3), mean weekly ride distance = 69.4km (24.4); mean total ride duration = 954.8 mins (202.6), mean total ride distance = 317.9km (113.8); 11 of the 20 participants rode at least 50% more than required by the researchers
					Experiences Benefits	All participants stated how fun the e-bike was and easy to ride. They were able to incorporate the e-bike into everyday life.
Plazier (2017b) [PL]	Netherlands, Groningen	**41 university students**	40.5% Female $Mean_{age}$ = 25 (SD 9.4)	**Single group intervention** 4-5 wk e-bike loan *Post paper qu* *Interviews*	E-bike use	During intervention 87% of total trips were made on the e-bike
					Purpose	Grocery shopping, going to library, social events, recreational. E-bike enabled participants to combine more activities
					AT	Significant ↓ in use of CB and bus ($p <.001$). Of e-bike trips that fully substituted completed trips (n = 155) 58.3% were previously done by CB; 25.2% by bus, 3.3% by train; 3.3% by bus and train, 1.3% by CB and bus and 8.6% by other modes (walking or by car). 62% of participants used less motorized transport during intervention
					Experience Benefits	Higher speed made for faster journeys; acceleration means participants feel less hindered at traffic lights and intersections; easy to use; reduced effort compared to CB; less perspiration compared to CB; reduced journey times; time savings; autonomy from PT; enjoyable; increased PA for some; ability to combine activities
					Experience Barriers	Not fast enough; a bit old fashioned; lack of parking; theft concern; ↓ PA for some; have to get used to bike charging; concerns about range; safety concerns due to speed; doesn't go fast enough; hard to judge other road users; high cost of e-bike; assistance required to fix electronic and mechanical issues
					Attitudes	Prior to intervention e-bikes perceived as old fashioned and for lazy people; participants were sceptical about e-bikes, changed after trying the e-bike. Participants stated that social stigma could be a potential barrier for some individuals

Stromberg (2016) [CP]	Sweden	**6 individuals lent e-bikes**	50% Female $Mean_{age}$ = 39.33 2 regular commuters, 1 cycled for sport, 2 cycle for exercise/sport, 1 didn't cycle	**Single group intervention** 6mnth bike loan, promised to replace 3 days of car journeys per wk with bike *Interviews*	Motivation riding	Cycle longer distances; continue to cycle despite fitness or injury concerns
					Experiences Benefits	Overcoming bad weather; less need to shower when arrive at destination
					Experiences Barriers	Theft concerns (bike and battery); transporting battery which is heavy and hard to carry; range anxiety; weight (esp. when battery dead); difficult to handle in city due to acceleration; too few gear options; perceptions of others (cheating); less exercise (compared to CB); hard to cycle with other who don't have e-bike; too slow (for some); **Cycling in general (also applied to e-bikes):** Bad weather; lack of time, too busy; lack of daylight, inconvenience, too dangerous; too much traffic; cycling infrastructure (poor cycle lanes, cycling in mixed traffic - cars and pedestrians)
					Attitudes	E-biking was seen as a mode of transport not exercise
Sundfor (2017) [PL]	Norway	**833 participants** **45 e-bike purchasers** **21 given e-bike subsides (exp.)** 767 control (no e-bike)	**E-bike purchasers:** 58% Female $Mean_{age}$ = 44.2 **Experimental:** 42% Female $Mean_{age}$ = 45.4 **Control:** 34% Female $Mean_{age}$ = 46.2	**Non-randomized trial (3-arm)** *Pre-6wk online Qu*	E-bike use	**E-bike purchasers:** increase from 102.2 mins of cycling per week to 226.6 mins per week; **Intervention group:** increase in cycling from 24.2 mins to 234.7 mins; **Control group:** no change: from 146.9 mins of cycling per week to 129.8 mins per week
					Purpose	Greater increase in minutes per week for transport than for exercise for customers and intervention group

[c-h] studies that are from the same data set; [i] Eddeger et al (2012) report on a series of e-bike projects conducted across the European Union. Projects pertinent to this review have been included
[CP]=conference proceeding; [PL]=primary literature; [PP]=project presentation; [PR]=project report; [TH]=thesis

Outcomes: AT = impact of e-bike use on alternative modes of transportation; Purpose=The purpose of e-bike use

CB=conventional bike; dpw=days per week; dpm=days per month; EV=electric vehicles; Exp.=experimental; IQR=interquartile range; km=kilometre; mins=minutes; PA=physical activity; PT=public transport; qu=questionnaire; RCT=randomized controlled trial; SD=standard deviation; T2DM=type 2 diabetes mellitus; wk=week

Appendix 5.1

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https://doi.org/10.1186/s40814-019-0508-4

Pilot and Feasibility Studies

STUDY PROTOCOL Open Access

Electrically assisted cycling for individuals with type 2 diabetes mellitus: protocol for a pilot randomized controlled trial

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Abstract

Background: The global incidence of type 2 diabetes mellitus (T2DM) is increasing. Given the many complications associated with T2DM, effective management of the disease is crucial. Physical activity is considered to be a key component of T2DM management. However, people with T2DM are generally less physically active than individuals without T2DM and adherence to physical activity is often poor following completion of lifestyle interventions. As such, developing interventions that foster sustainable physical activity is of high priority. Electrically assisted bicycles (e-bikes) have been highlighted as a potential strategy for promoting physical activity in this population. E-bikes provide electrical assistance to the rider only when pedalling and could overcome commonly reported barriers to regular cycling. This paper describes the protocol of the *PEDAL-2* pilot randomized controlled trial, an e-cycling intervention aimed at increasing physical activity in individuals with T2DM.

Methods: A parallel-group two-arm randomized waitlist-controlled pilot trial will be conducted. Forty individuals with T2DM will be randomly assigned, in a 1:1 allocation ratio, to an e-cycling intervention or waitlist control. Recruitment and screening will close once 20 participants have been randomized to each study arm. The intervention will involve e-bike training with a certified cycle instructor and provision of an e-bike for 12 weeks. Data will be collected at baseline, during the intervention and immediately post-intervention using both quantitative and qualitative methods. In this trial, the primary interests are determination of effective recruitment strategies, recruitment and consent rates, adherence and retention and delivery and receipt of the intervention. The potential impact of the intervention on a range of clinical, physiological and behaviour outcomes will be assessed to examine intervention promise. Data analyses will be descriptive.

Discussion: This paper describes the protocol for the *PEDAL-2* pilot randomized controlled trial. Results from this trial will provide information on trial feasibility and identify the promise of e-cycling as a strategy to positively impact the health and behaviour of individuals with T2DM. If appropriate, this information can be used to design and deliver a fully powered definitive trial.

Trial registration: ISRCTN, ISRCTN67421464. Registered 03/01/2019.

Keywords: Type 2 diabetes mellitus, Electrically assisted cycling, Intervention, Physical activity

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Background

Type 2 diabetes mellitus (T2DM) is one of the fastest growing global diseases [1]. In the UK, the prevalence of diagnosed T2DM is expected to rise from 3.7 million individuals in 2017 to 5 million by 2025 [2]. T2DM is associated with micro- and macrovascular complications and it is estimated that 10% of the NHS annual UK budget is spent on the treatment of diabetes and its associated complications [3].

Engaging in regular physical activity is a key component of T2DM management [4, 5] that can lead to lowering of glycated haemoglobin (HbA1c) concentration [6]. Physical activity also independently reduces cardiovascular risk factors and contributes to weight loss [7]. However, individuals with T2DM have lower levels of physical activity than individuals without diabetes [8]. Enrolment in structured lifestyle interventions is effective at increasing physical activity; however, when left to self-manage physical activity behaviour post-intervention, individuals often return to an inactive state [9–11] or fail to engage in physical activity of sufficient intensity or volume to positively impact glucose control [12]. With the increasing prevalence of T2DM, there is a need to develop sustainable interventions that can foster independent sustainable physical activity at an intensity that is high enough to generate positive health outcomes.

Active travel represents a potential means through which to increase physical activity. In the UK, approximately 50% of all journeys made by car, both for commuting and leisure purposes, are between 1 and 5 miles in length [13]. Given that individuals report a willingness to actively travel distances of 0.5–2 miles by walking [14] and 1.5–4.7 miles by cycling [15], it is feasible that these short motorized journeys could be replaced by active means and potentially increase physical activity [16]. For example, in healthy adults, active travel, particularly commuting, is associated with an increase in physical activity [17], reduced likelihood of diabetes diagnosis [18], lower body mass index (BMI) [19] and improved cardiovascular health [18]. Among individuals with T2DM, active commuting is associated with increased physical activity and lower BMI [20]. While both walking and cycle commuting serve to increase physical activity, research suggests that cycling may provide greater health benefits than walking [21], potentially due to the higher intensity of activity associated with cycling in comparison to walking [22].

Despite these positive health outcomes, rates of active commuting in the UK, especially cycling, are low in both the general population and among individuals with T2DM [20]. There are a number of barriers to regular cycling that could discourage engagement including physical constraints associated with hilly terrain and poor physical fitness as well as a lack of time and the distance people have to travel to work [23]. These barriers may be accentuated in individuals with T2DM given their overall lower levels of physical activity.

Electrically assisted bicycles (e-bikes), also known as Pedelecs, could help to overcome such barriers to regular cycling by providing electrical assistance only when the rider is pedalling leading to increased speed with reduced physical exertion compared to conventional cycling. This extra assistance is believed to be the main motivator for the increased popularity seen in e-bikes over recent years, particularly among middle- and older-aged adults [24, 25]. The provision of an e-bike has been associated with an increase in self-reported physical activity behaviour of approximately 353 min per week among inactive individuals [26]. Furthermore, evidence suggests that e-cycling can replace the sedentary behaviour of motorized transportation [27]. Despite the increased assistance, research indicates that among physically inactive adults riding an e-bike provides physical activity of at least a moderate-intensity (> 3 METs) and can lead to improvements in cardiorespiratory fitness [28] and glucose disposal rate [25].

Among individuals with T2DM, a feasibility study reported that the provision of an e-bike for 5 months led to a 10% increase in power output, a sign of increased fitness [29] likely to be the result of increased physical activity. Furthermore, e-cycling was perceived as enjoyable with 14 of the 18 participants purchasing the e-bikes at the end of the study. This study highlights the promise of e-cycling as a means of increasing physical activity in individuals living with T2DM. Building on this work, an adequately powered randomized controlled trial (RCT), comparing an e-cycling intervention to a control group is needed to assess the effectiveness of e-cycling on health and behavioural outcomes among individuals with T2DM. However, there is currently insufficient evidence to support a full-scale RCT, nor are there data to allow estimation of appropriate sample size. Therefore, a pilot RCT is needed to determine the feasibility of conducting such a trial and to provide key information needed for the design of a full-scale RCT trial, if warranted.

As such, the *primary* aim of this study is to test the feasibility of conducting a randomized e-cycling intervention among individuals with T2DM. In order to address this aim the primary objectives are to (1) identify effective methods of recruiting individuals with T2DM; (2) determine participants' willingness to be randomized, study retention rates, adherence to the intervention and data collection methods and harmful outcomes; (3) assess intervention fidelity; (4) qualitatively examine the acceptability of the intervention and study procedures to participants and instructors; and (5) qualitatively examine participants experiences of e-cycling. The *secondary* aim is to examine the association between the intervention and outcome measures to determine intervention promise. Accordingly, the secondary objective is to collect data on a range of individual health and behaviour outcomes in order to estimate the potential effect of the intervention (based on condition allocation) to inform outcome selection in future trials.

Methods

Study design

This pilot study is a parallel-group 2-arm, randomized waitlist-controlled trial comparing an e-cycling intervention (PEDAL-2) against a standard-care waitlist control among individuals with T2DM. A total of 40 participants will be randomized in a 1:1 allocation ratio to the two study arms. The single-centre trial will be conducted in the city of Bristol, England. Recruitment for the trial will begin in March 2019. The majority of measures will be collected at baseline (time 0 (T0)) and immediately following the intervention period (T1). In addition, data will be collected in the final week of the e-cycling intervention (physical activity and travel behaviour) and throughout the intervention (e-cycling time and distance). Figure 1 shows the study flow diagram and Additional file 1 provides the SPIRIT checklist for reporting intervention trials.

Ethical approval and data protection

The project has been approved by the NHS Health Research Authority South West/Central Bristol Research Ethics Committee (Ref: 18/SW/0164) and is sponsored by the University of Bristol. Any amendments to the protocol will be authorized by the sponsor (University of Bristol) and submitted to the REC and HRA for approval. All data collected in this study will be maintained and stored in strict accordance with the data protection regulations. All patient identifiable information (i.e. names, addresses, dates of birth etc.) will be stored in a database separate

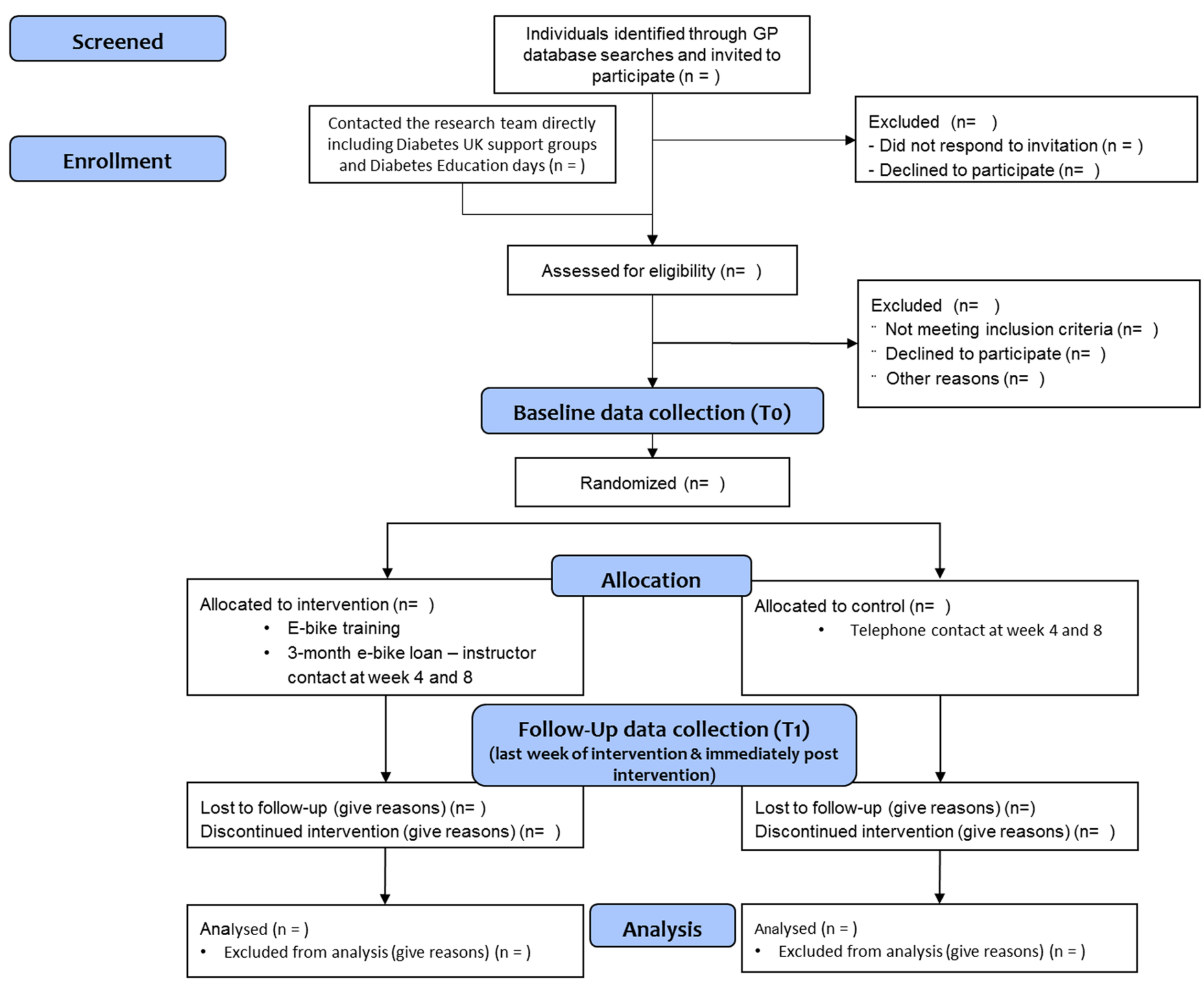

Fig. 1 Flow diagram of the PEDAL-2 trial

from the database that holds anthropometric measures, results of blood tests, physiological measures and travel and physical activity data. Personal data stored on NHS or university computers will be password protected and only the study investigators will have access to the passwords. Personal data on paper files will be stored in a locked filing cabinet within the Biomedical Research Centre at the University of Bristol.

Participant recruitment

Recruitment will occur over three settings. These recruitment settings include (1) primary care practices, (2) diabetes education days in Bristol run by the Diabetes and Nutrition service and (3) Diabetes UK Support Groups in Bristol. All primary care practices in the Bristol, North Somerset and South Gloucester Clinical Commissioning Group will be invited to act as participant identification sites for the study. All practices that wish to act as participant identification sites will conduct databases searches and send study information to all potentially eligible patients. At diabetes education days, nurses will provide study information sheets to all individuals attending the session. These education days occur approximately once a month in Bristol. At the four Diabetes UK support groups in Bristol, information about the study will be disseminated by a member of the research team. Individuals will also be provided with study information sheets. Individuals who wish to participate in the study will be asked to contact the study team directly by telephone, in writing or by email. Individuals who contact the research team will be asked how they learnt of the study. Eligibility will be determined over the telephone. Individuals deemed eligible will be asked to get clearance to engage in physical activity and have their blood pressure taken by their general practitioner. All participants deemed eligible for the study at this point will be invited for baseline testing. Table 1 outlines the recruitment and assessment schedule for *PEDAL-2*.

Eligibility

Individuals will be eligible to participate in the trial if they meet the following inclusion criteria:

- Clinical diagnosis of type 2 diabetes mellitus
- Aged 30–70 years

Individuals will be ineligible to participate if they meet any of the following criteria:

- Currently engage in ≥ 150 min of moderate to vigorous physical activity per week (assessed by the Get Active Questionnaire [30])
- Currently taking exogenous insulin
- Have uncontrolled hypertension (systolic blood pressure > 160 mmHg and/or diastolic blood pressure > 90 mmHg), for which they are not taking medication
- Have had a myocardial infarction or stroke within the past 6 months or have evidence of end-stage renal failure or liver disease
- Have any other contra-indications to exercise
- Are not cleared to engage in physical activity by their general practitioner
- Are unable to read and communicate in English

Sample size

We aim to recruit and randomize 40 individuals for the pilot study. This sample size is based on recommendations for pilot studies which aim to provide an estimation of a standard deviation for use in the sample size calculation to inform a larger randomized controlled trial [31, 32]. There are no explicit targets regarding the number of individuals to be recruited or screened as we are investigating de novo the feasibility of recruitment from primary care. Based on recruitment rates in a similar population and region, we would anticipate a recruitment rate of approximately 30% [33]. Recruitment rates are anticipated to be slightly lower for a cycling intervention compared to a combined diet and exercise intervention, with a previous e-cycling feasibility study reporting a recruitment rate of approximately 20% [29]. Recruitment and screening will close when 20 participants have been randomized to each of the two study arms. The number of individuals invited to participate in the study and the numbers recruited will be recorded. Based on a previous feasibility study, a retention rate of approximately 80% is anticipated [29].

Consent

Once participants have been identified as eligible to participate in the study, they will be booked in for their baseline data collection visit at the University of Bristol (T0). At this first face to face contact a member of the research team will outline the study procedures, as per the information sheet. Participants will be advised that the study is voluntary and that they have the right to withdraw at any time, without the need for explanation. After this, individuals who wish to participate will be asked to read, complete and sign a consent form, which will be countersigned by the member of the research team obtaining consent.

Allocation and randomization

Randomization will occur after consent is obtained and baseline (T0) data has been collected. Forty individuals will be stratified based on sex and then randomly assigned to either the e-cycling intervention or

Table 1 PEDAL-2 SPIRIT diagram displaying study recruitment and measures schedule

		STUDY PERIOD					
	Pre-enrolment	Enrolment	Allocation	Post-allocation			Follow-up
TIMEPOINT		***T0***	***Randomization***	***M1***	***M2***	***M3***	***T1***
ENROLMENT:							
Pre-screening*, if applicable	X						
Eligibility screening	X						
Informed consent		X					
Allocation			X				
INTERVENTIONS:							
E-bike intervention				←	—	→	
Waitlist control							
ASSESSMENTS:							
Demographics		X					X
Recruitment, retention and adherence							X
Process evaluation				X	X	X	X
Assessment of harm				X	X	X	
Clinical outcomes							
Anthropometrics		X					X
Biochemical variables		X					X
Health related quality of life		X					X
Physiological outcomes							
Cardiorespiratory fitness		X					X
Body composition		X					X
Behavioural outcomes							
E-cycling during intervention				X	X	X	
Total physical activity		X				X	
Travel behaviour		X				X	
Trip purpose						X	
Estimated CO_2 emissions		X				X	

***Pre-screening** will only occur in GP practices where databases are searched.* **M** = month. **CO_2** = carbon dioxide

*Pre-screening will only occur in GP practices where databases are searched. *M* month, CO_2 carbon dioxide

waitlist control in a 1:1 allocation ratio. Permuted blocks of random size will be used. The Biomedical Research Centre data manager will generate the random allocation sequences which will be accessible through a password protected web page. Researchers will enter the participant ID code and sex into the web page, and a random allocation will be issued. Researchers will be aware of the group allocation. Participants will be informed of the group allocation via telephone by a member of the research team. Blinding of intervention allocation will not be possible for any participant involved in the trial. A maximum of 20 participants will be randomized to each of the trial arms.

PEDAL-2 intervention

Intervention content

Intervention content was designed using qualitative data from one-to-one interviews with participants who took part in an e-cycling feasibility study conducted in the summer of 2016 [29]. Interviews were used to identify barriers and enablers to e-bike use which were then categorized using the Theoretical Domains Framework [34]. These barriers and enablers were mapped onto intervention functions [35], and behaviour change techniques (BCTs; i.e., the active ingredients of an intervention) deemed most appropriate to deliver the intervention functions were identified. In addition, behaviour change techniques identified in the literature as significantly impacting upon general physical activity behaviour in individuals with T2DM were incorporated into the intervention design [36, 37]. The utility of these BCTs in the current intervention was considered with regard to affordability, practicality, effectiveness, cost-effectiveness, acceptability, side-effects/safety, and equity (the APEASE criteria [35]). In the present study, 17 behaviour change techniques will be incorporated into the intervention (see Additional file 2 for intervention content and associated behaviour change techniques incorporated into PEDAL-2).

Instructor training
Four instructors from Life Cycle UK, a Bristol-based cycling charity who specialize in bicycle training, will deliver the intervention. All instructors will be disclosure and barring service checked and first aid qualified. Instructors are fully qualified National Standard cycle instructors, and so instructor training will focus on the behavioural aspects of the intervention content. In training session one (3 h), instructors will be taught how to communicate with participants in a way to promote and encourage behaviour change. Training session two (2 h) will be focused on reviewing the intervention manual and discussing the importance of completing intervention activities specified in the manual. Instructors will be provided with checklists to record and monitor intervention activities and report changes to the intervention content.

E-bike training
Following baseline measures (T0) participants allocated to the intervention will complete e-bike training at Life Cycle UK. The training will consist of two one-to-one sessions. Training session one is mandatory and will follow the National Standard for Cycle Training guidelines for level 1 and 2. Example activities include demonstration of safety equipment, starting, stopping, making U-turns, and demonstrating decision-making and safe riding strategy. Individuals' previous cycling experience will be considered when conducting the cycling-specific training.

Training session 2 will be optional and will occur within 2 weeks of session one. The instructor and participant will discuss the need or desire for session 2. Session 2 will provide participants with an opportunity to practice e-cycling skills with the instructor. Busier roads and complex junctions will be incorporated into the session if desired by the participant. Training sessions 1 and 2 will last approximately 2 hours each. Throughout the sessions, the instructors will provide participants with feedback on their e-cycling and give verbal encouragement. Practical e-cycle training will be followed by a discussion in which instructors will help participants identify cycle routes, encourage participants to think about where and when they plan to ride the e-bike and to set specific e-cycling goals. Participants will be encouraged to monitor their e-cycling and will be provided with a log-book to track activity. Alternatively, instructors will assist the participant in setting up a mobile tracking application (Garmin Connect mobile). Instructors will encourage participants to think about potential barriers to e-cycling that could arise and brainstorm strategies to overcome these barriers. Instructors will also discuss the potential health, social and environmental consequences of e-cycling. Participants will be invited to join a private social media group to share their experiences and ride ideas with other individuals participating in the intervention. Instructors will coordinate this group.

Following the training (1 or 2 sessions depending on participants demonstration of appropriate skill level and confidence) participants will be provided with an e-bike to take home. E-bikes can be ridden home or, if desired, transportation of the e-bike will be provided by Life Cycle UK. Upon taking the e-bike home, participants will be provided with the following:

- Maps of cycle routes in the area
- Instructions of a call out maintenance service in case of breakdown
- Helmet, pannier, bike lock and lights
- Garmin edge 130 GPS device to use and track cycling activity.

E-bike loan
Participants will be loaned an e-bike for 12-weeks. Participants will be informed that the e-bike is for use by themselves and not to be lent to friends or family. During this time, participants will be instructed to use the e-bike as they desire, this means that no specific daily or weekly cycling frequency or distance targets will be imposed on participants by the researchers. Four weeks after taking the bike home, participants will attend a 'refresher' session with their instructor (session 3). This session will take place at a location of the participant's choice (i.e., at their home or in the local community) and will last approximately 2 h. The content of the session will depend on the participant's needs but will include practicing riding skills on established or new routes and a review of participants e-cycling activity as well as action planning and goal setting for future rides. At week 8, the instructor will contact the participant by telephone to discuss the participants progress, barriers to e-cycling that have arisen, and strategies used to overcome them and e-cycling goals for the upcoming month (session 4). At the end of week 12, participants will be asked to return the e-bike to Life Cycle UK headquarters or an instructor will collect the e-bike from the

participant's preferred location. Throughout the loan period, Life Cycle UK will provide a call out e-bike maintenance service. If required, participants are instructed to call the maintenance number and a Life Cycle UK mechanic will come and repair the e-bike.

Control group

Individuals randomly assigned to the waitlist control after baseline data collection (T0) will receive two phone calls from the researcher at approximately week 4 and 8 in order to maintain engagement in the study. During these phone calls, the researcher will direct participants to diabetes support groups and additional diabetes services being offered in the local community, in line with standard-care procedures. After post-intervention data collection (T1) these individuals will be offered training session 1 and loaned an e-bike for 3 months. Sessions 2, 3 and 4 will not be conducted. Participants will be asked to report any contact they have with other individuals in the study to ensure no contamination between conditions has occurred.

Measures

Feasibility and acceptability

The following information will be recorded to assess the feasibility of recruitment through GP practices: the number of GP practices approached, the number of practices that agree to participate as participant identification sites, the number of individuals identified through database searches and the response rates. In addition, information on the number of individuals that attend diabetes education days and the Bristol Diabetes UK support group will be recorded. Recruitment rates from the three recruitment settings, consent rates and willingness to be randomized will also be recorded. Retention rates will be determined based on the number of individuals that complete the intervention and follow-up measures. Adherence rates to study procedures will be recorded. The acceptability of the intervention and data collection methodology will be explored through semi-structured one-to-one interviews with instructors and all study participants. These interviews will be conducted by a member of the research team. Interview questions for instructors will focus on factors that impact intervention delivery, including intervention content, facilities, time and burden. Interview questions for participants will focus on thoughts and feelings regarding participation in the intervention and data collection processes. The project team will track the costs and resources required in preparation for running the intervention. Life Cycle UK will track the staff costing of intervention delivery and from the maintenance service.

Process evaluation

We will evaluate whether the intervention was delivered and received as intended (implementation). This will be achieved through completion of intervention checklists by Life Cycle UK instructors and through semi-structured interviews with instructors and participants in the intervention group at the end of the intervention. Intervention intensity, recorded by instructors, will be determined through recording of the number of intervention sessions attended by participants as well as the volume of email and telephone contact between instructors and participants. To explore the mechanisms of impact, semi-structured interviews will be conducted with participants in the intervention group to identify barriers and enablers to engaging in e-cycling. These interviews will help to identify how the intervention impacts behaviour and to determine contextual factors that may influence the intervention.

Assessment of harm

Participants will be asked to report adverse events resulting from e-cycling (e.g., musculoskeletal problems, falls or road traffic accidents) by calling the study phone line. The number and types of adverse events will be reported. Adverse events that mean the participant is unable to continue with the intervention will also be documented under retention rates. Qualitative interviews will be used to explore any unintended consequences that arise from participation in the study.

Outcome measures

Clinical outcomes are those deemed to be of importance to clinicians in the treatment of T2DM. These outcomes will be assessed at baseline (T0) and immediately post-intervention (T1) and include the following:

Anthropometrics. Body weight will be assessed to the nearest 0.1 kg using digital scales (TANITA Corp, Tokyo, Japan) and height will be assessed to the nearest 0.1 cm (SECA, 700 SECA, Hamburg, Germany). These measures will be used to calculate BMI (kg/m^2). Waist circumference will be measured using a non-stretch tape measure to the nearest 0.1 cm, based on World Health Organization guidelines [38].

Biochemical variables. Baseline blood samples will be obtained by cannulation of the antecubital fossa from individuals in a fasted state (≥ 8 h overnight fast) to measure glucose, insulin, glycated haemoglobin (HbA1c), lipids (total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol and triglycerides) and C-reactive protein. A total of 8 mL of blood will be taken at this time. After baseline blood samples participants will complete an oral glucose tolerance test (OGTT) which will involve consuming 113 mL of Polycal (Nutricia Advanced Medical Nutrition, Trowbridge, UK) and 87 mL of water, equivalent to 75 g of anhydrous glucose, within 5-min. Further 7 mL blood samples will be drawn at 15-, 30-, 45-, 60-, 90-, and 120-min intervals. The first 5 mL of each draw will be discarded and 2 mL of blood taken for the analysis of glucose and insulin. The intravenous cannula will be kept patent through flushing with 5 mL 0.9% NaCI (B. Braun, Sheffield, UK). All blood samples will be transported immediately to the Bristol Royal Infirmary commercial laboratory and stored at − 80 °C until analysed. Samples will be analysed individually as soon as possible after delivery. Glucose, insulin, lipids and C-reactive protein will be analysed using a Roche Cobas C701 analyzer (Roche Diagnostics, Rotkreuz, Switzerland) and HbA1c will analysed using affinity chromatography. Basal insulin and glucose values will be used to calculate insulin resistance and beta-cell function using the Homeostasis Model Assessment calculator (University of Oxford, Diabetes, Trial Unit). Using values from the OGTT, incremental area under the curve (iAUC) for insulin and glucose will be calculated using the trapezoid rule. Glucose and insulin concentrations during the OGTT will be used to estimate insulin sensitivity using the Matsuda index [39]. The insulinogenic index and oral glucose disposition index will be used to assess beta-cell function. Once samples have been analysed, the remainder of the aliquot will be destroyed by the commercial testing laboratory. Once the study is complete, any remaining samples will be disposed of in accordance with the Human Tissue Authority's Code of Practice.

Health-related quality of life. The Short Form 36 Health Survey (SF-36 [40]) is a 36-item inventory designed to assess health-related quality of life (HRQL) from which 2 measures are derived, a physical component summary and a mental component summary. The physical component summary represents the average of the scales: physical functioning, role limitations due to physical health, bodily pain, and general health subscales. The mental component summary score is the average of the scales which assess energy/fatigue, social functioning, role limitations due to emotional health, and emotional wellbeing subscales. Summary scores are reported in a range from 0 to 100, with a lower score indicating lower quality of life.

Physiological outcomes will be assessed at baseline (T0) and immediately post-intervention (T1) and include the following:

Cardiorespiratory fitness will be determined by measuring maximum oxygen uptake (VO_{2max}) using a continuous incremental ramp maximal exercise test on an electronically braked cycle ergometer (Lode Excalibur, The Netherlands). The test will start with a 4-min warm-up at 30 W, with participants cycling at a cadence of approximately 60 revolutions per minute (rpm). Following the warm up, the resistance will increase by 1 W every 4 s (15 W per minute). The test will be terminated upon volitional exhaustion or when cadence falls below 50 rpm. Expired gas will be collected continuously by a metabolic cart (Parvomedics TrueOne 2400, Salt Lake City, UT, USA). VO_{2max} is defined as the highest 15-s moving average for VO_2 (in absolute [l/min] and relative [ml/kg/min] terms). Criteria for achieving VO_{2max} will be (1) respiratory exchange ratio > 1.15, (2) plateau in VO_2, (3) reaching age-predicted HR_{peak} (220-age); and/or (4) volitional exhaustion. Heart rate will be monitored using a Polar chest strap, which is integrated with the metabolic cart and cycle ergometer software (Lode Exercise Manager). HR_{peak} and peak power output (W_{peak}) will be recorded as the highest values attained in the test. Twenty minutes after completing the incremental VO_{2max} assessment, participants will complete a supramaximal test to confirm the findings of the incremental assessment. This assessment will follow guidelines outlined by Schaun [41]. The multistage test will consist of a 2-min warm-up at 30 W followed by 1 min at 60% of the incremental VO_{2max} then 110% of incremental VO_{2max} until volitional exhaustion or when cadence falls below 50 rpm [42]. The criteria for achieving VO_{2max} are the same as those reported above. Differences of ≤3% will be considered to demonstrate validation of the incremental VO_{2max} result. The higher of these two values will be taken as $VO_{2max.}$

Body composition. Dual-energy x-ray absorptiometry (Discovery-A; Hologic, Bedford, UK) scans will be used to assess whole-body and regional fat and lean mass using the manufacturers software. Peripheral quantitative computer tomography (pQCT; XCT 3000 scanner; Stratec, Medizintechnik GmbH, Pforzheim, Germany) will be used to assess intermuscular adipose tissue, muscle density and muscle cross-sectional area (MCSA) of the femur at 33% of the limb length. Data from the pQCT will be analysed using BoneJ [43], a freely available plugin for the software ImageJ2 [44]. Calibrations of these machines will be performed daily following manufacturers guidelines.

Behavioural outcomes

Physical activity will be measured at baseline (T0) and in the final week of the e-bike intervention. Participants physical activity will be assessed for 7 continuous days using an Actigraph accelerometer (GT3X, Actigraph, Florida, USA). The Actigraph accelerometer will be worn on an elasticated belt around the waist and taken off when sleeping, bathing or swimming. The accelerometer will record raw acceleration data at a sampling frequency of 30 Hz. Raw acceleration data will be processed using Actilife 6 software to reintegrate the data to 10-s epochs. Kinesoft software will be used to generate outcome variables describing physical activity intensity using equations developed by Freedson and colleagues [45], and the frequency and duration of physical activity. In the current study, the Actigraph accelerometer will be used to estimate total time spent in moderate-to-vigorous physical activity (MVPA) before and while having access to an e-bike. This measure has been extensively validated in both laboratory and free-living conditions [46] and has been reported to have a high completion rate in observational studies [47].

Travel behaviour will be measured at baseline (T0) and in the final week of the intervention, at the same time as physical activity monitoring. Spatial location will be recorded every 5 s using a personal GPS receiver (QStarz International Co. Ltd., Taiwan). Participants will be asked to wear the GPS receiver during waking hours and recharge the device at night. The device can be worn on the waist or in a pocket as desired. GPS data, in combination with accelerometer data, will be used to estimate (a) the modes of transport used by participants and (b) the amount of time spent in MVPA attributable to e-cycling and other modes of active transport.

Raw GPS data will be downloaded using Qtravel software (Qstarz International Co. Ltd. Taiwan) and extracted as csv files. Raw Actigraph acceleration data will be extracted as csv files using ActiLife 6 software (Actigraph, FL, USA). Data from these devices will be merged by timestamp using an open-source tool, which will (1) classify different modes of transportation and (2) determine the amount of MVPA attributable to different active transport modes in the merged data [48]. This tool has been found to accurately identify active travel 94.6% of the time in a cross-validation study. However, the tool has not been validated with e-cycling. As such, participants will be asked to wear a combined movement sensor and heart rate monitor (Actiheart®, CamNtech, Cambridge, UK) for the same time period as wearing the Actigraph monitor and GPS device. The Actiheart is a waterproof device worn on the left side of the chest and is attached with standard ECG electrodes. Accelerometer and heart rate data will be recorded at 15-s epochs (the shortest epoch available). Fifteen-second acceleration and heart rate data from the Actiheart device will be downloaded using Actiheart 4 software and merged with the GPS data. These data will be imported into ArcGIS for visual inspection and heart rate data will be used to confirm (or otherwise) identification of e-cycling. Once e-bike journeys have been identified, this will enable the estimation of physical activity associated with e-cycling.

Trip purpose

In addition to wearing a personal GPS, participants will be asked to complete a 7-day travel diary for the same time period. The travel diary will be adapted from Neves and Brand [49]. Specifically, participants will be asked to record the purpose of the trip, travel mode, the start and end time and the start and end location of each trip. Participants will be asked to classify their trip under one of eight categories: commuting, business, education, escort, shopping, visiting friends, entertainment, and recreation. For each journey, participants will be asked to report the travel mode, walking, cycling, e-biking, bus, train, car (as driver) and car (as passenger). This diary will be used to identify the purpose of trips being made by different transport modes and specifically the purpose of e-bike use.

Estimated CO_2 emissions

Transport-derived CO_2 emissions will be calculated by multiplying the distance travelled by each motorized mode (determined through GPS and accelerometer data) by the mode's average emissions factors following the procedure outlined by Neves and Brand [49]. For travel by bus, train and other non-car modes, the total distance travelled in past week, based on GPS and travel diary data, will be multiplied by the average emissions factors based on UK Green House Gases reporting guidelines [50]. For cars, CO_2 emissions will be estimated by considering the car size (based on engine size), fuel type, vehicle age, number of cold starts (calculated as the number of reported trips) and average speed (using GPS data). These factors underlie the National Atmospheric Emissions Inventory and will be obtained from DEFRA [50].

E-cycling during the intervention

The number of e-cycling journeys, the distance travelled on the e-bike and the pattern of e-bike use throughout the 12-week intervention will be determined through use of a cycling GPS unit (Garmin Edge 130). The GPS device will attach directly to the bicycle. Data will be automatically uploaded to the Garmin Connect website via Bluetooth connection with the participant's phone or manually by the instructor at monthly intervals during meeting times (if the participant does not wish to track their e-cycling via the Garmin Connect website). Participants will be provided with instructions on how to use the device and a power cable to charge the device. The e-bike odometer, which is permanently attached to the bike, will provide a total measure of total distance travelled over the three-months.

Analysis plan

Quantitative analysis

The primary outcomes of this pilot trial include recruitment and consent rates, retention and adherence to study procedures and data provision. Analysis of these data will be descriptive, expressed as frequencies and percentages. Any adverse events will be described appropriately. Characteristics of the sample will be summarized using

Table 2 List of PEDAL-2 study objectives, associated outcomes, data collection tools, time point measurements and analysis plan

Study objectives	Outcome	Data collection method/tool	Time point of measurement			Analysis plan
			Baseline (T0)	During intervention	Follow-up (T1)	
1. Identify effective methods of recruiting individuals with T2DM	• # GP practices approached; # that agree to act as PIC • # individuals identified through GP database searches; response rate to information letters • # participants recruited from each recruitment setting • # individuals that consent to be part of the study	Study records	X			Frequencies and percentages
2. Determine participants willingness to be randomized, study retention rates, adherence to the intervention and data collection methods and report harmful outcomes	• # participants retained in study following randomization • # Individuals that complete follow-up testing • # of participants that attend each of the intervention sessions and data collection sessions • # of harmful events	Study records		X		Frequencies and percentages
3. Assess intervention fidelity	• # of training sessions attended by participants and additional contact with instructors • Extent to which intervention content is completed as planned	Intervention checklists		X		Frequencies and Percentages
4. Estimate the potential effect of the intervention on a range of health and behaviour outcomes to inform outcome selection in future trials	• Weight, height, BMI	Tanita digital scales, SECA 700	X		X	Comparison of change scores between conditions
	• Waist circumference	Non-stretch tape measure	X		X	
	• Fasting glucose, insulin, lipids, C-reactive protein, HOMA-IR, HOMA-B	8-mL blood sample	X		X	
	• OGTT outcomes: iAUC for glucose and insulin, Matsuda index, insulinogenic index and oral glucose disposition index	2 mL blood samples at 15, 30, 45, 60, 90, 120 min post 75 g of anhydrous glucose	X		X	Reporting of effect estimates with 95% CI
	• Health-related quality of life: physical and mental summary	Short Form 36 Health Survey [39]	X		X	
	• Cardiorespiratory fitness	Maximum oxygen uptake using cycle ergometer	X		X	
	• Body composition: whole-body fat mass, regional fat mass, whole-body lean mass, regional fat mass	Dual-energy x-ray absorptiometry	X		X	Comparison of change scores between conditions
	• Femur intermuscular adipose tissue, muscle density and muscle cross-sectional area	Peripheral quantitative computer tomography				
	• Total physical activity (time spent in moderate-to-vigorous physical activity)	Actigraph (GT3X)	X		X	Reporting of effect estimates with 95% CI
	• Moderate to vigorous physical due to e-cycling and other modes of active travel	Actigraph (GT3X), Actiheart and QStarz GPS				
	• Transportation modes (walking, cycling, e-cycling, car,	Actigraph (GT3X), Actiheart and QStarz	X		X	

Table 2 List of PEDAL-2 study objectives, associated outcomes, data collection tools, time point measurements and analysis plan *(Continued)*

Study objectives	Outcome	Data collection method/tool	Time point of measurement			Analysis plan
			Baseline (T0)	During intervention	Follow-up (T1)	
	bus, train)	GPS				
	• Trip purpose (e.g., commuting, business, education, escorting, shopping, visiting friends, entertainment, recreation)	Travel diary	X		X	
	• Estimated CO_2 emissions	Actigraph (GT3X) and QStarz GPS, travel diary following procedures by Neves and Brand [48]	X		X	
	• E-cycling behaviour: # journeys, distance travelled, pattern of e-bike use	Bike odometer and Garmin 130 GPS		X		Mean and SD
Qualitatively examine the acceptability of the intervention and study procedures to participants and instructors	• Acceptability of intervention to participants • Acceptability of study procedures to participants • Acceptability of intervention delivery to instructors	Semi-structured interviews			X	Thematic analysis based on objective
Qualitatively examine participants experiences of e-cycling	• Participants barriers and facilitators to e-cycling	Semi-structured interviews			X	Thematic analysis based on objective

T2DM type 2 diabetes mellitus, *GP* general practitioner, *PIC* participant identification center, *HOMA-IR* Homeostasis Model Assessment for assessing insulin resistance, *HOMA-B* homeostatic model assessment for assessing β-cell function, *OGTT* oral glucose tolerance test, *iAUC* incremental area under the curve, CO_2 carbon dioxide, *CI* confidence interval, *SD* standard deviation

descriptive statistics (means and standard deviations, medians and interquartile ranges, or frequencies and percentages as appropriate). Descriptive comparisons of these data will be made between the intervention and the wait-list control. Evidence of promise of the intervention (i.e., whether the intervention can lead to changes in outcomes measures) will be examined using comparison of change scores between conditions for all outcome measures (except e-cycling during the intervention). See Table 2 for a description of the outcome measures and proposed analysis plan for each outcome. Effect estimates will be presented with 95% confidence intervals reported; p values will not be considered as the study is not powered to detect effectiveness.

Qualitative analysis

Recordings of interviews will be transcribed verbatim. An abductive approach to data analysis will be taken given the interaction between the data and the study objectives [51], this involves incorporating both deductive and inductive reasoning when analysing the data. Specifically, using the interview guide as a framework, deductive content-based analysis will be conducted to organize initial coding categories based on the study objectives, that is to determine the acceptability of the intervention and study procedures to participants and instructors as well as identify participants barriers and facilitators to e-cycling. Thematic analysis will then be carried out to inductively explore recurring patterns within subcategories. Content will be further delineated into sub themes with similar content. Each transcript will be analysed independently by two researchers. Once complete, the two researchers will compare and discuss coding and categorization. Any disagreements will be discussed and resolved through consensus.

The following progression criteria will be used to guide the decision as to whether to proceed to a definitive trial:

1. At least 20% of potentially eligible individuals express an interest in being part of the study. This criterion is based on previous feasibility work conducted in a similar population [29]. The proportion of individuals that express an interest in the study from each recruitment strategy will be calculated in order to identify the most effective

recruitment method and to determine, where appropriate, the number of GP practices, Diabetes Education sessions or Diabetes Support groups that need to be approached to successfully recruit for a future trial. The three methods of recruitment will be compared.
2. At least 80% of eligible individuals (identified through telephone screening and GP study clearance) are successfully randomized
3. Attrition of the pilot trial is low, with a study retention rate of ≥ 80%. This criterion is based on findings from a previous feasibility study conducted in a similar population [29].
4. At least 70% of participants in the intervention group attend at least 60% of the intervention sessions. This criterion is based on previous physical activity interventions conducted in individuals with type 2 diabetes [52].
5. Process evaluation findings suggest that > 80% of participants report the study methodology to be comprehensible and acceptable.

Discussion

Physical activity is a key component of managing T2DM. However, this population is less physically active than individuals without diabetes. E-cycling has been found to be an acceptable activity in individuals with T2DM; however, more research is needed to examine the feasibility of conducting a randomized controlled trial and to determine if e-cycling demonstrates a potential to positively impact both health and behavioural outcomes. This paper describes the protocol of *PEDAL-2*, a pilot randomized waitlist-controlled trial designed to evaluate the feasibility of conducting an e-cycling intervention in individuals with T2DM. The e-cycling intervention has been developed using previous literature and semi-structured interviews with the target population. It is important to acknowledge potential limitations in the proposed methodology. Specifically, the lack of blinding may create challenges with study retention particularly in the control group, potentially creating bias. This is common to many exercise studies and we have addressed this by offering all control participants the e-bike intervention at the end of the trial period. In addition, this single-centre pilot trial limits the ability to generalize to other cities across the UK or rural areas in which the feasibility and associated outcomes could be different.

Despite these limitations, the data collected in this trial could be used to inform the development of future e-cycling interventions and identify appropriate outcome measures for examination in a definitive trial if deemed appropriate.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s40814-019-0508-4.

Additional file 1. SPIRIT checklist.
Additional file 2. Behavioural Intervention.

Abbreviations

BCT: Behaviour change technique; BMI: Body mass index; CO_2: Carbon dioxide; HbA1c: Glycated haemoglobin; METs: Metabolic equivalents; MVPA: Moderate to vigorous physical activity; OGTT: Oral glucose tolerance test; pQCT: Peripheral quantitative computer tomography; RCT: Randomized controlled trial; T2DM: Type 2 diabetes mellitus

Acknowledgements

Not applicable.

Authors' contributions

JEB designed the study. AP, ARC, SL, CE and RA contributed to the design of the study. JEB drafted the full manuscript. All authors read and approved the final manuscript.

Funding

This study is funded by the National Institute for Health Research NIHR Bristol Biomedical Research Centre (Nutrition theme) at University Hospitals Bristol NHS Foundation Trust and The University of Bristol. The funding body had no role in the design of the study or writing the manuscript.

Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Ethical approval for this project was granted by the South West–Central Bristol Research Ethics Committee (REF reference number 18/SW/0164).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Received: 3 May 2019 Accepted: 1 October 2019
Published online: 23 November 2019

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Publisher's Note

Appendix 5.2 CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial

Section/Topic	Item No	Checklist item	page No or section
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	89
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	N/A
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	89-96
	2b	Specific objectives or research questions for pilot trial	97
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	98
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	99-100
	4b	Settings and locations where the data were collected	Figure 5.1
	4c	How participants were identified and consented	98-99, 100
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	102-106
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Table 5.2, Sections: 6.3, 7.3, 8.3
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	169
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	111-112
Sample size	7a	Rationale for numbers in the pilot trial	100-101
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	101
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	101
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	101
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	101

		interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	109-110
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	119-129
	13b	For each group, losses and exclusions after randomisation, together with reasons	126-127
Recruitment	14a	Dates defining the periods of recruitment and follow-up	119
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 6.3
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Table 6.6
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Sections 6.4, 7.4 , 8.5
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	130
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	6.5.8, 7.5.7, 8.5.6
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Sections 6.5,
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	7.5, 8.5
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	229
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	98
Protocol	24	Where the pilot trial protocol can be accessed, if available	89
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Appendix 5.1
	26	Ethical approval or approval by research review committee, confirmed with reference number	98

Appendix 5.3. Standards for Reporting Qualitative Research

No.	Topic	Item	page No or section
Title and abstract			
S1	Title	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	114, 198
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	N/A
Introduction			
S3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	114-115, 198-199
S4	Purpose or research questions	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	115, 200
Methods			
S5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale[b]	109-110, 118-119
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Appendix 5.16
S7	Context	Setting/site and salient contextual factors; rationale[b]	117
S8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[b]	N/A
S9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	98
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[b]	109-110, 118-119, 201
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	117

S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	134, 146, 202
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	109-110, 118-119, 201
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale[b]	109-110, 118-119, 201
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]	110-111
Results/Findings			
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Sections 6.4.4, 8.4
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Sections 6.4.4, 8.4
Discussion			
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/ generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Sections 6.5, 8.5
S19	Limitations	Trustworthiness and limitations of findings	Sections 6.5.8, 8.5.6
Other			
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	N/A
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Appendix 5.1

b The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Table 5.4. Overview of PPI event activities related to PEDAL2

Activity/Question	Group response
Provide a summary of the findings from the feasibility study (PEDAL1)	Some participants were initially sceptical that e-bikes were a form of 'lazy cycling'. One participant in the group took part in PEDAL1. They shared information about benefits of e-bikes – this had a big impact on attendees' perceptions of e-bikes. *Highlights potential for having an e-bike 'champion' with whom participants can identify*
Proposed methods for PEDAL2 outlined	
What is the best way to get information about the study to individuals with T2DM?	Participants were unsure of how best to reach this population and suggested education days or social media but realised this would not reach everyone.
We may ask people to get clearance to be in the study from their GP. What would you think about that?	No problem with asking GP for support if there is no cost incurred.
How would you feel if we asked you to come to Bristol and Bath for testing before and after the trial?	Testing in Bristol was no problem and generally felt going to Bath would be okay if there is reimbursement for travel expenses incurred. Participants highlighted the need for evening and weekend appointments to accommodate schedules of working individuals.
What do you think about the specific measures?	Some women did not want to see their DEXA scan results as it may cause anxiety if participants are conscious of their appearance.
	No concern about having blood taken. Several individuals talk about being used to having blood taken.
	Fitness assessment could be perceived as intimidating, so it is important to think about wording in the information letter to express that it is a gradual build up to being hard work, not hard from the beginning. There was an overwhelming preference for a bike fitness assessment, not a treadmill assessment.
	Fears about forgetting to put on the waist worn monitoring devices, suggest providing text reminders to put the devices on.
	In general individuals thought the assessments were exciting as they were unusual
How would you feel about being tracked while riding the e-bike	Not a problem with this. If there is something that they do not want the researcher to know about then they will not turn the device on.
What would you consider helpful to include in e-bike training?	Really liked the idea of having maps provided to show bike routes and working with the instructor to plan routes. Knowing where bike shops are would also be helpful. Would like puncture proof tires on the bikes to reduce likelihood of punctures.
Do you think there should be a free maintenance service available?	Having this service would remove anxiety for those that were unfamiliar with cycling.
Do you think there should be an online social community?	Mixed opinions. Some felt it should be offered for those that would want it but it was not essential.
What do you think would stop people from taking part in this study?	Not getting to try an e-bike.
What would encourage people to take part in this study?	Ensuring that at some point everyone had the chance to try out an e-bike

Appendix 5.5 HRA approval letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Ms Jessica Bourne
PhD student
University of Bristol
NIHR Bristol Biomedical Research Centre (Nutrition Theme)
Level 3 University Hospitals Bristol Education Centre
Upper Maudlin Street, Bristol
BS2 8AE

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

10 September 2018

Dear Ms Bourne

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Promoting electrically-assisted cycling in people with type 2 diabetes: A randomized pilot study**
IRAS project ID:	**244593**
Protocol number:	**2918**
REC reference:	**18/SW/0164**
Sponsor	**University of Bristol**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations in England and Wales that are **Other sites** should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter. You should then work with each organisation that has confirmed capacity and capability and provide clear instructions when research activities can commence.

Participating NHS organisations in England and Wales that are **PIC sites will not** be required to formally confirm capacity and capability before you may commence research activity at site. As such, you may commence the research at each organisation 35 days following sponsor provision to the site of the local information pack, so long as:

- You have contacted participating NHS organisations (see below for details)

- The NHS organisation has not provided a reason as to why they cannot participate
- The NHS organisation has not requested additional time to confirm.

You may start the research prior to the above deadline if the site positively confirms that the research may proceed.

If not already done so, you should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. After entering your IRAS ID you will be able to access a password protected document (password: **House45**). The password is updated on a monthly basis so please obtain the relevant contact information as soon as possible; please do not hesitate to contact me should you encounter any issues.

Commencing research activities at any NHS organisation before providing them with the full local information pack and allowing them the agreed duration to opt-out, or to request additional time (unless you have received from their R&D department notification that you may commence), is a breach of the terms of HRA and HCRW Approval. Further information is provided in the "*summary of assessment*" section towards the end of this document.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Jessica Bourne
Tel: 0117 342 1883
Email: jessica.bourne@bristol.ac.uk

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **244593**. Please quote this on all correspondence.

Yours sincerely,

Natalie Wilson
Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Birgit Whitman, University of Bristol, Sponsor contact*
Ms Rachel Avery, Avon Primary Care Research Collaborative, Lead NHS R&D contact

Promoting **E**lectrically-assisted cycling in people with type 2 **D**iabetes: **A randomized piLot study** (PEDAL2)

Participant Invitation Letter

You are being offered the opportunity to take part in a new research project at the University of Bristol. This project will explore whether the personal use of an electrically-assisted bicycle (e-bike) for three months will help people with type 2 diabetes to become more active and improve health.

If you take part you could...

- *Have personal use of an electrically-assisted bicycle for three months, free of charge*
- *Be supported by trained professionals to learn how to ride an e-bike and basic bike maintenance*
- *Be provided personalized feedback on how riding an e-bike impacts a range of health outcomes*

The project is being run by researchers at the Bristol Biomedical Research Centre (Nutrition Theme); the same team who ran a similar study looking at electrically assisted cycling in similar individuals last year. You are being offered the opportunity to take part in this new project because you have been diagnosed with type 2 diabetes.

Please find enclosed an information sheet which will tell you much more about the study and what it involves.

If you are interested in taking part, or would like a bit more detail, then we would like to hear from you. Please either complete the attached reply slip and post it to the address listed using the free post envelope provided or contact Jessica Bourne on +44 (0)117 342 1883/4 or jessica.bourne@bristol.ac.uk

Thank you very much for taking the time to read this information.

Yours sincerely

_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Jessica Bourne
Chief Investigator
(On behalf of the study team)

PEDAL2 Reply Slip

Name		
Address		
Post code		

Would you be interested in taking part in this study? (Please circle)	Yes	No

If no, please say why. *(You do not have to write anything here if you do not wish to tell us your reasons for not taking part, but any information you provide could help us to improve how we communicate with people about studies we are conducting.)*	

If yes, please let us know the best way for a member of the study team to contact you to arrange an initial appointment.

Please circle the best option and please give the relevant contact details. We will not share these outside of the study team.

Mobile telephone: ____________________
Landline: ________________________ Best time to call? Morning/lunch/afternoon/early evening
Email: ___________________________

Please return this slip to:
Jessica Bourne,
NIHR Bristol Biomedical Research Centre (Nutrition Theme)
Education and Research Centre
Upper Maudlin Street
Bristol
BS2 8AE

Thank you, and if you said yes a member of the study team will be in touch soon!

Appendix 5.7 PEDAL2 study information sheet

Promoting **E**lectrically-assisted cycling in people with type 2 **D**iabetes: **A randomized piLot study** (PEDAL2)

INFORMATION SHEET

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your friends, relatives or a health professional if you wish. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information.

What is this study about?

We know that physical activity is very important for health. Regular physical activity can help with glucose control, and improve blood pressure and cholesterol, but it can be difficult to make a regular commitment to be active. Many people start off with good intentions but find they don't have time, they don't have the right equipment, or it is difficult or too expensive to go to a gym or sports club regularly. We know that physical activity that is a part of daily life is more likely to be sustained. Cycling is an activity that can be built into someone's day but, for many people cycling is very hard work and the idea of cycling around a hilly city like Bristol is off-putting. Recently, electric bikes (e-bikes) have become more popular as a fun and easy way to be more active and offer a healthy alternative to using the car for short journeys. This study will look at the feasibility and acceptability of a 12-week individualized e-bike programme for individuals with Type 2 Diabetes. The study will also examine if e-biking can influence a range of positive health outcomes including fitness and quality of life. Individuals in the study will have training on the e-bike and basic bike maintenance. Additional support will be provided to help overcome some of the challenges to becoming more active that people with type 2 diabetes face. We will lend people an e-bike, a bike lock, cycling helmet, bike panniers and lights for the duration of the 12-weeks. This study will help us to understand if e-biking can help people with type 2 diabetes engage in more physical activity.

What is an electrically-assisted bicycle, or e-bike?

An e-bike is like a normal bicycle with the addition that it helps you up the hills. E-bikes are common across Europe and are becoming more available and affordable in the UK. The e-bike uses battery power to provide assistance as you pedal. It is not like a motorized vehicle as you still have to pedal to make it move, but the effort required to get moving, and keep moving when you reach a hill, is less than if you were riding a normal bike.

Why have I been contacted?

We are asking you to take part in this study because you have been diagnosed with Type 2 Diabetes and are between 30 to 70 years of age.

What will happen to me if I take part?

If you are interested in taking part, a member of the research team will contact you to determine whether it is appropriate for you to participate. Specifically, you will be asked to provide your latest HbA1c measurement, your level of physical activity and some additional general health questions. This discussion will take place on the telephone and will take no longer than 30-minutes. If it appears that it could be appropriate for you to participate you will be asked to visit your GP to obtain medical clearance for participation in the study. At this time the GP will take your blood pressure and report the result on the appropriate form. The GP will also record any hypertension medication you are taken. This information will be shared with the researchers. Once complete, the GP clearance document can be sent directly to the research team via email or post in the stamped addressed envelope provided. If expenses are incurred from this visit these will be covered by the research team.

After medical clearance documentation has been received you will be contacted to make an appointment for your first visit. At visit 1 you will be able to ask any questions and decide whether you want to take part in the study.

Visit 1, Day 1 (Approximately 210-minutes – Clinical Research and Imaging Centre, Bristol)

Visit 1 will consist of coming to the Clinical Research and Imaging Centre, Bristol fasted, that is, not having eaten in the last 8 hours. At this time a member of the research team will confirm your eligibility for the study, which will include asking you to complete a consent form if you wish to continue in the study and taking your blood pressure. You will have your height, weight and waist circumference measured.

You will then be asked to complete two food-related tasks. In the first task, the food preference task, you will be presented with images of foods commonly eaten in the UK on a computer screen, and you will have to select the foods you would "most like to eat" at that point in time, as well as your ideal portion size. In the second task, the motivation for food reward task, you will be asked to squeeze a dynamometer (applying as much force as you wish) for 30 seconds to obtain a food reward to take home at the end of assessment.

A member of the research team (a trained phlebotomist) will then insert a cannula into a vein in your forearm to allow for repeated blood sampling. After the first blood sample is taken you will be asked to ingest a drink containing 75g of sugar (glucose) and then remain rested for two hours with regular blood samples being taken (total of six samples). Each sample will involve approximately two teaspoons of blood being taken, 1ml will be taken to assess insulin and 1ml to assess glucose. This will allow us to determine how efficiently your body processes sugar. To make sure that the cannula is kept clean 5ml of saline will be flush the cannula after each blood sample is taken (excluding the last). This means a total of 30ml of saline will be used to flush the cannula at this time. If cannulation is not possible then we will take one blood sample (approximately two teaspoons of blood) and no drink or follow up blood samples will be conducted.

During this visit we will ask you to complete a questionnaire regarding some general information about yourself, your thoughts and feeling towards physical activity and your dietary beahviour.

After this time, the researcher will attach a physical activity monitor to your chest to wear for seven days. The waterproof device is attached to the chest using electrical tape, shown in the picture on the right, and will record all your activity. You will be provided with spare electrodes so that you can change them if required during the seven days. The research nurse will demonstrate how to do this. You will also be given a physical activity monitor to wear on your hip for the same time. The monitors will be returned to the study researcher at visit 2. For the same seven days we will ask you to carry a personal GPS receiver on all trips you make outside the house and keep a travel diary to compliment this device.

Visit 2 (Approximately 120-minutes – University of Bath)

At least seven days after visit 1 you will be invited to the University of Bath for visit 2. There are facilities to park at the university or you can catch the train and the study researcher can meet you at the train station in Bath before making your way to the university.

After this you will be invited to have a scan of your upper thigh using a machine called a peripheral quantitative computer tomography machine, shown in the picture on the right. For this scan you will sit on a chair and put your leg through the hole in the machine. You will need to bring shorts or stretchy leggings so that there are no clothes covering the area to be scanned.

You will then be invited to have a full body scan called a dual-energy -x-ray absorptiometry (DEXA). The DEXA scan is a simple assessment that requires you to lie still on a bed, like the one shown in the picture on the right, for approximately 5-minutes. The radiation exposure is extremely low and equivalent to approximately 1 day of natural background radiation (i.e., no more risk than a normal day of living). We ask that you wear or bring lightweight clothing (shorts/t-shirt) for the assessment. The DEXA scan must be taken without any metal objects, so we ask that you not wear any clothing with metal buttons, zips, clasps, snaps, drawstrings etc. We will also ask you to remove any metal piercings.

After this measurement you will be invited to complete a VO_{2peak} fitness measurement. This measure is performed on a stationary bike and assesses how much oxygen your body is capable of using. The image below provides a representation of the equipment used to conduct the fitness measure. This measurement will take approximately 15 minutes and involves cycling at a level that will increase in difficulty as time passes until you can no longer continue, or until you reach your age predicted maximum heart rate. After this assessment we will ask you to perform a very similar test in much shorter period, approximately five minutes, with an intensity slightly higher than in the initial assessment. This assessment is conducted to ensure our results from the first assessment are accurate. You will have a 20-minute rest period between completing the two assessments.

This study involves random assignment to one of two groups. These two groups are 1) immediate e-bike training and access or 2) waitlist control, e-bike training and access in approximately 16-weeks. The only difference between the groups is when you have access to the e-bike. At the end of this session individuals will be randomly assigned to one of two groups in the study.

E-bike Training

Following these assessments, you will be invited to Life Cycle UK to participate in a familiarization phase. During this time, you will learn how to use the e-bike with fully trained instructors for two one-to-one training rides. The Life Cycle instructors will work with you to identify potential cycle routes from your house or work, in addition you will work with the training to discuss and plan some goals for when and where to ride your e-bike at home. It is anticipated that this training period will last approximately two weeks. After this time, you will be provided with all necessary equipment and safety kit for the loan period of the e-bike. At the end of the training phase you will be free to take the e-bike home. Life Cycle UK will arrange for transportation of the e-bike to your home if required.

E-biking Maintenance
After e-bike training you will have an e-bike on loan for 12-weeks. There will also be a training session on week four of the loan period with a Life Cycle instructor. This can take place at a location of your choice. In addition, the Life Cycle instructor will contact you on week eight to discuss your progress with the e-bike. For the duration of this time a GPS will be attached to the e-bike for us to see the frequency and duration of any e-bike rides. We will not monitor where you go on the e-bike.

In week 10 of the loan period a member of the research team will come out to visit you and provide you with the activity monitors, personal GPS and travel diary to complete during the last week with the e-bike (following the same procedure as before). After seven days a member of the research team will collect the devices and the e-bike will be collected by an individual from Life Cycle UK.

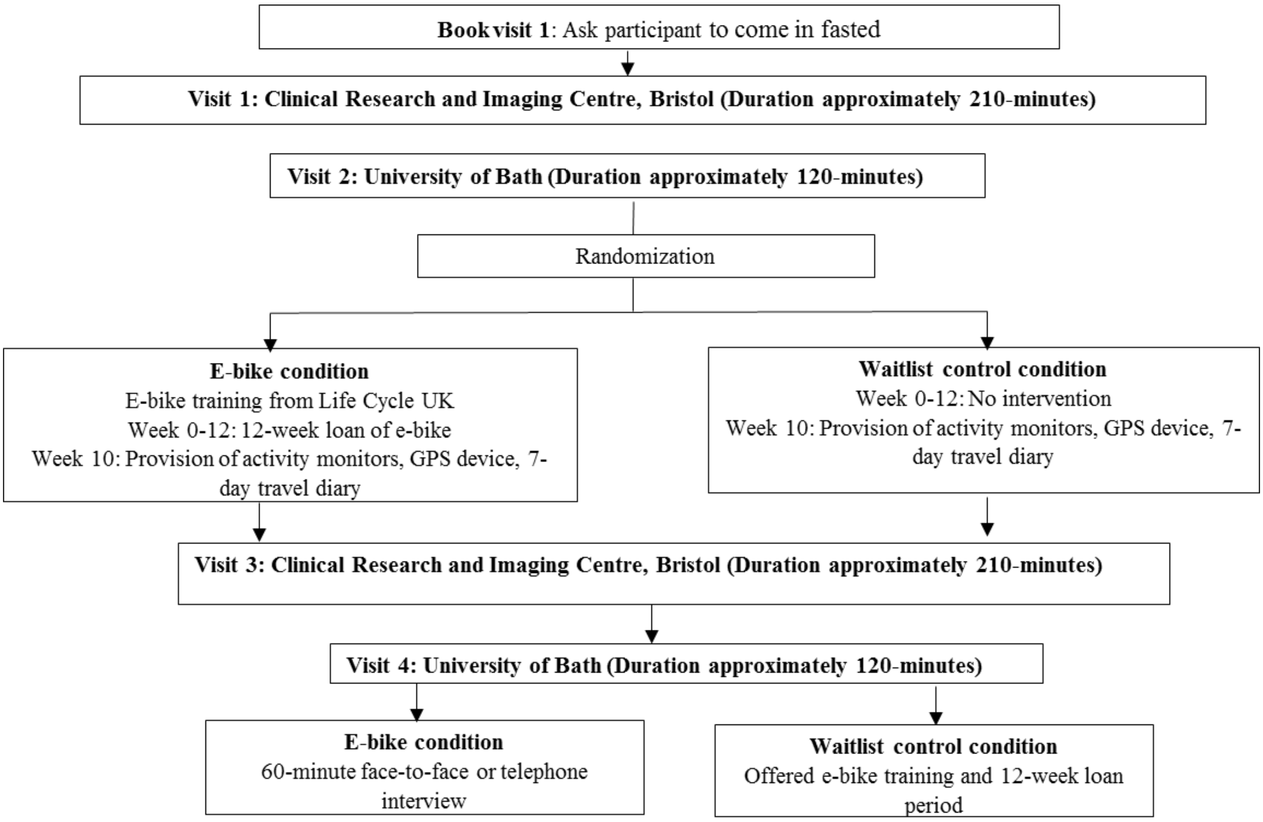
Visit 3, (Approximately 210-minutes – Clinical Research and Imaging Centre, Bristol)
This visit will include coming fasted to the appointment and having blood taken at baseline and at 30-minutes intervals following consumption of a sugar drink as in visit 1. You will have your weights, waist circumference and blood pressure measure at the start of this visit. You will be asked to complete a questionnaire, a food preference task and a motivation for food reward task.

Visit 4 (Approximately 120-minutes – University of Bath)
As soon as possible after visit 3 you will be invited to return to the University of Bath to complete the same assessments as in Visit 2. These include completing a questionnaire, a scan of your femur, a full body scan and a maximal exercise assessment and verification.

Follow-up
One-to-one interview (Approximately 60-minutes – telephone or face-to-face) – E-bike condition only
You will be invited to participate in a one-to-one interview at a time of your choosing after the study to discuss your experiences of using an e-bike and thoughts and feelings regarding the support your received during the 12-week loan period.

E-bike training and access – Waitlist control only
After completion of visit 4 individuals in the waitlist control will be invited to e-bike training at Life Cycle UK. E-bike training and access will be the same as is described above however, the assessments (i.e., visit 1 to 4) will not be re-done.

Below is an outline of what will happen during the study and the difference between the two conditions:



Do I have to take part?

It is up to you to decide whether to take part. If you do decide to take part, you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. We will keep the data collected up until this point to include in analyses unless you wish for all your data to be destroyed.

Are there any disadvantages/risks in taking part in the study?

The potential risks to you if you choose to participate in this research relate to the blood sampling, exercise testing procedures, leg scan and engaging in physical activity in a free-living setting.

There is some small discomfort from the needle that is used for collecting blood during the study. There is the possibility that you may experience feelings of nausea or may faint when having blood drawn. The blood sample procedures are similar to what you would experience at a doctor’s office or medical laboratory. The insertion of a needle for blood sampling is a common medical practice and involves minimal risk provided proper precautions are taken. The needle is inserted under completely sterile conditions, however there is a theoretical risk of infection because venepuncture breaches the closed sterile circuit of the circulatory system. There is also a risk of bruising and soreness around the puncture site, resulting from poor technique. Prolonged bleeding time may also occur in patients on blood thinning medication to address blood pressure, increasing the risk of haematoma. These risks will be minimised through using a trained phlebotomist to conduct these measures, who will ensure proper technique and preventive steps are applied, including a medication check prior to procedures.
There are some risks involved in flushing a cannula with sodium chloride. These include a cold feeling or mild burning. There could be some irritation around the insertion site. These risks will be minimised through using a trained research nurse, who will ensure proposer technique.

There are no serious risks of the oral glucose tolerance test. Some individuals find the drinks difficult and may experience feelings of nausea or stomach discomfort. We will provide a pre-packaged snack at the end of the test.

There are risks associated with participating in a maximal and supramaximal exercise test. These risks include fatigue, fainting, and or muscle soreness. These risks will be minimized by ensuring that a first aid trained researcher is present at all times and that a standardized warm-up and cool-down procedure is followed prior to and at the conclusion of the exercise measurement. A more severe risk, although very uncommon at only one in 40,000, is the risk of heart attack. Maximal and supramaximal exercise assessments are routinely performed on a range of 'high risk' patients without any negative side effects. To further minimize these risks, each participant will be cleared by a GP for participation in the study and to conduct the maximal exercise test. When completing the baseline assessments participants may feel some discomfort when wearing the facemask. The study researcher will adjust the equipment to make you as comfortable as possible.

Assessment of femur composition will be assessed using peripheral quantitative computer tomography, which does incur a very low dose of ionizing radiation. The radiation exposure during a scan is lower than 0.01 mSv, equivalent to about one days' worth of natural background radiation. Consistent with this would be that the risk to you is negligible and no greater than a normal day living.

Body composition assessed using DEXA does incur a very low dose of ionizing radiation. The radiation exposure during a full body scan on the Hologic Discovery A device is 0.008 mGy, equivalent to about one days' worth of natural background radiation. Consistent with this would be that the risk to you is negligible and no greater than a normal day living. DEXA is a standard tool in the measurement of body composition and bone density in adults and children throughout multiple institutions.

The activity monitor is worn on the chest and is attached to ECG electrodes. There is a risk that the electrodes may cause some discomfort to participants' skin. To prevent skin irritation, you will be provided with skin sensitive electrodes, in addition to the regular electrodes in case you feel discomfort. In addition, we will provide enough electrodes to change on a two day basis as regularly changing the electrodes will reduce skin irritation.

There may be times when you will be cycling on roads with motorized traffic, which presents certain risks. However, you will be supported in becoming confident and safe during the cycle training. All training rides and potential group rides will be delivered by Life Cycle instructors who are Bikeability and first aid-trained and very experienced at delivering both individual and group cycle sessions. They will make every effort to minimize these risks and ensure your safety.

There is a time commitment involved in taking part; we will ask you to visit our research centers at the start and at the end of the study at pre-agreed times to be measured. These visits will be as brief as we can make them, and we will offer appointment times on evenings and weekends to try to fit in with individuals' schedules.

What are the benefits of taking part in the study?
One benefit from entering the study is individual assessments that will take place including physical fitness, leg muscle composition and bloods. You will be able to see how these assessments change over time and will be provided with a personalized report describing these assessments after the study. In addition, you will have your physical activity measured using advanced measurement techniques and you will be provided with a report of your activity levels

after the study. You will have the chance to be trained on, and practice riding, an e-bike, free of charge for 12-weeks.

What will happen to the information I give to you?
The University of Bristol is the sponsor for this study base in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bristol will keep identifiable information about you for 10-years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your ridges, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Jessica Bourne. The researchers will collect information from you for this research study in accordance with our instructions. The research team will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Bristol and regulator organisations may look at your research records to check the accuracy of the research study. The research team will pass these details to the University of Bristol along with the information collected from you. The only people in the University of Bristol who will have access to information that identifies you will be people who need to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. This personal information will be stored in a locked research store at the Nutrition Theme, Biomedical Research Centre, Bristol. The research team will keep identifiable information about you from this study until the study has been completed. Research data will be made anonymous and stored on University of Bristol and NHS computers for 10-years. We are also asking for your permission to use your anonymous research data in future studies, with ethical approval, and to use your personal data to tell you about other research studies that you may be interested in joining.

What will happen to any samples I give to you?
After blood samples have been taken they will be transported on foot to the Bristol Royal Infirmary laboratory and stored in designated freezers in the commercial laboratory facility. These freezers will remain locked when not in use to ensure no other partiers can gain unauthorised access. Access to the building is strictly controlled by use of an ID card and PIN number. The samples will be analysed as soon as possible after they arrive at the laboratory. . Once the samples have been tested and the study is complete all remaining samples will be disposed of in accordance with the Human Tissue Authority's Code of Practice. It is anticipated that the study will end in December 2019.

What if something goes wrong?
All the measurements and the cycle training sessions are being performed by trained professionals who have done these things many times before. Participants are all provided with safety equipment and a D-lock. All the measurements are safe, and the training sessions are tailored to suit you, therefore we do not expect anything to go wrong. However, there will always be medical experts and trained first aiders on hand just in case. All participants will have a separate cycle insurance policy taken out for them for the duration of the study, so they will be insured against theft, accidental damage, personal accidents and third-party claims whilst they are

in possession of the bike. This will come at no cost to the participant. The research team are available during working hours and may be contacted at any time if you encounter difficulties. This study will be sponsored by the University of Bristol. The University has Public Liability insurance to cover the liability of the University to research participants.

Will taking part in the study remain confidential?
All information collected during the study will be kept strictly confidential. It will be accessed only by members of the research team.

What will happen to the results of the research study?
Results from the research study will be published in peer reviewed journals and presented at scientific and medical conferences and shared with patient groups, charities such as Diabetes UK and with health professionals on-line, via social media and via magazines. At the end of the study all participants will be sent a summary of the findings.

Who is organising and funding the study?
The chief investigator of this study is Jessica Bourne and it is being run by the Biomedical Research Unit in Nutrition, Diet and Lifestyle at the University of Bristol. This research is part of Jessica Bourne's PhD studies. A research nurse and specialists in cycling from Life Cycle UK are all involved in the study. The study is funded by a grant from the National Institute for Health Research (NIHR).

Will there be money for travel expenses?
Yes, reasonable travel expenses will be covered for any trips to the research study center in Bristol and Bath. Travel expenses to Life Cycle UK for training will not be covered.

Ethical approval
This study has been reviewed by the NIHR, NHS Research & Development and the South West – Central Bristol Research Ethical Committee in accordance with local regulations.

Who do I contact for further information or to sign up?
Please phone (you may need to leave a message) or e-mail:

Jessica Bourne (Chief investigator)
+44 (0)117 342 1883/4
jessica.bourne@bristol.ac.uk

Please take this information to your GP and discuss the study with them to obtain medical clearance to participate

Appendix 5.8 PEDAL2 GP clearance form

Ms. Jessica Bourne
NIHR Biomedical Research Centre in Nutrition, Diet and Lifestyle
Level 3 University Hospitals Bristol Education Centre
Upper Maudlin Street
Bristol BS2 8AE

DATE

PHYSICAL ACTIVITY CLEARANCE

Dear Dr,

Your patient XX is interested in taking part in a research study being conducted at the University of Bristol. The study is titled: *Promoting electrically-assisted cycling in people with type 2 diabetes: A randomized pilot study* (Known as **PEDAL2**).

The purpose of this study is to investigate whether providing an electric bicycle to people with type 2 diabetes is an effective way to increase their physical activity and improve health. A previous feasibility study by our group found that people with type 2 diabetes were very positive about using e-bikes and we now wish to extend this work. More information about the nature and purpose of the study is provided in the attached information sheet.

All potential participants are being asked to consult their GP to confirm that they are able to exercise. In the study they will be required to:

- Complete a maximal exercise test on a cycle ergometer. The test will begin with a 4-minute warm-up at 30 Watts, with participants cycling at a cadence of approximately 60 revolutions per minute (rpm), after which resistance will be increased by 1 every Watt every 4 seconds (15 Watts per minute). The test will be terminated upon volitional exhaustion or when cadence falls below 50 rpm. This will be conducted at the start and end of the study.
- Complete a brief supramaximal test to confirm the maximal exercise test findings, consisting of a two minute warm up at 30 Watts followed by one minute at 60% of the incremental VO_{2peak} following by 110% of incremental VO_{2peak} until volitional exhaustion or when cadence falls below 50 rpm.
- Use an e-bike under free-living conditions for three months.

Based on the exercise involved participants are required to have systolic blood pressure (BP) of less than 160 mmHg and diastolic BP less than 90 mmHg. Please complete and sign this form, indicating any necessary physical activity restrictions, and have your patient return the form to the study team. Please see the participant information sheet for a more detailed outline of the study procedures.

Based upon my review of the health status of ______________________, I recommend:

- Unrestricted physical activity based on the *UK Physical Activity Guidelines* - start slowly and build up gradually, including assessment of cardiorespiratory fitness by means of a maximal exercise test before and after the intervention.
- Progressive physical activity:
    - With avoidance of: ____
    - With inclusion of: ____
- Only a medically-supervised exercise program until further medical clearance
- No physical activity

Please provide your patient's blood pressure measurement: __________________________

Is the patient currently taking hypertension medication? ____

If yes, please state what medication: _____________________________________

GP name (please print): ____

Signed: ______________________________ Date: __ / __ / ____

Surgery stamp:

The study is sponsored by the University of Bristol and was approved by the South West/Central Bristol Research Ethics Committee (Ref: 18/SW/0164) on 06.09.2018. If you would like more information about ethical approval please contact nrescommittee.southwest-bristol@nhs.net

If you have any questions regarding the physical activity proposed, the research study or the study team, please contact:

Study Coordinator: Jessica Bourne, MA

Email and Phone: Jessica.bourne@bristol.ac.uk | +44 (0)117 342 1883/4

Yours sincerely

[redacted]

Ms. Jessica Bourne
Chief Investigator /Study coordinator
Under the supervision of Professor Angie Page

Participant ID: ______________

CONSENT FORM

Promoting electrically-assisted cycling in people with type 2 diabetes: A randomized pilot study

Please read each of the following statements and initial in the box if you agree.

Please initial box

1. I confirm that I have read and understand the information sheet dated 12.02.2019 (version 3.3) for the above study. ☐

2. I have had the opportunity to ask questions and understand that I can withdraw my consent if I am not entirely satisfied with any of the answers that are provided to me. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. If I withdraw my participation I may ask for my data to be destroyed, and where possible this will be done. However, I understand that any results already anonymised, and therefore unidentifiable, will be kept. ☐

4. I understand that relevant sections of my medical notes and data collected during this study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to records. ☐

5. I agree to give blood samples for research in the above project. I understand that giving a blood sample for this research is voluntary and that I am free to withdraw at any time without giving a reason and without my medical treatment or legal rights being affected. If I decide to stop taking part in the study, I can ask for samples to be destroyed, but I understand that any experimental results already obtained with them will be kept. ☐

6. I understand that the data collected during this study will be made anonymous and confidential. ☐

7. I understand that anonymised data will be used for future studies, with ethical approval. * ☐

8. I understand that personal data will be stored on password protected computers and paper documents will be stored in locked filing cabinets in the Biomedical Research Centre at the University of Bristol. I understand that all data collected will be anonymised and stored in a database separate to personal information. ☐

9. I understand that interviews will be audio-recorded, but that any information I share will be made anonymous. ☐

10. I agree that I have been advised of the risks of undertaking a fitness test, leg scan, blood sampling along with the risks and liability considerations of using an electric bicycle on public roads and do so of my own accord. ☐

11. I agree to be contacted in the future to see if I am interested in taking part in future research. * ☐

12. I agree to participate in this study. ☐

* *Optional*

____________________	____________________	____________________
Name of Participant	Date	Signature
____________________	____________________	____________________
Name of Person taking consent	Date	Signature

Appendix 5.10 PEDAL2 instructor information sheet

Promoting **E**lectrically-assisted cycling in people with type 2 **D**iabetes: **A randomized piLot study** (PEDAL2)

INSTRUCTOR INFORMATION SHEET

We would like to invite you to take part in an interview as part of the PEDAL2 research study. Before you decide, it is important for you to understand why the interview is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with your friends, relatives or a colleague if you wish. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information.

What is this study about?
We know that for individuals with type 2 diabetes physical activity is key to help manage the disease. However, while many people start off with good intentions they often find they don't have time, they don't have the right equipment, or it is difficult or too expensive to go to a gym or sports club regularly to be physically active. As an alternative, e-bikes have been highlighted as a potential means through which to increase physical activity behaviour. The current study, PEDAL2 was conducted to find out if the provision of e-bikes for 12-weeks influenced a range of health outcomes including fitness and quality of life in individuals with type 2 diabetes. Alongside understanding the effectiveness of e-biking on user's health it is essential to understand the impact of programme implementation on the individuals who are being asked to deliver it. In PEDAL2 that is the instructors at Life Cycle UK, yourselves. This information is important as it gives us an understanding of the barriers and enablers to delivering a programme such as PEDAL2. This information will help us to understand the feasibility to implementing and maintaining PEDAL2 in the future and understand where and how changes may be required to promote long term sustainability.

Why have I been contacted?
We are asking you to take part in this interview because you are an instructor at Life Cycle UK who was involved in delivering the PEDAL2 intervention.

What will happen to me if I take part?
If you are interested in taking part, the study researcher will contact you to determine an appropriate time to conduct the interview. The interview can be conducted at a time and date that works for you. When you meet with the study researcher you will have the opportunity to ask any questions you have and if you wish to participate in the interview you will be asked to sign a consent form. Following this, you will be invited to participate in the 60-minute interview. This interview will be audio-recorded for later transcription.

Do I have to take part?
It is up to you to decide whether to take part. If you do decide to take part, you will be asked to sign a consent form. If you decide to take part, you are still free to terminate the interview at any time and without giving a reason. We will keep the data collected up until this point to include in analyses unless you wish for all your data to be destroyed.

Are there any disadvantages/risks in taking part in the study?

There are no known risks associated with participating in this study.

What are the benefits of taking part in the study?
You will have the opportunity to share your thoughts and feelings about the PEDAL2 programme which may lead to improvements in the programme in the future.

What will happen to the information I give to you?
The University of Bristol is the sponsor for this study base in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bristol will keep identifiable information about you for 10-years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Jessica Bourne. The researchers will collect information from you for this research study in accordance with our instructions. The research team will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Bristol and regulator organisations may look at your research records to check the accuracy of the research study. The research team will pass these details to the University of Bristol along with the information collected from you. The only people in the University of Bristol who will have access to information that identifies you will be people who need to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. This personal information will be stored in a locked research store at the Nutrition Theme, Biomedical Research Centre, Bristol. The research team will keep identifiable information about you from this study until the study has been completed. Interviews will be transcribed and anonymised. These will be stored on University of Bristol and NHS computers indefinitely.

What if something goes wrong?
As we are not asking you to do anything different than normal it is not anticipated that there will be any negative outcomes associated with taking part in this interview. However, the research team are available in normal working hours and may be contacted at any time.

Will taking part in the study remain confidential?
All information collected during the study will be kept strictly confidential. It will be accessed only by members of the research team.

What will happen to the results of the research study?
Results from these interviews may be included publications in peer reviewed journals and presented at scientific and medical conferences.

Who is organising and funding the study?
The chief investigator of this study is Jessica Bourne and it is being run by the Biomedical Research Unit in Nutrition, Diet and Lifestyle at the University of Bristol. This research is part of

Jessica Bournes PhD studies. The study is funded by a grant from the National Institute for Health Research (NIHR).

Will there be money for travel expenses?
No reimbursement will be provided for taking part in this study.

Ethical approval
This study has been reviewed by the NIHR, NHS Research & Development and the South West – Central Bristol Research Ethics Committee Research Ethical Committee in accordance with local regulations.

Who do I contact for further information or to sign up?
Please phone (you may need to leave a message) or e-mail:

Jessica Bourne (Chief investigator)
+44 (0)117 342 1883/4
jessica.bourne@bristol.ac.uk

Appendix 5.11 PEDAL2 instructor consent form

Participant ID: ______________

CONSENT FORM FOR INSTRUCTORS

Promoting electrically-assisted cycling in people with type 2 diabetes: A randomized pilot study

Please read each of the following statements and initial in the box if you agree.

Please initial box

1. I confirm that I have read and understand the information sheet dated 03.09.2018 (version 2.2) for the above study. ☐

2. I have had the opportunity to ask questions and understand that I can withdraw my consent if I am not entirely satisfied with any of the answers that are provided to me. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. If I withdraw my participation I may ask for my data to be destroyed, and where possible this will be done. However, I understand that any results already anonymised, and therefore unidentifiable, will be kept. ☐

4. I understand that interviews will be audio-recorded, but that any information I share will be made anonymous. ☐

5. I understand that personal data will be stored on password protected computers and paper documents will be stored in locked filing cabinets in the Biomedical Research Centre at the University of Bristol. I understand that all data collected will be anonymised and stored in a database separate to personal information. ☐

6. I understand that data collected during this study will be looked at by members of the study team but will be made anonymous before any results are published. I give permission for these individuals to have access to the data. ☐

7. I agree to participate in this study. ☐

____________________	____________________	____________________
Name of Participant	Date	Signature
____________________	____________________	____________________
Name of Person taking consent	Date	Signature

Appendix 5.12 PEDAL2 Intervention Design

Development of a theory informed behaviour change intervention to increase e-cycling in individuals with T2DM

Rationale

Theories provide an evidence-based starting point for intervention development. Various theories have been used to explain and promote physical activity behaviour in a variety of populations including Self-Determination Theory, Social Cognitive Theory, Theory of Planned Behaviour and Transtheoretical Model to name a few, all which report varying degrees of effectiveness at changing and maintaining physical activity behaviour. Furthermore, each theory assumes that behaviour is driven by different components ranging from the social environment, personal beliefs and perceptions or unconscious action. While the use of theory enables researchers to identify and build upon the 'active ingredients' of effective interventions no one theory appears to comprehensively account for the major determinants of behaviour change. The Behaviour Change Wheel (BCW) synthesizes the common features of 19 behaviour change theories, identified through systematic review (1), into one unifying framework. The BCW can assist in identifying the sources of the behaviour of interest and can help guide the development of interventions by being relatively broad.

At the heart of the BCW is the COM-B model (see Figure 1). COM-B provides the basis of designing an intervention through enabling the researcher to understand the behaviour. This model specifies that capability, opportunity and motivation are essential for a behaviour to occur (1).

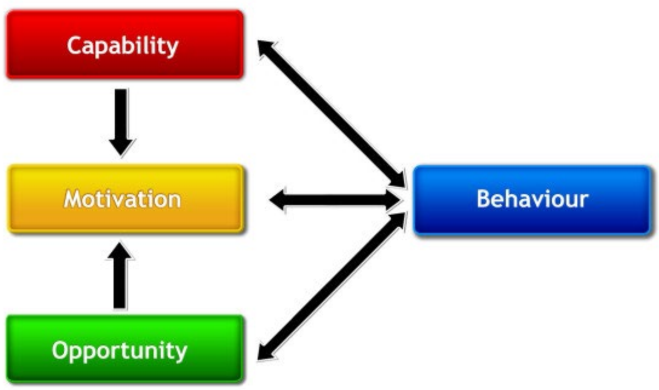


Figure 1. The COM-B system – A framework for understanding behaviour. Reproduced from Michie et al. (1)

The COM-B model is surrounded by nine intervention functions that can be used to address deficits related to capability, opportunity, or motivation. These intervention functions can then be linked to behaviour change techniques (BCTs), the 'active ingredients' to be implemented within an intervention (2).

The Theoretical Domains Framework (TDF) is an extension of the COM-B model that enables a more comprehensive behavioural analysis to identify the drivers of a behaviour than is possible from the COM-B alone. The TDF is a synthesis of 33 behaviour change theories into 14 theoretical domains which can be mapped directly onto the COM-B model and allow the identification of intervention functions to target within an intervention. See Table 1 for how the COM-B, TDF and Intervention Functions map onto each other. The TDF has been used to identify the drivers to health behaviours to inform intervention development (3).

The BCW and TDF have been used to design interventions in a variety of contexts. The aim of the current project is to use the TDF and BCW to develop a theoretical understanding of e-cycling behaviour when an individual has access to an e-bike and to design a brief theoretical based behavioural intervention (PEDAL2).

Table 1. The proposed links between COM-B factors, the TDF and intervention functions. Adapted from Michie, Atkins and West, 2011. For BCTs associated with each of intervention function see pg 151-155 of The Behaviour Change Wheel, A Guide to Designing Interventions (1).

COM-B	Theoretical Domain Framework	Intervention Function
Physical capability	Physical skills	Training
Psychological capability	Knowledge	Education
	Cognitive and interpersonal skills	Training
	Memory, attention and decision processes	Training Environmental restructuring Enablement
	Behavioural regulation	Education Training Modelling Enablement
Physical opportunity	Environmental context and resources	Training Restriction Environmental restructuring Enablement
Social opportunity	Social influence	Restriction Environmental restructuring Modelling Enablement

Reflective motivation	Professional/social role and identity	Education Persuasion Modelling
	Beliefs about capabilities	Education Persuasion Modelling Enablement
	Optimism	Education Persuasion Modelling Enablement
	Beliefs about consequences	Education Persuasion Modelling
	Intentions	Education Persuasion Incentivisation Coercion Modelling
	Goals	Education Persuasion Incentivisation Coercion Modelling Enablement
Automatic motivation	Reinforcement	Training Incentivisation Coercion Environmental restructuring
	Emotion	Persuasion Incentivisation Coercion Modelling Enablement

Context of the current intervention

In the summer of 2016, 18 individuals in Bristol, with T2DM, were provided with e-bikes for up to 20-weeks. Prior to receiving the e-bike, individuals were given a one-to-one training session from a local non-profit organisation on how to ride the e-bike. They were then free to take the bike home to use as they wished. Individuals were provided with access to a call out maintenance service in case of breakdowns or malfunctions. The intervention was deemed a success with individuals leg power increasing by 10% over the 20-weeks and a total 14 of the 18 individuals purchasing e-bikes at the end of the programme. This feasibility study demonstrated the potential impact on e-cycling on health, however further work needs to be conducted. Specifically, whether the programme changed physical activity behaviour was not reported. In addition, the programme was not based on any theoretical underpinning. Research suggests that to encourage long term behaviour change it is key to understand the theoretical mechanisms underpinning behaviour change. As such, this study will use the TDF and BCW to identify the barriers and facilitators to e-cycling identified by individuals in the feasibility trial. This will enable the researchers to identify intervention functions that can be targeted, through selection of BCTs, to promote sustainable behaviour change through a theoretical-driven behaviour change intervention.

The process for designing PEDAL2 involved the following stages:

Stage 1: Identify what needs to change
Behavioural analysis of e-cycling among individuals with T2DM in Bristol to identify the barriers and facilitators to e-cycling when individuals have access to an e-bike. For the purposes of this analyses a barrier or facilitator was operationalised as any factor, characteristic, view, or belief that either impedes (barrier) or enables (facilitator) engagement in e-cycling.

The behavioural analysis was carried out using interviews conducted with individuals who were provided with an e-bike for 20-weeks. Interviews were completed immediately post e-bike loan and six months after the e-bike loan period. All interviews were imported into NVivo and underwent content analysis. Content was organised into the 14 domains of the TDF. Thematic analysis was then conducted to identify specific barriers and facilitators within the interviews under these 14 domains.

Stage 2: Identify intervention functions
The results of the behavioural analysis and a matrix of COM-B components mapped against intervention functions was used to identify the intervention functions likely to be effective for promoting e-cycling behaviour. The identification of intervention functions deemed to be appropriate to target e-cycling behaviour was considered in the context of local knowledge and the affordability, practicality, effectiveness and cost-effectiveness, acceptability, side-effects/safety and equity; the APEASE criteria (4).

Stage 3: Identify behaviour change techniques

The 93-item behaviour change technique taxonomy (BCTTv1) (5) has previously been linked to intervention functions within the BCW (4). BCTs associated with intervention functions to be included in the current intervention were identified.

In addition, BCTs that have been reported as important in changing physical activity behaviour among individuals with T2DM were reviewed. Specifically, Avery and colleagues (6) identified the following BCTs as important for promoting physical activity among individuals with T2DM:

- Prompt focus on past success
- Barrier identification/problem solving
- Use of follow-up prompts
- Provide information on when and where to perform physical activity (action planning)

While Cradock and colleagues (7) identified the following BCTs as important for promoting physical activity in individuals with T2DM (note: This study examined BCTs associated with physical activity and diet. However, they do report physical activity specific BCTs in additional files)

- Instruction on how to perform behaviour
- Credible source
- Behavioural practice/rehearsal

The suitability of each potential BCT for inclusion in the intervention was considered according to the APEASE guidelines. The potential efficacy of each intervention function and BCT was judged by JEB and reviewed by one supervisor (AP).

Stage 4: Identify the mode of delivery

The potential modes of delivering the intervention were considered by the research team based on the affordability and practicality (JEB, AP and ARC). In addition, Life Cycle UK (LCUK) instructors were consulted about the mode of intervention delivery. The feedback obtained was used to make changes to the intervention delivery modes.

Results

Stages 1 to 3

Table 2 provides an overview of the results from Stages 1 to 3. Barriers and facilitators to engaging in e-cycling are organised under the 14 theoretical domains. In addition, proposed intervention functions to target and associated BCTs were identified. Suggestions on how these will be incorporated into the intervention are reported. Reasons for not included some features in the intervention are outlined.

Table 2. Identified TDF domains and associated barriers and facilitators to e-e-cycling from PEDAL1. Potential intervention functions and BCTs are proposed. Method of incorporating these BCTs into the intervention are proposed

COM-B	Theoretical Domain Framework	Specific Barrier/Facilitator (Sub Theme)	Intervention Function to be targeted	Appropriate Behaviour Change Techniques to be used	When and how these BCTs could be targeted
Physical capability	Physical skills	**Facilitator** Physical training on e-bikes including using gears, how to ride in traffic	Training	2.2 Feedback on the behaviour 4.1 Instruction on how to perform behaviour 6.1 Demonstration of the behaviour 8.1 Behavioural practice/rehearsal	**E-bike training** One-to-one e-bike training sessions with instructor
Psychological capability	Knowledge	**Facilitator** Knowledge on how to use specific aspects of the e-bike	Education	2.2 Feedback on behaviour	**E-bike training** Feedback from instructor during sessions
	Memory, attention and decision processes	**Barrier** Pre-preparation involved in cycling	Enablement	1.4 Action planning 12.5 Adding objects to the environment	Instructor to help participant plan when and where they will ride Provide panniers, helmet, waterproof gear
		Barrier/Facilitator Cycling routes – knowing where to ride to get to a location is a facilitator. If unaware of cycle routes this was a barrier to riding	Enablement	1.4 Action planning 12.5 Adding objects to the environment	Participant and instructor plan routes to specific locations Plan when and how they will engage in identified routes Provide cycle route maps
	Behavioural regulation	**Facilitator** Monitoring use of assistance level used on e-bike and how this felt	Training	2.3 Self-monitoring of behaviour	Participant encouraged to record behaviour and how it felt to select level of assistance. Provide logbook and show participant how to record rides, distances and assist levels –for personal use
		Facilitator Regular contact with the instructor	Enablement	3.1 Social support (unspecified)	Contact with instructor during e-bike loan period.

Physical opportunity	Environmental context and resources	**Facilitator** Access to maintenance service	Enablement	3.2 Social support (practical)	LCUK to provide access to a maintenance service during the loan period
		Facilitator Having appropriate e-bike accessories	Enablement	12.5 Add objects to the environment	Provide accessories for e-bike loan period - panniers, bike lock, helmet
		Barrier Weather restricting riding e-bike	Enablement	1.2 Problem solving	Instructor and participant to brainstorm problems and come up with some solutions. Discuss barriers faced and solutions and revisit on a regular basis
		Barrier Other commitments that stop engagement in cycling	Enablement	1.1 Goal setting (behaviour) 1.2 Problem solving 1.4 Action planning	Set specific e-cycling goals. Instructor and participant to discuss barriers to riding and come up with solutions on how to overcome these
		Barrier Uncomfortable seats	Enablement	1.2 Problem solving	Discuss ways to overcome barriers such as uncomfortable seats
		Facilitator/Barrier Access/maps of cycle routes	Enablement	1.4 Action planning 12.5 Adding objects to the environment	Discuss and plan routes to specified locations. Provide maps of cycling routes to participants
Social opportunity	Social influence	**Facilitator** Riding with others Verbal support from friends and family	Enablement	3.1 Social support (unspecified) 3.2 Social support (practical)	Encourage individuals to talk to friends and family about e-cycling goals and to engage them in riding Develop a group riding aspect to the study
		Barrier Unable to attend group rides	Enablement	3.1 Social support (unspecified)	Advise on opportunities for interacting with others, e.g., provide information on group rides, develop a social media/email group with other participants, help participant find riding groups in his/her local area
Reflective motivation	Professional/social role and identity	**Facilitator** Purchasing cycling specific clothing helps individual feel like a cyclist	Education	*Not appropriate for current intervention*	
		Facilitator Identifying as someone who rides a bike	Modelling	6.1 Demonstration of the behaviour 16.3 Vicarious consequences	Video of the consequences of e-cycling by previous participants

	Beliefs about capabilities	**Barrier** Lack of confidence in environment (traffic, other riders) and specific riding skills (Conversely, individuals with high confidence in ability to ride in the given environment and possessing riding skills felt confident to ride)	Enablement Persuasion	2.2 Feedback on behaviour 2.3 Self-monitoring of behaviour 3.1 Social support (unspecified) 15.3 Focus on past success	Instructor to provide feedback on participants e-cycling and provide lots of verbal support about the individuals capabilities. Have participant keep track of their behaviour and focus on what they have achieved.
	Optimism	N/A	N/A		
	Beliefs about consequences	**Facilitator** Psychological and physical benefits	Education	5.1 Information about health consequences 5.4 Information about emotional consequences	Instructor to provide information about the positive health and emotional outcomes associated with PA in general and e-cycling
		Facilitator Environmental Benefits	Education	5.3 Information about social and environmental consequences	Instructor to provide information about the positive social and environmental consequences that can come from riding a bike
	Intentions	**Barrier** Intention/Environment interaction – Intend to continue to ride if they can purchase an e-bike	Environmental restructuring	*Restructuring the physical environment – reducing rate for e-bikes*	*Outside the control of this study*
	Goals	**Facilitator** Setting goals for riding the e-bike encouraged riding	Enablement	1.1 Goal setting (behaviour) 2.3 Self-monitoring of behaviour	Instructor to encourage participant to set specific e-cycling goals. Provide logbook for monitoring behaviour
Automatic motivation	Reinforcement	**Facilitators** Personal sense of accomplishment Social praise Material rewards	Incentivisation	2.3 Self-monitoring of behaviour 10.9 Self-reward	Encourage use of logbook to monitor behaviour. Instructor to encourage participant to reward themselves in small ways for riding
	Emotion	**Facilitator** Enjoyment	Persuasion	5.6 Information about emotional consequences	Instructor to highlight potential enjoyment from riding e-bike
		Barrier Fear of other road users	Modelling and Enablement	1.2 Problem solving 1.4 Action planning 6.1 Demonstration of the behaviour	Instructor to discuss road use and show participant how to ride in traffic

Based on this analysis and the review of previous literature the research team selected 17 BCTs that would be appropriate to include in the PEDAL2 intervention (see Table 3). The primary BCTs were those considered key to include in the intervention.

Table 3. Primary and secondary BCTs to be included in the analysis

Primary Behaviour Change Techniques (n=12)	**Secondary Behaviour Change Techniques (n=5)**
1.1 Goal setting (behaviour)	5.1 Information about health consequences
1.2 Problem solving	5.3 Information about social and environmental consequences
1.4 Action planning	5.6 Information about emotional consequences
2.2 Feedback on behaviour	10.9 Self-reward
2.3 Self-monitoring of behaviour	16.3 Vicarious consequences*
3.1 Social support (unspecified)	
3.2 Social support (practical)	
4.1 Instruction on how to perform the behaviour	
6.1 Demonstration of behaviour	
8.1 Behavioural practice/rehearsal	
12.5 Adding objects to the environment	
15.3 Focus on past success	

***** Not included in the final intervention design due to being unfeasible given desired mode of delivery

Stage 4:

The research team and LCUK agreed upon an e-bike training phase and a loan period. It was considered appropriate to conduct the e-bike training phase at LCUK Headquarters in Bristol. Instructors were familiar with this location and were therefore aware of safe locations in which to have participants practice riding an e-bike. It was agreed that the format of face-to-face sessions would consist of a practical training session followed by a brief behaviour change counselling discussion in a relaxed, convenient location (e.g., at the centre coffee shop or on a park bench). Individuals from the PPI event expressed that they would be happy to travel to this central location for e-bike training. Based on the intended relaxed nature of the discussion instructors felt it was not feasible to show participants a video of other individuals engaging in the same behaviour as this would require access to a laptop. Therefore, the video was not shown to participants and BCT *16.3 Vicarious consequences* was not included in the intervention.

An e-bike loan period of 12-weeks was considered appropriate due to the availability of resources (16 e-bikes) while still being deemed to provide participants sufficient time with the e-bike through which they could practice riding. Two contacts points with the instructor were considered appropriate by the instructors and the PPI group.

Participants from the feasibility trial explained how they would like to have connected with other individuals from the study. It was proposed that LUCK run a PEDAL2 specific group session. However, LCUK and the instructors felt that there were a significant number of group rides already being run by the charity and that participants should be made aware of these group rides and invited to attend if they desired.

Based on the results of this behavioural analysis the following intervention was designed:

E-Bike Training (Up to two weeks)

Following baseline testing the participant will complete e-bike training at LCUK. Bristol-based charity LCUK will perform the training throughout the intervention. All cycle training and rides will be delivered by National Standard Instructors who are DBF checked and first aid qualified. Training will consist of the follow sessions:

- **Up to two one-to-one training sessions** – Training session one will follow the National Standard for Cycle Training guidelines. Example activities include; demonstration of safety equipment, starting, stopping and controlling the bike, riding on the road, making U-turns, how to behave at road junctions. Individuals previous cycling ability will be considered when conducting the cycling specific training. Training session two will provide the participant an opportunity to practice e-cycling and get feedback from the instructor. Busier roads and more complex junctions will be addressed if desired by the participant.

- **One group ride (if desired).** This will be an optional activity and will enable participants to meet with other individuals in the study and ride with an instructor. LCUK already runs group riding sessions and the participant will be invited to join these sessions if they desire.

In addition, the following will be provided to participants in the training period:

- Maps of cycling routes in the area
- Helmet, panniers, lights, gloves for the duration of the period
- Invitation to be part of a private social media group (Facebook). The purpose of this group is for individuals to share their experiences or ride ideas with other members of the group. This group will be administrated by LCUK

Throughout the practical sessions the instructors will provide feedback on the participants behaviour and offer support. At the end of the practical sessions LCUK instructors will engage in a brief behavioural counselling session with participants on sessions one and two. During this time the instructors will help participants plan routes to locations of the individual's choice, provide feedback on the behaviour, work with the participant to identify potential barriers to e-cycling and develop solutions on how to overcome these barriers, help the individual set goals and plan how and when they will ride the e-bike and teach the participant how to monitor these goals. E-bike training will take place over two weeks. At the end of the two weeks the participant will be free to take the e-bike home and use as they wish. E-bikes can be ridden home, or transportation of the bike will be provided by LCUK.

E-bike Maintenance Phase

When participants come to collect the e-bike they will be provided with an e-bike self-monitoring log book and cycling GPS device to track all e-cycling activity for the duration of the intervention. Participants will also be provided with a schedule of upcoming group rides already established by LCUK and will be invited to join these rides if desired. The location of these group rides varies on a weekly basis.

Week 4: Participants will attend their 'skills and confidence check' e-cycling session with the LCUK instructor. This session will take place at a location of the participant's choice (i.e., at their home or in the local community) and will last approximately 1.5 to 2hours. The content of this session will be dependent on the participants needs but will include a review of participants e-cycling progress so far, action planning and goal setting for future riding and practicing riding on established or new routes as requested by the participant.

Weeks 8: The LCUK instructor will contact the participant to check in on his/her progress, discuss barriers, provide tips and suggestions on overcoming barriers and e-cycling routes as required.

Week 10: The study researcher will visit the participant at a location of his/her choice and provide them with the accelerometers, personal GPS device and seven day travel diary to complete in the final week of the study. At the end of week 12 the e-bike, accelerometers, personal GPS and cycling GPS device will be personally collected by the study researcher.

The specific content for inclusion in the intervention and associated BCTs are reported in Appendix 5.13.

Intervention fidelity and impact

To assess the fidelity of intervention delivery, instructors will be provided with checklists to complete during each session. These checklists highlight the topics that must be covered during each session. Audio-recordings or observations of sessions are the most objective method of determining intervention fidelity, as they enable the context of intervention delivery to be considered. However, in the current intervention this was not deemed feasible. Rather, checklists were considered the most practical method of determining the delivery of the intervention.

At the end of the intervention participants will be invited to take part in one-to-one interviews. In addition, LCUK instructors delivering the intervention will be invited to take part in one-to-one interviews to understand the ease of delivering the intervention.

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Appendix 5.13 PEDAL2 intervention content

Session	Intervention content	Associated behaviour change technique
E-bike training phase		
Session 1 Mandatory Face-to-face	One-to-one physical training on e-bike with LCUK instructor, National Skills Level one. Example activities include carry out a simple bike check, stop quickly under control, look all around when riding without loss of control (eight unique skills)	4.1 Instruction on how to perform behaviour 6.1 Demonstration of behaviour 8.1 Behavioural practice/rehearsal
	One-to-one physical training on e-bike with LCUK instructor, National Skills Level two. Example activities include be able to signal intentions to other road users, make a u-turn, demonstrate a basic understanding of the Highway Code (14 unique skills)	4.1 Instruction on how to perform behaviour 6.1 Demonstration of behaviour 8.1 Behavioural practice/rehearsal
	Instructor to provide participant with feedback on their e-cycling during and after session	2.2 Feedback on the behaviour
	Instructor to provide positive encouragement to participant throughout the session	3.1 Social support (unspecified)
	Importance of tracking behaviour is discussed and how e-cycling felt. Participant is provided with paper logbook and Garmin GPS (if desired) and encouraged to record their e-cycling activity	2.3 Self-monitoring of behaviour
	Instructor to provide verbal information on potential health and emotional benefits associated with physical activity and specifically e-cycling. The potential environmental consequences of e-cycling will also be discussed.	5.1 Information about health consequences 5.4 Information about emotional consequences 5.3 Information about social and environmental consequences
	Instructor to encourage participant to think about when and where they plan to ride the e-bike and whether alone or in a group and make ride plans	1.4 Action planning
Session 2 *Optional Face to face	One-to-one physical training on e-bike with LCUK instructor following National Skills Level three. Example activities include demonstrate how to safely pass queuing traffic, demonstration of how to use roundabouts, how to use multi-lane roads.	4.1 Instruction on how to perform behaviour 6.1 Demonstration of behaviour 8.1 Behavioural practice/rehearsal
	Instructor to provide participant with feedback on their e-cycling during and after session	2.2 Feedback on behaviour
	Instructor to congratulate participant on session	3.1 Social support (unspecified)
	Participant encouraged to record their e-cycling in the logbook or online	2.3 Self-monitoring of behaviour
	Instructor to encourage participant to think about when and where they plan to ride the e-bike and what for.	1.4 Action planning
	Provide participant with cycling maps to help them identify routes. Discuss potential cycling routes with participants and plan how they will get to those routes	1.4 Action planning 12.5 Adding objects to the environment
	Encourage participant to set specific (i.e., SMART) e-cycling goals for the upcoming e-bike loan period	1.1 Goal setting (behaviour)
	Participant encouraged to identify potential barriers to e-cycling and come up with ways to overcome these barriers	1.2 Problem solving
When e-bike taken home	Participant provided with helmet, panniers, and lights for the duration of the e-bike loan period	12.5 Adding objects to the environment
	Participant connected to other participants via social media (WhatsApp Group) and provided with information on LCUK social rides.	3.1 Social support (unspecified)

	Participant provided with details of bike breakdown and maintenance service which can be utilised throughout the intervention period	3.2 Social support (practical)
E-bike loan phase		
Session 3 Face to face Location of participants choice	Participant and instructor ride together. Participant to decide on where they would like to practice riding – could involve trying a new route or trying a busy road	4.1 Instruction on how to perform behaviour 6.1 Demonstration of behaviour 8.1 Behavioural practice/rehearsal
	Instructor to provide feedback to the participant on their riding	2.2 Feedback on behaviour
	Instructor and participant to review past four weeks of e-cycling. Instructor to provide positive encouragement and to encourage participant to focus on past success	3.1 Social support (unspecified) 15.3 Focus on past success
	Review barriers to e-cycling that have arisen in the past four weeks and how these were overcome or could be overcome in the future.	1.2 Problem solving
	Review e-cycling goals and encourage participant to amend if necessary	1.5 Review behaviour goals
	Participant encouraged to plan where and when they want to ride in the future, discuss potential cycling routes	1.4 Action planning
	Provide participants with details of upcoming group rides at LCUK that the participant could attend	3.1 Social support (unspecified)
Session 4 Telephone	Review of e-cycling behaviour over the past month and instructor to provide feedback	2.2 Feedback on behaviour
	Instructor to focus on successes and provide positive encouragement	3.1 Social support (unspecified) 15.3 Focus on past success
	Review of barriers that have arisen and discussion on how these were overcome/plan ways to overcome these	1.2 Problem solving
	Review e-cycling goals and encourage participant to amend if necessary	1.5 Review behaviour goals
	Discuss how and where participants plan to ride in the final four weeks. Discuss potential cycling routes	1.4 Action planning
	Provide participants with details of upcoming group rides at LCUK that the participant could attend	3.1 Social support (unspecified)
	Participants advised to connect with friends and family and to inform them of their goals to build support and have some accountability	3.1 Social support (unspecified)
	Remind participants of the importance for rewarding themselves for achieving their goals or making progress towards their goals	10.9 Self-reward

PEDAL2 Training Session 1 Checklist

The following checklist provides an outline of topics to be covered in session 1. In addition to the physical skills required to ride an e-bike there are several things that instructors can do to increase the chance of the client riding the e-bike independently after completing the training. If you are unable to complete specific aspects of the training, please record these in the space provided below.

	Completed
Life Cycle consent form reviewed and signed	

Practical Session

NS Level 1 – Bike Control Skills

Demonstrate and have participant perform the following:	Practiced	Completed
Demonstrate understanding of safety equipment – helmet and clothing		
Carry out a simple bike check		
Get on, start cycling, stop and get off the bike		
Stop quickly with control		
Use of gears and electric assistance		
Make the bike go where you want		
Look all around when riding without loss of control		
Control the bike with one hand, including signalling		
Signed by Instructor **Comments**	**Date**	

NS Level 2 – Riding on quieter or residential roads

Demonstrate and have participant perform the following:	Practiced	Completed
Start and finish a journey on road, including passing parked cars or slowing moving traffic		
Be aware of potential hazards		
Be able to signal intentions to other road users		
Understand where to ride on road - positioning		
Correct use of junctions, including: passing a junction, turning left and right into and out of minor and major roads		
Make a U-turn		
Demonstrate decision making and safe riding strategy		
Decide where cycle infrastructure can help a journey and demonstrate correct use		

Demonstrate a basic understanding of the Highway Code including road signs		
Discuss with participant how to decide whether or not to use cycle infrastructure		
Go straight on from minor road to minor road at a crossroads		
Use mini-roundabouts or single lane roundabouts		
Demonstrate how to safely lock the bike in a suitable location		
How to use a bike lock		
Signed by Instructor **Comments**	**Date**	

Provide feedback to participant throughout the practical session in a supportive manner to help build confidence.

After completing the training find an area to sit and chat with the participant

<u>Discussion Session</u>

	Completed
Congratulate participant for the session they just completed	
Provide feedback on the practical session highlighting successes and potential areas you can work on together next time	
Discuss the importance of keeping track of your behaviour through self-monitoring: • *Recording sessions helps us to be able to look back and see what we have done. It is easy to forget just what you have achieved when life is so busy* • *This is important, so you can celebrate your successes or see if you want to do a little bit more* • *There a lots of tracking applications available on mobile applications or you can use this paper one that we provided*	
Provide participant with **<u>log book</u>** and show them how to fill it in – date, time, duration and distance (not mandatory to complete – just a suggestion)	
If participant would prefer – discuss recording data on mobile applications – set participant up on the **<u>Garmin Connect app</u>** Record login name so instructor can follow participant	
Discuss some of the benefits of physical activity in general and those specific to e-cycling • *Improve fitness* • *When you exercise your muscles use glucose, this will help lower your glucose levels in the blood* • *Exercise can help protect you from developing heart disease and some cancers* • *Lots of people report enjoying e-cycling – exercise can help to improve mood* • *Can help you be active when you commute – you will be provided with panniers so can us it to go to the shops* • *Could mean you use your car less, maybe quicker if areas with lots of traffic* Lots of benefits to be had and even just one session can have a positive	

impact on your health	
Ask participant to think about some journeys that they think they could make on an e-bike – to be discussed in more detail at the next session	
Ask participant to also think about some things that could be barriers to riding an e-bike on a day to day basis – to be discussed next session	
Ask participant to think about how they would like to ride – in groups or by themselves	
Signed by Instructor	**Date**

Additional Session Comments:

Is participant booked in for second session? (record date and time)

Is participant taking the e-bike home?________________________

If so:

E-bike loan agreement signed	
Provide participants with accessories for biking (helmet, gloves, panniers, bike lock, lights)	
Provide the participant with the GPS computer – ensure the participant knows how to use the computer – you may want the participant to practice using the device on the bike during their sessions	
If the participant wants the device to be paired with their phone, help the participant set this up using the details provided on the GPS instruction sheet	
Provide participant with maps of cycle routes in the area	
If participant is going to take the bike home at this session, ask participant if he/she would like to join the study Whatsapp group. If so, record email address to add after the session Phone number:	
Ask participant to think about how they would like to ride – in groups or by themselves	

Record bike odometer before leaving:________________________

PEDAL2 Training Session 2 Checklist

The following checklist provides an outline of topics to be covered in session 2. If you are unable to complete specific aspects of the training, please record these in the space provided below.

Practical Session

This practical session can be tailored to suit the individual. Please record all practical skills covered.

Practical skills rehearsed and successfully completed	Practiced	Completed

If appropriate, please complete level 3 skills and report which skills were practiced and successfully completed

NS Level 3 – Advanced cycling skills

Participant successfully completed the following activities:	Practiced	Completed
Demonstrate understanding of advanced road position (primary position vs. other suitable positions)		
Demonstrate how to safely pass queuing traffic		
Participant can perceive hazards and safely deal with them		
Participant understands driver blind spots – especially larger vehicles		
Participant can identify hazardous road surfaces and react to them		
Demonstration of how to use roundabouts		
Demonstration of how to use traffic light-controlled junctions		
How to use multi-lane roads		
How to use on and off-road cycle infrastructure		
Participant can deal with vehicles that pull in and stop in front of them		
Participant knows how to share the road with other cyclists		
Can cycle on roads with a speed limit above 30mph		
How to cycle in a bus lane		
How to cycle in pairs or groups		
Signed by Instructor **Comments**	**Date**	

After completing the training find an area to sit and chat with the participant

Discussion Session

	Completed
Congratulate participant for the session they just completed	
Provide feedback on the practical session highlighting successes and potential areas you can work on together next time	
Encourage the participant to record the session as activity	
Discuss with the participant how they think they will use the bike: • *When, where* • *What days do they think they can use the bike and what for*	
Discuss cycling routes with participant • *How will they get to the location of choice on their e-bike?* • *Look at the route on google maps (use computer) – discuss best route to get to chosen location (distance, traffic, safety etc.)*	
Provide participant with map of cycle routes (Bristol city council maps) and 10 easy rides around Bristol	
Encourage participant to set some specific e-cycling goals – best to be: - Specific, measurable, attainable, realistic, time-based - E.g., ride e-bike 2 times per week to work - Have the participant record their goal in their log book	
Discuss what barriers the participant thinks they could face to completing the routes. Encourage participant to record barriers on paper	
Discuss some solutions to these barriers: *What do you think you could do to stop XX from getting in the way of cycling?* Encourage participant to write down this solution Record discussed barriers:	
Give participant detail of upcoming group rides (Bike minded and over 55yrs)	
Ask participant if he/she would like to join the study Facebook group (private): If so record email address to add after the session: Email:	
Provide participant with information on the e-bike maintenance service (phone number and instructions)	
Provide participants with accessories for biking (helmet, gloves, panniers, bike lock, lights)	
Provide participant with maps of cycle routes in the area	
Ask participant to think about how they would like to ride – in groups or by themselves	
E-bike loan agreement signed	
Signed by Instructor	**Date**

University Hospitals Bristol NHS Foundation Trust

Life Cycle UK — start cycling · keep cycling · love cycling

University of BRISTOL

Record bike odometer before leaving: ______________________

Additional Session Notes:

PEDAL2 Training Session 3 Checklist: 1 Month

The following checklist provides an outline of topics to be covered in session 3. In addition to the physical skills required to ride an e-bike there are several things that instructors can do to increase the chance of the client riding the e-bike independently after completing the training. If you are unable to complete specific aspects of the training, please record these in the space provided below.

Practical Session

This practical session can be tailored to suit the individual. Please record all practical skills practiced and completed.

Practical skills rehearsed and successfully completed	Practiced	Completed

Provide feedback to participant on his/her behaviour on the e-bike

After completing the training find an area to sit and chat with the participant (can be in a coffee shop if required)

Discussion Session

	Completed
Ask participant about his/her e-cycling over the past month – if possible look at log book Record general response:	
If successful congratulate participant and focus on successes	
If limited, focus on sessions that have been completed and focus on discussion of barriers	
Discuss what barriers the participant has faced over the past month Record barriers:	
Brainstorm some ways to overcome these barriers	
Review behavioural goals set in the last meeting. Is the participant: □ Achieving goals □ Not achieving goals Discuss with the participant if they want to revisit their goals or stick with	
If new goal is set, encourage the individual to record this goal on paper: Record goal:	
Discuss with the participant how they think they will use the bike in the upcoming two months: • *When, where* • *What days do they think they can use the bike and what for*	
Discuss cycling routes with participant • *How will they get to the location of choice on their e-bike?* • *Look at the route on google maps (use computer) – discuss best route to get to chosen location (distance, traffic, safety etc.)*	
Give participant detail of upcoming group rides	
If appropriate, help individual to look up group rides in his/her area	
Ensure the participant is able to download the GPS computer data onto his/her phone. If not using the phone app the let the participant know that the researcher will be in touch to come and download the data from the device	

Record bike odometer before leaving: ________________________

Additional Session Notes:

University Hospitals Bristol NHS Foundation Trust

Life Cycle UK start cycling • keep cycling • love cycling

University of BRISTOL

<u>**PEDAL2 Session 4 Checklist: 2 Month Telephone**</u>

The following checklist gives information on some of the things to discuss with the participant during your two-month check in which will take place over the phone.

	Completed
Ask participant about his/her e-cycling over the past month. Have they been recording their activity? If so how: Record general response:	
If successful congratulate participant and focus on successes	
If limited, focus on sessions that have been completed and congratulate the for that.	
Discuss what barriers the participant has faced over the past month Record barriers:	
Brainstorm some ways to overcome these barriers	
Review behavioural goals set in the last meeting. Is the participant: □ Achieving goals □ Not achieving goals Discuss with the participant if they want to revisit their goals or stick with	
If new goal is set, encourage the individual to record this goal on paper: Record goal:	
Discuss with the participant how they think they will use the bike in the upcoming two months: • *When, where* • *What days do they think they can use the bike and what for*	
Discuss cycling routes with participant • *How will they get to the location of choice on their e-bike?* • *Look at the route on google maps (use computer) – discuss best route to get to chosen location (distance, traffic, safety etc.)*	
Give participant detail of upcoming group rides	
Discuss with participants the importance of involving family and friends in your goals so that they will help hold you accountable.	
Ask the participant if he/she is able to download data to phone. If not using the	

phone app the let the participant know that the researcher will be in touch to come and download the data from the device	

Record bike odometer value: ___________________________

Additional Session Notes:

University Hospitals Bristol NHS Foundation Trust   Life Cycle UK start cycling • keep cycling • love cycling   University of BRISTOL

Appendix 5.15 Lincoln and Guba's trustworthiness criteria for qualitative research and it's application to the current study

Trustworthiness criteria	Addressing the criteria in the current study
Credibility ***The degree of congruency between the participants true views (reality) and the researcher's interpretation of these views (the research findings)***	• *Prolonged familiarization with data*: JEB conducted all interviews, listened to all recordings, and read and re-read transcripts. • *Researcher consensus*: JEB and AS independently coded four participant transcripts and 2 instructor transcripts before coming to consensus on the initial analytical framework. Both researchers were involved in the generation and review of categories and broader themes. • *Respondent validation*: Four participants and one instructor were sent a copy of their interview transcript and an early interpretation of the data. These individuals were asked to review their transcribed data and comment if they felt the initial interpretations were misrepresentative. • *Use of an analytical framework*: This enables comparison within and between participants.
Transferability ***The generalisability of the findings to other contexts. This can be problematic for qualitative research with small sample sizes or specific population groups***	• *Provide contextual information on the data collection process and study participants:* Details of participant characteristics, study setting, and procedures are included to enable the reader to determine whether the research can be transferred to other settings.
Dependability ***The consistency of the findings and the extent to which research processes are clearly documented***	• *Audit trails*: The methods of data collection, analysis and reporting are transparently reported. Audit trails of code, categories, and theme generation were kept.
Confirmability ***The confidence that the findings are shaped respondent's data and not from researchers' motivation or biases***	• *Researcher discussion:* AS had no prior relationship with the participants and independently coded four participant. transcripts and two instructor transcripts. The codes and themes were extensively discussed by the two researchers. • *Reporting process of coding and analysis in sufficient detail:* the coding framework developed includes descriptions of each code and category.

Appendix 5.16 Reflexivity statement

Reflexivity

It is important that the researcher acknowledges and reflects on any potential sources of bias due to their own experience with the phenomenon under investigation that could impact interpretation of the data. The following section is reported in the first person:

> I created the current e-cycling intervention and planned the data collection methods and procedures. I developed a good rapport with the participants, and they were aware that this study was part of my PhD research. This knowledge may have impacted how they responded to the questions regarding their perceptions of the study procedures and intervention as they may not have wished to criticise what they believed was of importance to me. I encouraged participants to be open and honest about their experiences through the premise of improving the study for their peers. However I cannot guarantee that this increased the honesty of responses. On a personal level, I am a cyclist, previously a recreational mountain biker and now more for utilitarian purposes. As such, I face my own challenges to riding. Participants often asked me about whether I was a cyclist, and this disclosure may have impacted how they responded. This was unavoidable and, in an attempt, to express understanding I shared some of my challenges with riding. I am younger than the individuals interviewed, and it may make it difficult for me to relate to specific circumstances the participants experienced. Upon data analysis I tried to detach myself from my investment in the study and personal riding experiences and focus on the data itself. Nonetheless, it is difficult to fully remove one's personal views, knowledge, and experience from the analysis process. Therefore, the interpretation of the data and the final themes developed to some degree represent my own, and my collaborators, interpretation of the data. Steps such as member checking and double coding were used to ensure that these interpretations accurately reflect the data.

Appendix 6.1 PEDAL2 participant interview guide

Rationale for Question	Interview Questions
Background – all participants	
Background *To find out where participants are located in the city and their work situation as this could impact perception of e-cycling or the study procedures*	Where do you live? Are you working? (Regular 9-5 or shift work?)
Process evaluation questions – all participants	
Broad questions to start discussion *Asked to reflect on study*	Tell me about your experience of participating in the study? Which of the assessments do you remember? Which things did you enjoy/not enjoy about taking part? What did you think about taking part in the different assessments? How could we have improved any of the assessments or the study in general?
Theoretical Domains Framework	
Knowledge:	Tell me how you felt riding the e-bike? (to being with and also at the end) How did you get on with the e-bike to being with and at the end (PROMPT: comfort, handling, technical aspects, use of assistance, utility etc.) Was it as you expected? (PROMPT: In what way)
Skills:	Have you done much cycling in the past (PROMPT: As a child, adult) Do you feel as though you were provided with adequate training on how to ride an electric bike? Would you have liked more training before taking the e-bike home?
Social/Professional Role and Identity:	Has using the e-bike made a difference to the way you see yourself in relation to being a ‘cyclist’? Did you purchase/acquire any equipment for cycling? (e.g., clothes, lights, gloves etc.) during the intervention or do you plan to?
Beliefs about Capabilities:	Did you feel confident riding the electric bike? (At the start, did this change over time?) Were there specific situations in which you felt more or less confident?

	Prompt: different kinds of roads, heavy traffic, riding with others? What would help you feel more confident/make it easier to ride the bike?
Optimism:	At the outset, did you feel that the intervention would be positive for other things, e.g. how you feel, how much activity you do?
Beliefs about Consequences:	Tell me about e-biking in relation to your health? Do you think e-cycling has the potential to help you manage your diabetes? If so, in what way can if help? How does e-cycling compare with other self-management behaviours (medicine, diet, other physical activity?) What do you think about the impact of e-biking on the environment? (e.g., replace car journeys, bus etc) Does choosing to e-bike have a financial impact for yourself? Do you think there are any negative outcomes or harms associated with e-biking?
Reinforcement:	Would you say you are in the habit of riding you bike on a regular basis? If not – what would be helpful in developing more of a routine/habit for biking?
Intentions:	At the start of the program, how did you think you would use the e-bike? (e.g., commuting, leisure, shopping, social) Did these intentions match how you used the bike? (expand)
Goals:	To what extent was riding the bike a priority for you during the intervention?
Memory, Attention and Decision Processes:	Can you tell me about how you made decisions about using the bike on a day to day basis? - PROMPT – feelings, environment, weather, sweaty, effort? How did location and infrastructure (roads, cycle routes/paths, terrain etc) influence your decision to e-cycle? How easy or difficult was it to remember all the accessories you needed when riding the bike (e.g., panniers, lights, clothes)? Can you give me an example of the types of journey you made on the e-bike? Can you tell me why you decided to use the e-bike for this journey?

Environmental Context and Resources:	What barriers did you experience riding the e-bike on a day-to-day basis? (PROMPT: equipment, weather, time or competing interests, pressure from others) Did you have all the equipment to ride the e-bike?
Social Influences:	Tell me about the training you received on how to ride an e-bike? How did it make you feel? How did you feel about the follow-up sessions with the instructors? Did your friends and family express any opinions about you riding the e-bike? Did their view make any difference to your bike riding? Did you join any organized cycling rides or ride with others (expand)? Do those closest to you cycle (Friends or family)?
Emotions:	When we ask about riding the e-bike what emotions come to mind?
Behavioural Regulation:	Did you have any systems in place to ensure that you rode the e-bike on a regular basis? E.g. reminders, set rides with other people, particular places?
Closing	
	What is your perception of cycling after participating in this study? How do you feel about coming to the end of the study and handing the bike you loaned back? Do you have any plans or are you interested in looking at options to carry on e-biking? What would you say to other about e-bikes and being in the study?

Appendix 6.2 PEDAL2 instructor interview Guide

The interview topic guide for instructors was based on the dimensions of Rogers Diffusions of Innovations theory (1) which has been used to understand how public health initiatives are adopted and factors that influence adoption (2).

Rationale for Question	Interview Questions
Broad Questions/Of Interest Questions	
Broad questions to start discussion	What did you like about the PEDAL2 programme? What did you not like about the PEDAL2 programme?
Diffusion of Innovations – Five Factors of an Innovation	
Relative advantage: How improved an innovation is over the previous generation.	Was this programme an improvement over the previous e-bike intervention run at the centre? (move to next question if individuals not involved in previous study) (if yes, how, if no, why not)
Compatibility: The level of compatibility that an innovation has to be assimilated into an individuals life.	Did you find the content of the programme appropriate for the individuals participating in PEDAL2 at your centre? (training sessions, resources, discussion points etc.) How would you consider changing the programme in the future? Did any participants drop out during the programme during the 2-week training period? If so, why do you think they dropped out? Did they have any unique characteristics?
Complexity or simplicity: If the innovation is perceived as complicated or difficult to use, an individual is unlikely to adopt it.	How easy was the programme to deliver? • E-bike skills training • Behavioural discussions Were there any aspects that were more complex to implement? (prompt; group ride, individual sessions, discussions etc.) Were the facilities available to you to run the programme appropriate? (area for discussions, roads to ride along, access to bikes) Was the equipment available to you appropriate for the participants? (e.g., e-bikes and accessories)
Trialability: How easily an innovation may be experimented. If a user is able to test an innovation, the individual will be more likely to adopt it.	Did you feel as though you were able to adapt the PEDAL2 programme to participant? If you adapted the program, did you feel as though you were able to touch on all the key aspects of the programme content?

Observability: The extent that an innovation is visible to others. An innovation that is more visible will drive communication among the individuals peers and personal networks and will, in turn, create more positive or negative reactions.	Did you have opportunities to discuss aspects of programme implementation with other instructors within your site? Did you get to observe any of your colleagues implementing the programme before you ran it?

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Appendix 6.3 The seven stages of the framework method of qualitative analysis and a description of how they apply to the current study

Procedure for analysis	Application in the current study
Stage 1 Transcription	All interviews were conducted by JEB and transcribed by a university approved transcription service, Transcription UK. The transcripts were checked against the original recordings to ensure reliability.
Stage 2 Familiarization	JEB became immersed in the data by listening to each audio recording and reading each transcript, making notes about potential codes and data relating to overarching research questions and general thoughts. AS read four participant interview transcripts (10%) and two instructor interview transcripts (20%). JEB selected the specific transcripts to represent diverse experiences and opinions of participating in the study.
Stage 3 Coding	To develop a coding frame JEB and AS independently assigned codes to each segment of the data deemed to be potentially relevant to the research questions from the selected transcripts. An inductive approach to coding was taken. N-Vivo 12 software was used to review, organise, and combine the data.
Stage 4 Develop an analytical framework	After coding the initial transcripts, the researchers met to discuss coding and an analytical framework was developed. This consisted of a set of codes, each with a brief description. The two researchers independently coded two more participant transcripts and one instructor transcript, noting any new codes. The researchers met again to discuss the coding and to revise the initial framework to incorporate new or redefined codes. At this point the conceptual relationship between codes was considered and similar codes were grouped together into categories, while taking into consideration the research objectives. The researchers did not look beyond what was explicitly said by participants, adopting a semantic approach to identifying categories. In this sense, the categories were a method of organising the data, acting to display common patterns within the dataset. An 'other' code was included under each category to avoid ignoring data that does not fit.
Stage 5 Applying the analytical framework (Indexing)	JEB used this framework to code the remaining transcripts using NVivo software. If a new code was required as it was not covered by the initial framework, this was discussed with AS before adding to the analytical framework. If a new code or category was added, previously coded transcripts were checked for data relevant to the new code.
Stage 6 Charting data into the framework matrix	After finalising codes and categories, a framework matrix was developed. N-Vivo was used to create matrices that encapsulate data from each category and code. Following this, each participants data was described and summarised to develop a chart. This was conducted in Excel and consisted of participants in rows with summaries of categories in columns. The matrix contained summaries of the data for each participant with references to specific examples but not the actual raw data. The framework matrix enabled the investigation of data horizontally (case-by-case) and vertically (to investigate themes and sub-

Procedure for analysis	Application in the current study
	themes). AS checked the summaries of the first 4 transcripts to ensure the summaries captured the essence of the data. Following stage 6, four participants and one instructor were sent a copy of their interview transcript and an interpretation of the data. They were asked to review their transcribed data and comment if they felt the interpretations represented or misrepresented their views.
Stage 7 Mapping and Interpreting the data	The significance and implications of the categories, and how they relate to one another was examined to generate broader categories, while considering the research objectives. This was done by JEB and AS collaboratively. The findings are reported narratively in the results and illustrative quotes presented.

Appendix 6.4 Primary care practices search strategy and number of information packages sent out

Primary Care Practice	Inclusion criteria	Exclusion criteria	# Information packs sent
Wellspring Surgery	T2DM diagnosis; Age	BP	212
Merrywood Practice	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD	204
The Fishponds Family Practice	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD; contraindications for ex	224
The Family Practice - Western College	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months	29
Greenway Community Practice	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD; contraindications to exercise (housebound or registered disabled)	183
Kingswood Health Centre	T2DM diagnosis; Age	Exogenous insulin; Myocardial Infarction/stroke past 6-months; RF; LD; contraindications to exercise (housebound or registered disabled)	235
Maytrees medical practice	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD; contraindications to exercise	174
Eastville medical practice	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD	193
Charlotte Keel Health Centre	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD; contraindications to exercise	181
Broadmead medical centre	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD; contraindications to exercise	34
The Lennard Surgery	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD	159
Pembroke Road Surgery	T2DM diagnosis; Age	Exogenous insulin; BP; Myocardial Infarction/stroke past 6-months; RF; LD; contraindications to exercise	27

BP=blood pressure; LD=liver disease; RF=renal failure; T2D=type 2 diabetes mellitus

Appendix 6.5 Demographic characteristics of those that completed follow-up and those that dropped out of the study

Variable	Completed post testing (n = 35)	Lost to follow-up (n = 5)
Age (y), mean (SD)	57.9 (7.9)	51.2 (12.1)
Gender (n, % female)	15 (42.9)	0 (0.0)
Ethnicity (n, % White)	27 (77.1)	3 (60.0)
Education (n, %)		
≤ High school	3 (8.6)	0 (0.0)
High school	4 (11.4)	2 (40.0)
Apprenticeship or trade certificate	6 (17.1)	1 (20.0)
College or diploma	8 (22.9)	1 (20.0)
Bachelor's degree	11 (31.4)	1 (20.0)
Post-graduate degree	3 (8.6)	0 (0.0)
Employment status (n, %)		
Working full-time	13 (37.1)	2 (40.0)
Working part-time/occasionally	7 (20.0)	1 (20.0)
Unworking	2 (5.7)	0 (0.0)
Retired	9 (25.7)	1 (20.0)
Voluntary	1 (2.9)	0 (0.0)
Self-working	2 (5.7)	1 (20.0)
Homemaker	1 (2.9)	0 (0.0)
Household income (n, %)		
< £24,999	12 (35.3)	2 (40.0)
£25 - £49,999	13 (38.2)	2 (40.0)
£50 – 74,999	6 (17.7)	1 (20.0)
£75 – 99,999	2 (5.9)	0 (0.0)
£100,000 +	1 (2.9)	0 (0.0)

Appendix 6.6 Detailed report of the feasibility of collecting each outcome measure

Feasibility of conducting anthropometric measures and collecting valid data

Height, weight, and waist circumference were successfully collected in all participants at baseline (100.0%). At post testing 13 individuals in the intervention group and 18 in the control group completed anthropometric data collection (77.5%). All measures were used in analyses. As previously stated, five individuals dropped out of the study, two did not want to attend post testing and COVID-19 caused the cancellation of two participants post testing.

Feasibility of conducting fasting blood samples and collecting valid data

Fasting blood samples were successfully collected in 97.5% (n=39) of participants at baseline. Blood sampling was not available for one participant as the research team was unable to insert a cannula or conduct venepuncture. At post testing, 70.0% (n=28) of participants had fasting blood taken and provided valid results. Some baseline blood sampling results were not reported from the laboratory. Specifically, at baseline no HbA1c was reported for one participant, no LDL cholesterol was reported for one participant and no fasting insulin was reported for another participant. The research team were unable to insert a cannula or conduct venepuncture on two participants (5.0%). One participant declined blood sampling (2.5%). As reported above five participants had dropped out of the study (12.5%), two participants did not want to attend post testing (5.0%), two participants had testing cancelled due to COVID-19 (5%).

Feasibility of conducting the oral glucose tolerance test (OGTT) and regular blood sampling and collecting valid data

An oral glucose tolerance test with blood sampling was conducted in 92.5% (n=37) of participants at baseline. In addition to the fasting blood sampling numbers reported above two participants could not be cannulated (but completed venepuncture for fasting bloods). Blood could not be drawn from two participants at 120-minutes. Therefore, a total of 35 individuals provided all blood samples (87.5%). At post testing, an OGTT with blood sampling was conducted in 62.5% (n=25) of participants. Cannulation failed on three participants. In addition, regular blood sampling failed for some participants. Specifically, two participants missed the 120-minute blood sample, one participant missed samples at 15 and 30-minutes and one participant missed samples at 30, 45, 60 and 90 minutes. As such 52.5% of the sample (n=21) provided full blood samples at post testing.

Feasibility of conducting the incremental fitness assessment and collecting valid data

Overall, 87.5% of participants (n=35) completed the incremental fitness assessment at baseline. Four participants were not cleared to conduct the fitness assessment by their general practitioners (10.0%) and one participant did not bring appropriate clothing in which to conduct a fitness assessment (2.5%). Of the 35 participants that completed the fitness assessment, 31 met the criteria for reaching maximum oxygen (i.e., at least two of the four criteria for achieving maximum were completed). As post testing 60.0% (n=24) of participants completed the incremental fitness assessment. Twenty-two of these individuals were deemed to have reached VO_{2max}. One participant did not complete the fitness assessment due to an ankle injury, unrelated to the study and one participant did not want to attend the physiology testing session in Bath. All incremental fitness assessment data was valid and used in the analyses.

Feasibility of conducting the supramaximal fitness assessment and collecting valid data

In total, 80.0% of participants (n=32) completed the supramaximal fitness assessment at baseline. In addition to the four participants that could not complete any fitness assessment due to lack of GP clearance and one participant who did not bring appropriate clothing, one participant did not want to complete the supramaximal fitness assessment due to feeling unwell after the incremental assessment. For two participants the researcher decided that the supramaximal assessment was inappropriate due to a) one participant having a fixed rate pacemaker, not previously disclosed and b) one participant recently having an operation for sciatica and the incremental assessment aggravating the pain symptoms. At post testing 52.5% of participants (n=21) completed the supramaximal fitness assessment. Of the 24 participants that completed the incremental fitness assessment three participants did not want to complete the supramaximal test. Two participants did not provide reasons and one stated that they felt unwell.

Feasibility of conducted the dual-energy x-ray absorptiometry (DEXA) scans and collecting valid data

All participants (n=40) completed the DEXA scan a baseline and provided valid scans. For two participants the researcher was unable to fit their whole body on the scanning table.

Therefore, as per the manufacturers guidelines, one leg and arm could lay outside the scanning area and the software duplicated the results from the dominant side to the non-dominant side. At post testing 30 participants (75.0%) completed the DEXA and provided valid scans. One participant did not fully fit on the scanning table and the scans of one side were replicated to the other side. Of the 30 participants that completed the DEXA scan at post testing, 19 had a post testing appointment within two hours of the baseline appointment time (i.e., the same time of day). Twenty-six participants ate the same breakfast at baseline and post testing, while 23 were void at both baseline and post testing, two were not void at both and five participants differed from baseline to post testing.

Feasibility of conducting the pQCT scans and collecting valid data

In total, 38 (95.0%) participants provided pQCT scans at baseline. Two of the participants were unable to fit in the gantry of the pQCT machine due to size. All 38 scans were considered sufficient quality to include in the analyses. Twenty-eight scans were rated one, eight rated two and two rated three. At post testing 28 (70.0%) participants completed the pQCT scan. One participant did not fit in the pQCT gantry. One pQCT was not performed due to the operator being unable to work the scanner. Of these scans 25 were considered valid with three scoring four on the quality control check.

Feasibility of conducting a HRQoL questionnaire and collecting valid data

At baseline, 100.0% (n=40) of participants completed the physical component of the HRQoL questionnaire and 95.0% (n=39) completed the mental HRQoL component. One participant felt they were unable to complete the mental component of the survey due to personal problems. At post testing 75.0% of participants (n=30) completed the physical and mental components of the HRQoL questionnaire. All completed measures were used in the analyses.

Feasibility of collecting valid vehicle use data to estimate carbon emissions

At baseline, all 40 (100.0%) participants reported vehicle information for their household, including vehicles make, model and engine size. Within the survey participants were asked to report the vehicle most often used by themselves. Unless stated otherwise in the travel diary, this vehicle information was used to calculate vehicle emissions. If multiple cars were present in the household participants rarely reported which specific car was used in the travel diary.

At post testing 31 (77.5%) participants, all those that attended post testing, completed vehicle information questions.

Feasibility of conducting physical activity measures and collecting valid data

All participants (100.0%) wore the Actigraph at baseline and 30 (75.0%) at post testing. Physical activity data meeting the criteria for inclusion in analysis was available from 36 (90.0%) participants at baseline and 27 (67.5%) at post testing. The average number of wear days for those meeting the three-day minimal criteria for inclusion was 5.4 (SD=2.22) at baseline and 5.2 (SD=2.25) at post testing. On average, participants wore the accelerometer for 14½ hours a day (mean=870, SD=93.29 minutes) at baseline and 14¼ hours a day (mean=855, SD=84.04 minutes) at post testing.

Thirty-nine participants (97.5%) wore the Actiheart at baseline and 25 (62.5%) wore it a post testing. Data from two participants at baseline and three at post testing could not be retrieved due to initialization error (n=2) and device malfunction (n=3). As such, data were available for 37 participants at baseline (92.5%) and 22 (55%) at post testing. In the current study all available activity data was used. However, previous research has specified a minimum of 72 hours wear time (three days) to be included in the analysis (1). For the purposes of feasibility, the number of participants with the data was explored. Non-wear time was identified as any continuous zero acceleration counts ≥ 90-minutes if accompanied by no heart rate data. Once non-wear time had been identified the number of participants with >72hours of data was calculated. Overall, 35 (87.5%) participants recorded at least 72 hours of valid data at baseline and 20 (50.0%) at post testing. The mean wear time for those who met the criteria was 152.8 hours (SD=25.3) at baseline and 157.6 hours (SD=16.8) at post testing.

Feasibility of conducting GPS measures and collecting valid data

Thirty-nine (97.5%) participants wore the GPS device at baseline and 30 (75.0%) at post testing. While all available data was included in the analyses, for the purpose of feasibility, a valid day was classified as having at least eight hours of GPS data to ensure participants travel behaviour was captured. The mean number of days with 8+ hours of GPS data was 5.4 (SD=1.5, median=6, IQR=5 to 6) at baseline and 5.4 at post testing (SD=1.3, median=6, IQR=4 to 6).

Feasibility of collecting valid travel diary data

At baseline, thirty-nine (97.5%) participants completed at least one day of the travel diary. The mean number of days in which travel was recorded was 6.1 (SD=1.6; median=7, IQR=6 to 7). At post testing, 26 participants (65.0%) completed the travel diary. On average, travel data was recorded on 6.1 days (SD=1.6, median=7, IQR=6 to 7).

References

1. Lindsay T, Westgate K, Wijndaele K, Hollidge S, Kerrison N, Forouhi N, et al. Descriptive epidemiology of physical activity energy expenditure in UK adults (The Fenland study). International Journal of Behavioral Nutrition and Physical Activity. 2019;16(1):126. doi:10.1186/s12966-019-0882-6

Appendix 6.7 Content of the PEDAL2 intervention and number of individuals that received that content

Session	Intervention content	Number of attendees who received this content (%)	Comments
E-bike training phase			
Session 1 (n=19)	National Skills Level one. Example activities include carry out a simple bike check, stop quickly under control, look all around when riding without loss of control (8 unique skills)	19 (100%)	Two participants completed this in session 2
	National Skills Level two. Example activities include be able to signal intentions to other road users, make a u-turn, demonstrate a basic understanding of the Highway Code (14 unique skills)	7 (37%) completed all skills 7 (37%) completed 10-13 skills 3 (16%) completed 8-9 skills	Six participants completed some of this training in session 2
	Instructor to provide participant with feedback on their e-cycling during and after session	15 (80%)	
	Instructor to provide positive encouragement to participant throughout the session	16 (84%)	
	Importance of tracking behaviour is discussed and how e-cycling felt. Participant is provided with paper logbook and Garmin GPS (if desired) and encouraged to record their e-cycling activity	17 (89%)	
	Instructor to provide verbal information on potential health and emotional benefits associated with physical activity and specifically e-cycling. The potential environmental consequences of e-cycling will also be discussed.	15 (80%)	
	Instructor to encourage participant to think about when and where they plan to ride the e-bike and whether alone or in a group and make ride plans	12 (63%)	
Session 2 *Optional (n = 15)	National Skills Level three. Example activities include demonstrate how to safely pass queuing traffic, demonstration of how to use roundabouts, how to use multi-lane roads.	4 (27%) completed all skills 2 (13%) completed 12-13 skills 1 (7%) completed 4 skills	Seven participants (53%) worked on level two skills during session 2 One no checklist
	Instructor to provide participant with feedback on their e-cycling during and after session	13 (87%)	One no checklist
	Instructor to congratulate participant on session	13 (87%)	One no checklist
	Participant encouraged to record their e-cycling in the logbook or online	12 (80%)	One no checklist

			One participant still not confident to ride alone
	Instructor to encourage participant to think about when and where they plan to ride the e-bike and what for.	12 (80%)	One no checklist One participant still not confident to ride alone
	Provide participant with cycling maps to help them identify routes. Discuss potential cycling routes with participants and plan how they will get to those routes	12 (80%)	One no checklist One participant still not confident to ride alone
	Encourage participant to set specific (i.e., SMART) e-cycling goals for the upcoming e-bike loan period	13 (87%)	One no checklist
	Participant encouraged to identify potential barriers to e-cycling and come up with ways to overcome these barriers	14 (93%)	One no checklist
When e-bike taken home (n=19)	Participant provided with helmet, panniers and lights for the duration of the e-bike loan period and cycle maps	18 (95%)	One no checklist
	Participant asked if they wanted to connect with other participants via social media (WhatsApp Group) and provided with information on Life Cycle UK social rides.	18 (95%)	One no checklist
	Participant provided with details of bike breakdown and maintenance service which can be utilized throughout the intervention period	18 (95%)	One no checklist
E-bike loan phase			
Session 3 Location of participants choice (n = 10)	Participant and instructor ride together at a location of the participants choice	9 (90%)	One completed as phone call
	Instructor to provide feedback to the participant on their riding	10 (100%)	
	Instructor and participant to review past four weeks of e-cycling. Instructor to provide positive encouragement and to encourage participant to focus on past success	10 (100%)	
	Review barriers to e-cycling that have arisen in the past four weeks and how these were overcome or could be overcome in the future.	10 (100%)	
	Review e-cycling goals and encourage participant to amend if necessary	10 (100%)	Four participants report not achieving e-bike goals. Two set new goals
	Participant encouraged to plan where and when they want to ride in the future, discuss potential cycling routes	10 (100%)	One participant unlikely to ride alone yet but was discussed

	Provide participants with details of upcoming group rides at LifeCycle UK that the participant could attend	10 (100%)	One participant given information but unlikely to use as not confident to ride e-bike alone
Session 4 Telephone (n=6)	Review of e-cycling behaviour over the past month and instructor to provide feedback	6 (100%)	One session conducted as a face-to-face session
	Instructor to focus on successes and provide positive encouragement	6 (100%)	
	Review of barriers that have arisen and discussion on how these were overcome/plan ways to overcome these	6 (100%)	
	Review e-cycling goals and encourage participant to amend if necessary	6 (100%)	One participant not achieving goal as still not confident on the e-bike therefore barely riding
	Discuss how and where participants plan to ride in the final four weeks. Discuss potential cycling routes	6 (100%)	One participant unlikely to ride alone yet but was discussed
	Provide participants with details of upcoming group rides at LifeCycle UK that the participant could attend	6 (100%)	One participant given information but unlikely to use as not confident to ride e-bike alone
	Participants advised to connect with friends and family and to inform them of their goals to build support and have some accountability	6 (100%)	
	Remind participants of the importance for rewarding themselves for achieving their goals or making progress towards their goals	6 (100%)	

Appendix 6.8 Occurrence and rationale for adaptations made to the intervention as intended

Adaptation	# Participants affected	Reported reason(s)
E-bike training phase		
E-bike training conducted at participants home	1	Participant unable to find time to come to centre for training
E-bike training lasted longer than four weeks	3	Participant broke elbow and training had to be paused (n=1); participant required special equipment for the e-bike (n=1); participant went on holiday during the training phase (n=1)
Additional e-bike training sessions	3	Participant lacked confidence riding the e-bike (n=1); participant required assistance with riding different routes and requested instructor assistance (n=1)
National skills level 1 and 2 conducted in session 2		Participants were unable to complete all NS1 and NS2 skills in session 1 therefore these were complete during session 2.
Session 1, not delivered BCT: *Feedback on behaviour*	4	Reason unknown
Session 1, not delivered BCT: *Social support (unspecified)*	3	Reason unknown
Session 1, not delivered BCT *self-monitoring of behaviour*	2	Participants not given logbooks, reason why unknown
Session 1, not delivered BCT, *information about health, emotional and social and environmental consequences of physical activity and e-cycling*	4	Reason unknown
Session 1, not delivered BCT, *Action planning*	7	Participants were not at a stage where they would be planning their own journeys. Instructors felt it was more appropriate to wait until session 2, immediately prior to the e-bike being taken home.
Checklists not completed but session conducted	1	Session 2 for one participant was completed but no checklist completed
Session 2, BCT not delivered, *feedback on behaviour*	1	Reason unknown
Session 2, BCT not delivered, *social support (unspecified)*	1	Reason unknown
Session 2, BCT not delivered, *feedback on behaviour*	1	Reason unknown

Session 2, BCT not delivered, *self-monitoring of behaviour*	1	Reason unknown
Session 2, BCTs not delivered, *action planning, adding objects to the environment*	2	Reason unknown (n=1); not sufficiently confident to ride e-bike alone (n=1)
Session 2, BCT not delivered, *goal setting (behaviour)*	1	Reason unknown
E-bike loan phase		
E-bike loan period lasted longer than 3-months (+1 week to allow for return)	6	Loan period extended due to illness meaning participant unable to ride e-bike (n=2; 22 wks, 20wks); Post testing appointment could not be coordinated for earlier (n=2; 16 wks, 16wks); Participant unconfident on e-bike so extended by instructor in effort to increase cycling confident (n=1; 31 wks); Post testing changed and later cancelled due to COVID-19 (n=1; 23 wks)
Session 3, BCTs not delivered, *instruction on how to perform behaviour, demonstration of behaviour, behavioural practice/rehearsal*	1	Session conducted over the telephone rather than face to face
Session 3 not delivered	3	Three participants could not find the time to complete session 3. Four participants, reason not provided by instructor
Session 4 not delivered	10	No reasons were provided by the instructors for session 4 being missed by 10 participants

Appendix 6.9 Additional details of the qualitative analysis of participant and instructor acceptability of the study and intervention

Participant process evaluation

Table 1 displays the original code book created after JEB and AS independently coded four transcripts and met to discuss the findings. A total of 44 codes were identified. Codes were further discussed and refined. Changes included merging codes of similar content to make them bidirectional or changing code names to make them more explanatory to the reader (e.g., *randomization to control group* was changed to *reaction to randomization* and *difficulty travelling or parking in Bath, difficulty travelling or parking in Bristol, no concerns with travelling or parking to study visits* was merged to *experience travelling or parking at appointments).* Table 2 displays the finalised codebook including a description of the data that was captured within each code. A total of 35 codes were included in the final codebook.

Table 1. Original code book participants process evaluation

	Code Name
1	appointment flexibility
2	apprehension about participation
3	being part of study is motivational
4	being part of the study was interesting and enjoyable
5	blood sampling concerns
6	blood sampling was okay
7	chest monitor difficult to wear
8	desire for group rides
9	desire to contribute to research
10	did not join group rides
11	difficulty travelling or parking in Bath
12	difficulty travelling or parking in Bristol
13	e-bike equipment provided was appropriate
14	e-bike loan period
15	e-bike sessions during intervention enjoyable and useful
16	e-bike sessions during intervention unnecessary
17	e-bike size concerns
18	engagement with the instructor
19	enjoyed using the Garmin GPS
20	exercise test was difficult
21	extra e-bike equipment purchased or desired
22	garmin GPS was complicated
23	interest in study results
24	more convenient appointment locations
25	more information about the study

26	mouthpiece discomfort
27	no concern regarding scans
28	no concern regarding travel or parking to study visits
29	no concern wearing waist monitors
30	participant co-morbidity issues
31	perception of e-bike training
32	randomization to control group
33	reaction to Actiheart pads
34	request for reimbursement
35	scanner was awkward
36	staff were friendly
37	study procedures were clear
38	time commitment
39	travel diary no problem
40	travel diary not easy to complete
41	waist worn monitors noticeable
42	waiting to get e-bike
43	wanting to try an e-bike
44	worried about e-bike being stolen as not theirs

Table 2. Final participant process evaluation codebook and associated descriptions

Code	Description
appointment flexibility	Participants discuss their ability to book appointments a different time
apprehension about assessments	Participants shared anxiety or apprehension about being in the study or the assessments as they are unknown
appropriateness of extra equipment	Participants discuss the appropriateness of extra e-bike equipment (in addition to the e-bike) for engaging in e-cycling
being part of study is motivational	Being part of a study encourages the individual to think about their health and provides motivation to improve their health
being part of the study was interesting and enjoyable	Participants comment that being part of the study was enjoyable and/or they found it interesting
chest monitor difficult to wear	Participants comment that the chest monitor (Actiheart) was noticeable when wearing it and it required work to make sure it stayed attached
clarity of procedures	Participants discuss how clear or unclear they perceived the study information provided to them was
completion of travel diary	Participants discuss their ease or difficulty of completing the travel diary
desire for group rides	Wanting to feel part of a group in a similar situation

desire to contribute to research	Participants are drawn to taking part in the study as they want to contribute to research
e-bike loan period	Participants share issues with the e-bike loan period in regard to then length of the loan period or the time of year
e-bike size concerns	Participants discussed issues with the size of the e-bike they were given. This impacted their e-cycling
engagement in group rides	Participants discuss their engagement in group rides
engagement with instructor	Participants comment on the interactions they had with their instructor
experience of blood sampling	Participants share their experiences of having blood taken
experience of exercise test	Participants share their experience of the exercise test
experience of scans	Participants share their experience of the whole body and leg scans
experience of waist worn monitors	Participants comments of wearing the GPS and accelerometer
experience travelling and parking	Participants discuss their experiences of driving to and parking at the study locations
extra equipment purchased or desired	Participants share details on extra equipment they bought or borrowed whilst having the e-bike or extra equipment that they would have liked
garmin GPS experience	Participants in the intervention group comment on their experience of using the Garmin GPS
interest in study results	Participants discuss how they are interested in the results of the study to give them insight into their health
more convenient appointment locations	Participants express a preference for appointments closer to home or in one location for convenience
mouth piece discomfort	Reported discomfort when having to use the mouth piece for the fitness assessment
necessity of e-bike sessions during the intervention	Participants discuss how necessity of one-to-one sessions with the instructor during the intervention
participant co-morbidities	Participants discuss co-morbidity issues and discuss how they impacted involvement in the study
perception of e-bike training	Participants discuss their perception of the two week e-bike training
reaction of randomization	Participants share feelings of being assigned to the different study groups
reaction to actiheart pads	Participants discuss the skin reactions they had when wearing the chest activity monitor (Acitheart)
request for reimbursement	Participants discuss how they need to put in to be reimbursed for travel for the study visits as the costs of the visits add up
staff were friendly	Participants report that the staff at the study visits were friendly

time commitment	Comments regarding the time required to participate in the study
waiting to get e-bike	Participants in the intervention group discuss how they had to wait before they could get an e-bike on loan.
wanting to try an e-bike	Participants report wanting to take part in the trial to try out an e-bike. With the perception that e-cycling will improve health and fitness
worried about e-bike being stolen as not theirs	Participants in the intervention group discuss concerns about the e-bike being stolen and being aware that it was not their property

Codes were inductively grouped into sub-themes and deductively grouped into over-arching themes that aligned with the research objectives. Table 3 provides an outline of the themes and sub-themes and the codes which inform each of the subthemes. Sixteen sub-themes were generated that aligned with four overarching themes.

Table 3. Participant process evaluation themes and sub-themes

Overarching themes	Sub-theme	Codes included in the subtheme
Study participation	Benefit the community	Desire to contribute to research
	Participant co-morbidities	Participant co-morbidities
	Personal interest	Apprehension about assessments; being part of study is motivational; interest in study results; wanting to try an e-bike
	Reaction to randomization	Reaction to randomization
Acceptability of assessments and monitoring devices	Compatibility with lifestyle	chest monitor difficult to wear, completion of travel diary, experience of waist worn monitors, garmin GPS experience
	Physiology assessment experience	experience of blood sampling; experience of exercise test, experience of scans, mouth piece discomfort
	Reaction of electrodes	Reaction to actiheart pads
Experience of research visits	Engagement with staff	Staff were friendly
	Perception of participation	Being part of the study was interesting and enjoyable; clarity of procedures
	Time requirement to participate	Appointment flexibility; time commitment
	Travel requirements	Experience travelling and parking; more convenient appointment locations; request for reimbursement
Experience of e-bike training and intervention	Access to e-bike	e-bike loan period; waiting to get e-bike
	Appropriateness of equipment	Appropriateness of extra equipment; e-bike size concerns; extra equipment purchased or desired
	E-bike community	Desire for group rides; engagement in group rides

	Perceived efficacy of instructor and instruction	Engagement with instructor; necessity of e-bike sessions during the intervention; perception of e-bike training
	Theft concerns	Worried about being stolen as not theirs

Instructor process evaluation

Table 4 displays the original code book created after JEB and AS independently all the instructor transcripts and met to discuss the findings. A total of 33 codes were identified. Codes were further discussed and refined. Changes included merging codes of similar content or changing code names to make them more explanatory to the reader (e.g., *e-bike size concerns* and *e-bike weight concerns* were merged to form *suitability of e-bike. Discussion of barriers and benefits* was changed to *perception of behavioural counselling).* Table 2 displays the finalised codebook including a description of the data that was captured within each code. A total of 25 codes were included in the final codebook.

Table 4. Original instructor code book

	Code Name
1	administration
2	characteristics of participants
3	communication LCUK and instructors
4	contributing to research
5	desire to close the loop
6	desire to connect with instructors
7	difficulty with contact
8	disappointment at not reaching participants
9	discussion of barriers and benefits
10	e-bike size concerns
11	e-bike weight concerns
12	engaging with participants
13	equipment
14	familiarity with the programme
15	future changes
16	garmin difficulty
17	helping those in need
18	incorporation of discussions
19	information overload
20	instructor comfort with discussions
21	knowledge applied outside PEDAL2
22	location of training and e-bikes
23	minimal interaction with other instructors
24	more information about participants

25	motivation levels
26	pleasure in others enjoyment and or success
27	programme adaptability
28	programme paperwork
29	range of abilities
30	session attendance
31	skills training easy to deliver
32	study drop outs
33	support for participants

Table 5. Final instructor evaluation codebook and associated descriptions

Code	Description
additional equipment	Discussion about the accessories provided in addition to the e-bike
administration time	Discussion of the time taken to contact participants and book appointments
comfort with discussions	Instructors share their comfort levels with conducting the behavioural counselling
communication with LCUK	Instructors discuss communication between themselves and lifecycle UK
communication with other instructors	Instructors discuss contact between instructors delivering the PEDAL2 programme
cycling ability	Acknowledgement of the impact of individuals past cycling experience and of the range of cycling abilities among participants
desire to close the loop	Discussion of how these participants will access an e-bike after the trial
desire to connect with instructors	Instructors discuss a desire to connect with other instructors delivering the programme
difficulty with contact	Instructors discuss how they did not have follow-up contact with the participant and getting in touch with them was difficult or time consuming
engaging with participants	Instructors discuss how they enjoyed engaging with participants and developing relationships. Enjoyment from their success
familiarity with the programme	Discussion on how being unfamiliar with the programme made it hard to complete and how with increased familiarity they became more comfortable
GPS burden	Discuss use of garmin GPS for instructors and participants
helping those in need	Instructors express pleasure in helping those who haven't cycled before, or they perceive as needing to be active for their health
incorporation of discussions	Instructors share how and when they incorporated behavioural discussions into the training
knowledge applied outside PEDAL2	Ability to apply knowledge learnt or shared from PEDAL2 to other situations
location of training and e-bikes	Instructors comment on the location of e-bike training and e-bike storage

motivation levels	Discussions of participants motivation levels often in comparison to other adults they have taught or others in the trial
participant co-morbidities	Instructors discuss participants co-morbidities and the impact this has on attending sessions
perception of behavioural counselling	Instructors share how they perceived the behavioural counselling component of the intervention
programme adaptability	Instructors discuss how they adapted the programme or how adaptable they felt the programme was
programme paperwork	Instructors discuss likes or dislikes regarding the paperwork they were asked to complete
session attendance	Concerns regarding attendance to training sessions
skills training delivery	Instructors share their perceptions on delivering the e-bikes skills training
study dropouts	Discussion of reasons individuals dropped out of the study and specific characteristics of these dropouts
suitability of e-bike	Instructors share concerns about the size and weight of the e-bike

Codes were grouped into nine sub-themes and two overarching themes, that aligned with the research objectives were developed. Table 6 provides an outline of the themes and sub-themes and the codes which inform each of the subthemes.

Table 6. Instructor process evaluation themes and sub-themes

Overarching themes	Sub-theme	Codes included in the subtheme
Perception and delivery of intervention content	Delivery of behaviour counselling	Perception of behavioural counselling; comfort with discussions; incorporation of discussions
	E-bike skills training	Skills training delivery; location of training and e-bikes
	Intervention adaptability	Programme adaptability; familiarity with the programme
	Compatibility with values as an instructor	Engaging with participants; helping those in need; knowledge applied outside PEDAL2; desire to close the loop
Logistics of intervention delivery	Participant characteristics	Motivation levels; cycling ability; participant co-morbidities; study dropouts
	Communicating with participants	Difficulty with contact; session attendance
	Communication with peers	Communication with LCUK; communication with other instructors; desire to connect with instructors
	Equipment	Suitability of e-bike; GPS burden; additional equipment
	Administration	Administration time; programme paperwork

Appendix 7.1 Medication status of participants at baseline and post-testing

ID	Baseline Medication List	Post-Testing Medication List	Medications Stopped	Medication Started
Control condition				
PS001	Meformin (500mg 4xday) Gliclazide (80mg am, 40mg pm) Liraglutide (Victosa) (1.2mg injection am) Empagliflozin (10mg am) Sertraline (100mg 1xday)	Metformin (500mg 4xday) Gliclazide (2 x 80mg 2xday) Sertraline (100mg am) Statin (40mg pm) Liraglutide (1.2mg injection am)	Empagliflozin (10mg) [a]	Gliclazide: + 40mg [a]; Statin (40mg)
PS003	Metofrmin (500mg 4xday) Liraglutide (1.2mg injection) Levothyroxine (200mcg 1xday) Atorvastatin (20mg 1xday) Vitamin D3 (1000mcg OD)	Meformin (500mg 4xday), Liraglutide (1.2mg injection), Levothyroxine (200mcg 1xday)	Atorvastatin (20mg), Vitamin D3 (1000mcg)	
PS006	Not medication	No medication		
PS016	Metformin (500mg 4xday) Amlodipine (5mg 1xday) Atenolol (50mg 1xday) Candesartan (4mg 1xday) Simvastatin (20mg 1xday)	Metformin (500mg 4xday) Alogliptin (25mg 1xday) Amlodipine (5mg 1xday) Atenolol (50mg 1xday) Candesartan (4mg 1xday) Simvastatin (20mg 1xday at night)		Alogliptin (25mg 1xday) [a]
PS018	Metformin (500mg 5xday) Liraglutide (120mg 1xday injection) Empaglifozin (10mg 1xday) Ramipril (5mg 1xday) Simvostatin (20mg 1xday)	Meformin (500mg 5xday) Liraglutide (injection 120mg 1xday) Empagliflozin (10mg 1xday) Ramapril (5mg 1xday) Simvostatin (20mg 1xday at night)		
PS019	Allopurinol (300mg) Beclometasone (brown inhaler - 100mcg 2xday) Salbutamol (100mcg 2 puffs as required)	Allopirinol(300mg) Beclometasone (brown inhaler - 100mcg 2xday) Salbutamol (100mcg 2 puffs as required)		
PS020	Metformin (500mg 2xday) Amitryptiline (20mg)	Meformin (500mg 2xday) , Amytriptiline (20mg)		
PS021	Metformin (500mg 1xday)	Metformin (500mg 1xday)		
PS024	Rivaroxaban (20mg 1xday) Perindophril (4mg 1xday)	Rivaroxaban (20mg 1xday) Perindophril (4mg 1xday)		
PS025	Metformin (500mg 2xday) Atorvastatin (20mg 1xday)	Metformin (500mg 2xday) Atorvastatin (20mg 1xday)		
PS026	Metformin (1000mg 2xday) Venlafaxine (75mg 1xday) Methadone (30ml day)	Metformin (1000mg 2xday) Venlafaxine (75mg 1xday) Methadone (30ml day)		
PS028	Metformin (500mg 4xday) Gliclazide (80mg 4xday) Dulaglutide (1.5ml injection 1xweek) Atorvastatin (40mg 1xday) Enalapril (20mg 1xday) Amlodopine (10mg 1xday) Omeprazole (20mg 1xday)	Metformin (500mg 4xday) Gliclazide (80mg 4xday) Dulaglutide (1.5ml injection 1xweek) Atorvastatin (40mg 1xday) Enalapril (20mg 1xday) Amlodopine (10mg 1xday) Omeprazole (20mg 1xday)		
PS032	Sukkarto (500mg 4xday) Ramipril (10mg 1xday) Amlodipine (10mg 1xday) Indapamide (2.5mg 1xday)	Sukkarto (500mg 4xday) Ramapril (10mg 1xday) Felodpine (5mg 1xday) Bendroflumethizide (2.5mg 1xday)	Amlodipine (10mg 1xday) Indapamide (2.5mg 1xday)	Felodpine (5mg 1xday) Bendroflumethiazide (2.5mg 1xday)

PS033	Metformin (500mg 1xday) Amlodipine (5mg 1xday) Atorvastatin (20mg 1xday) Levothyroxine (50mcg 1xday) Losartan (25mg 1xday) Tacrolimus 0.1% ointment (when needed)	Metformin (500mg 1xday) Amlodipine (5mg 1xday) Atorvastatin (20mg 1xday) Levothyroxine (50mcg 1xday) Losartan (25mg 1xday) Tacrolimus 0.1% ointment (when needed)		
PS034	Metformin (500mg 1xday)	Metformin (500mg 1xday)		
PS042	Allopurinol (300mg 1xday), Dabigatran (150mg 2xday) Doxycycline (100mg 1xday - finish in 4 weeks)	Allopurinol (300mg 1xday), Dabigatran (150mg 2xday)	Doxycycline	
PS046	Apixaban (5mg 2xday), Diltiazem, Candesartan, Vit D	Apixaban (5mg 2xday), Diltiazem, Candesartan, Vit D		
PS051	Metformin (500mg 2xday) Omeprazole (20mg 1xday) Atorvastatin (20mg 1xday) Apixaban (5mg 2xday) Flucloxacillin (500mg 4xday)	Metformin (500mg 4xday) Omeprazole (20mg 1xday) Atorvastatin (20mg 1xday) Apixaban (5mg 2xday) Fostair inhaler (200/12mcg 1xday)	Flucloxacillin (500mg 4xday)	Metformin (1000mg) [a], Fostair inhaler (200/12mcg 1xday)
Experimental condition				
PS002	Sukkarto SR (500mg 4xday) Amlodipine (10mg 1xday) Atorvastatin (10mg 1xday) Ramipril (10mg 1xday) Tadalafil (20mg 1 as directed)	Sukkarto SR (500mg 3xday), Amlodipine (10mg 1xday), Atorvastatin (10mg 1xday), Ramapril (10mg 1xday), Tadalafil (20mg 1 as directed)	Sukkarto (500mg x 1) [a]	
PS007	Meformin (500mg 4xday) Atorvastatin (10mg 1xday)	Meformin (500mg 4xday) Atorvastatin (10mg 1xday)		
PS008	Metformin (500mg 4xday) Ramapril (5mg 1xday) Atenolol (5mg 1xday) Atorvastatin (amount not known) Levothyroxine (100mcg 1xday)	Meformin (500mg 4xday) Ramipril (5mg 1xday) Atenolol (5mg 1xday) Atorvastatin (amount not known) Levothyroxine (100mcg 1xday)		
PS009	Statin (40mg 1xday) Levothyroxine (75mg 1xday)	Statin (40mg 1xday) Levothyroxine (75mg 1xday) Omeprazole (20mg 1xday)		Omeprazole (20mg 1xday)
PS011	Atorvastatin (20mg 1xday), Calcium carbonate (1.25g 2xday), Colecalciferol (400U 2xday) Omeprazole (20mg 1xday)	Amitripyline (10mg 2xday at night), Atorvastatin (20mg 1xday am), Calcium carbonate (1.25g 2xday), Colecalciferol (400U 2xday), Miconazole 2% cream (2xday for rash), Omeprazole (20mg 1xday), Paracetamol (500mg up to 4 per day as needed)		Amitripyline (20mg), Miconazole (2xday), Paracetamol
PS012	Salbutamol (blue inhabler - 100mcg 2xam 2xpm) Beclometasone (brown inhabler - 100mcg 2xam, 2xpm)	Salbutamol (blue inhabler - 100mcg 2xam 2xpm) Beclometasone (brown inhabler - 100mcg 2xam, 2xpm)		
PS013	Bendroflumethiazide (2.5mg 1xday) Bisoprolol (1.25mg 1xday) Simvastatin (40mg 1xday) Rampiril (5mg 1xday) Lansaprazole (15mg 1 or 2 am) Beclometasone (brown inhabler - 100mcg 2xday) Salbutamol (100mcg 2 puffs as required) Aspirin (75mg 1xday)	Bendroflumethiazide (2.5mg 1xday) Bisophrolol (1.25mg 1xday) Simvastatin (40mg 1xday) Rampiril (5mg 1xday) Lansaprazole (15mg 1 or 2 am) Beclometasone (brown inhabler - 100mcg 2xday) Salbutamol (100mcg 2 puffs as required) Aspirin (75mg 1xday)		

PS015	Sukkarto SR (400mg 4xday) Empagliflozin (25mg) Atorvastatin (80mg 1xday) Clopidogril (75mg 1xday) Indapamide (1.5mg) Lansoprazole (30mg) Colecalciferol (1000U 1xday) Terbinafine (250mg 1xday)	Sukkarto SR (400mg 4xday) Dulaglutide (1.5ml injection 1xweek) Empagliflozin (25mg 1xday) Atorvastatin (80mg 1xday) Clopidogril (75mg 1xday) Indapamide (1.5mg 1xday) Lansoprazole (30mg 1xday) Colecalciferol (1000U 1xday) Losartan (100mg 1xday)	Terbinafine (250mg)	Losartan (100mg 1xday) Dulaglutide (1.5ml 1xweek) [a]
PS022	Meformin (500mg 2xday) Ramapril (2.5mg 1xday) Ticagrelar (90mg 2xday) Atorvastatin (80mg 1xday) Bisoprolol (1.25mg 1xday) Aspirin (75mg 1xday)			
PS023	Metformin (500mg 4xday) Atorvastatin (20mg day 1xday) Vit D (800mg day)			
PS027	Sukkarto SR (500mg 2xday) Lisinopril (20mg day) Atorvastatin (40mg 1xday) Amlodipine (5mg 1xday)	Sukkarto SR (500mg 2xday) Lisinopril (20mg day) Atorvastatin (40mg 1xday) Amlodipine (5mg 1xday)		
PS041	Ramapril (2.5g 1xday) Atorvastatin (20mg 1xday) Metformin (500mg 2xday)	Ramapril (2.5g 1xday) Atorvastatin (20mg 1xday) Metformin (500mg 2xday)		
PS043	Metformin (500mg 4xday) Dapagliflozin (10mg 1xday) Levothyroxine (175mg a day) Pravastatin (20mg 1xday) Ramapril (10mg 1xday)			
PS044	Metformin (500mg 4xday) Gliclazide (40mg 2xday) Rouvastatin (5mg 1xday)	Sukkarto SR (1000mg 1xday) Gliclazide (40mg 2xday) Rouvastatin (5mg 1xday)	Metformin (2g day) [a]	Sukkarto SR (1g day) [a]
PS047	Sukkarto SR (500mg 1xday)Linagliptin (5mg 1xday) Amlodipine (10mg 1xday) Ramapril (10mg 1xday)			
PS048	Ramapril (2.5g 1xday) Colecalciferol (20000 IU)	Ramapril (5mg 1xday)		
PS049	Metformin (500mg 4xday) Saxagliptin (5mg 1xday) Atorvastatin (20mg 1xday) Ramapril (10mg 1xday) Duloxotine (60mg 1xday)	Metformin (500mg 4xday) Saxagliptin (5mg 1xday) Atorvastatin (20mg 1xday) Ramapril (10mg 1xday) Duloxotine (60mg 1xday)		

[a] glucose regulation medication

List of medications reported by participants and their purpose

Drugs	Purpose
Diabetes medication	
Metformin	An oral antidiabetic drug – helps body respond more effectively to own insulin
Sukkarto SR (also known as Metformin SR)	Oral antidiabetic drug
Gliclazide	Oral medication used to treat T2DM. Increases the amount of insulin the body produces
Liraglutide (Victosa)	Injection used to treat T2DM. Less preferred to metformin.
Empagliflozin (Jardiance)	Oral medication used treat T2D. Helps the kidneys removed glucose from the bloodstream through the urine. SGLT2 inhibitor
Dulaglutide	Injection used to treat T2DM. It is a GLP-1 receptor agonist. It stimulates the body's natural production of insulin and inhibits the release of glucagon and slows digestion
Alogliptin	Oral medication used to treat T2DM. It increases the amount of insulin that your body makes
Dapagliflozin	Oral medication used to treat T2DM. Usually prescribed if cannot take metformin
Linagliptin	Oral medication used to treat T2DM. It increases the amount of insulin the body makes.
Saxagliptin	Oral medication used to treat T2DM. It increases the amount of insulin that your body makes
Antidepressant medication	
Sertraline	Oral antidepressant drug (SSRI)
Amitriptyline	Oral antidepressant drug. Used to treat low mood and depression
Venlafaxine	Oral antidepressant drug. Also used to treat anxiety and panic attacks
Citalopram	Oral antidepressant drug (SSRI)
Duloxetine	Oral antidepressant drug
Blood pressure medication	
Amlodipine	Oral medication used to treat high blood pressure. If have high blood pressure it helps prevent heart disease, heart attacks and strokes
Losartan	Oral medication used to treat high blood pressure and heart failure and to protect the kidneys if you have both kidney disease and diabetes. Helps prevent future strokes, heart attacks and kidney problems.
Felodipine	Oral medication used to treat high blood pressure. If have high blood pressure then helps prevent heart disease, heart attacks and strokes. Also used to prevent angina
Diltiazem	Oral medication used to treat high blood pressure. If you have high blood pressure it can help prevent future heart disease, heart attacks and strokes.
Ramipril	Oral medication used to treat high blood pressure and heart failure. Also prescribed after a heart attack. Helps prevent future strokes, heart attacks and kidney problems
Candesartan	Oral medication used to treat high blood pressure and heart failure. Helps prevent future strokes, heart attacks and kidney problems.
Perindopril	Oral medication used to treat high blood pressure and heart failure. Also prescribed after a heart attack. Helps reduce risk of future strokes and heart attacks
Lisinopril	Oral medication used to treat high blood pressure and heart failure. Also prescribed after a heart attack and in diabetic kidney disease. Helps prevent future strokes and heart attacks

Bisoprolol	Oral medication used to treat **high blood pressure** and **heart failure**. If have high blood pressure it helps prevent future heart disease, heart attacks and strokes. Also helps prevent chest pain caused by angina
Enalapril	Oral medication used to **reduce high blood pressure** and to prevent or treat **heart failure.** If have high blood pressure it helps prevent future heart attack or stroke
Bendroflumethiazide	A diuretic medicine. Oral medication used to treat high blood pressure and the build-up of fluid in your body (oedema). Helps the body get rid of extra fluid in your body.
Indapamide	A diuretic medicine. Oral medication used to treat high blood pressure and sometimes used to treat heart failure
Atenolol	A beta blocker. Oral medication used to treat high blood pressure and irregular heartbeats (arrhythmia). Can also be used to prevent chest pain caused by angina.
Heart drugs	
Propranolol	A beta blocker. Oral medication used to treat heart problems (high blood pressure, irregular heartbeat, prevent heart attack and stroke, prevent chest pain from angina), help with migrane
Digoxin	A cardiac glycoside. Oral medication used to treat abnormal heart rhythms (arrhythmias) including atrial fibrillation. Helps manage symptoms of heart failure
Statins	
Simvastatin	Oral medication used to lower cholesterol if you have been diagnosed with high blood cholesterol. Also prevents heart attacks and strokes.
Atorvastatin	Oral medication used to lower cholesterol if you have been diagnosed with high blood cholesterol. Also taken to prevent heart disease including heart attack and strokes
Pravastatin	Oral medication used to lower cholesterol if you have been diagnosed with high blood cholesterol. Also helps prevent heart attacks and strokes
Rosuvastatin	Oral medication used lower cholesterol if you have been diagnosed with high cholesterol. Helps prevent heart and blood vessel disease, heart attacks and strokes
Anticoagulants	
Apixaban	An anticoagulant. Oral medication used to treat people who have had a health problem caused by a blood clot such as a stroke, heart attack, DVT or pulmonary embolism
Rivaroxaban	An anticoagulant. Oral medication used to prevent blood clots in those at risk such as with abnormal heartbeat, recently had surgery to replace hip or knee, unstable angina, CHD, peripheral artery disease
Dabigatran	An anticoagulant. Oral medication used to treat people who have had a health problem caused by a blood clot such as a stroke, heart attack, DVT or pulmonary embolism
Clopidogrel	An antiplatelet medicine. Oral medication used to help blood flow through veins more easily to prevent dangerous blood clots
Ticagrelor	An antiplatelet medicine. Oral medication used to help blood flow through veins more easily to prevent dangerous blood clots
Indigestion	
Omeprazole	Oral medication to reduce the amount of acid the stomach makes. Widely used treatment for indigestion, heartburn and acid reflux. Also taken to prevent stomach ulcers
Lansoprazole	Oral medication to reduce the amount of acid the stomach makes. It’s used for indigestion, heartburn, acid reflux and gastroesophageal-reflux-disease (GORD). It also helps prevent and treat stomach ulcers

Calcium carbonate	Oral medication used to treat symptoms caused by too much stomach acid such as heartburn, upset stomach or indigestion
Hormone replacement	
Levothyroxine	Oral medication used to treat an underactive thyroid gland (hypothyroidism). The thyroid gland makes thyroid hormone which helps to control energy levels and growth. Levothyroxine is taken to replace the missing thyroid hormone.
Nebido	Injection. A testosterone replacement therapy in men with low or no production of testosterone
Pain relief	
Methadone	A synthetic opiate as an alternative to heroin also for pain relief
Antibiotics and Antifungals	
Doxycycline	An antibiotic. Oral medication used to treat chest infections, skin infections, rosacea, dental infections and STIs and other rare infections
Flucloxacillin	An antibiotic. Oral medication used to treat skin and wound infections, chest infections such as pneumonia and bone infections
Miconazole	A cream applied for fungal skin infections
Terbinafine	An oral antifungal medication to treat fungus that affect fingernails and toenails
Asthma	
Salbutamol (blue inhaler)	An inhaler to relieve symptoms of asthma. Salbutamol's primary function is to relax muscles in the air passages of the lungs making it easier to breathe. Also relieves symptoms of COPD
Beclometasone (brown inhaler)	An inhaler. Steroid medication to reduce sensitivity and swelling of the airways and reduce chance of serious asthma attacks
Budesonide with Formoterol	An inhaler to treat asthma, maintenance therapy
Fostair inhabler (combination inhaler) beclometasone dipropionate/ formoterol fumarate dihydrate.	A combination inhaler to treat asthma
Other	
Tadalafil	Oral medication used to treat erection problems and symptoms of an enlarged prostate
Colecalciferol	An oral medication - A form of Vitamin D
Finasteride	Oral medication used to treat enlarged prostate or hair loss in men. It is also used to treat excessive hair growth in women and as part of hormone therapy for transgender women
Allopurinol	Oral medication used to lower levels of uric acid in your blood. If you produce too much uric acid or your kidneys do not filter enough out, it can build up and cause tiny, sharp crystals to form in and around your joints. Also used to treat gout and kidney stones
Tacrolimus	Oral medication for short-term treatment of moderate to severe eczema
Fexofenadine	Oral antihistamine medication that helps with the symptoms of allergies.
Adalimumab	Injection. A biological medicine used to reduce inflammation by acting on your immune system. Used to treat inflammation of joints, skin, back pain, gut, ulcers etc.

Appendix 7.2 Justification for the selection of the secondary outcome measures

Secondary outcome measures

Clinical outcomes

Anthropometric outcomes

Overweight and obesity is independently associated with mortality in adults (1). Among individuals with type 2 diabetes mellitus (T2DM), increased weight is associated with a greater risk of cardiovascular disease (2), retinopathy (3, 4), chronic kidney disease (5) and mortality (6, 7). Physical activity (PA) has been found to contribute to weight loss in individuals with T2DM as part of a lifestyle intervention and is a key component of diabetes management (8, 9). BMI is the most common measure of weight status. Measurement of BMI will allow for characterisation of participants weight category (i.e., underweight [<18.5kg/m2], healthy weight [18.5-24.9.0kg/m2]; overweight [25.1-29.9kg/m2]; obese [≥30.0kg/m2]) and can be used to compare the current sample with samples reported in other exercise trials. BMI can also impact fitness and blood measures. Waist circumference measures the accumulation of body fat around the waist and maybe more reflective of body fat distribution than BMI (10). It is a measure commonly used in clinical settings. Research has shown the waist circumference specifically is positively associated with cardiovascular disease in individuals with T2DM (10).

Metabolic outcomes

Fasting measures of glucose and insulin

Assessment of fasting glucose and/or HbA1c are the current WHO recognised diagnostic criteria T2DM (11). Reducing the time spent in hyperglycaemia is the primary objective of diabetes treatment. As such, these measures are important clinical outcomes for a future trial.

The measure of HbA1c is linked to red blood cell count. When red blood cell turnover is decreased it will result in a disproportionate number of older red blood cells. Inversely, increased red blood cell count turnover leads to a greater proportion of younger red blood cells and falsely lowered HbA1c values. As such, HbA1c does not provide an acute measure of glucose control. Fasting glucose is more susceptible to daily changes in glucose control, while fasting insulin provides an acute measure of insulin secretion. These measures can be used to examine the interrelationship between glucose and insulin to provide insight into beta cell function and insulin resistance (12). The most commonly used of these indices is the homeostasis model assessment calculator (HOMA)(13). These mathematical models enable the estimation of beta cell function (HOMA-B) and insulin resistance (HOMA-IR). Given the close relationship between the beta cell function and insulin resistance regarding glucose homeostasis the two indices should be reported together. HOMA has been validated against the hyperglycaemic (HOMA-B) and euglyceamic-hyperinsulinemic clamp (HOMA-IR) (12).

PA has a positive impact on fasting measures of glucose control. A meta-analysis demonstrated the long-term beneficial role of exercise on reducing HbA_{1c} in individuals with T2DM (14-16). While Grace and colleagues (17) conducted a meta-analysis of 27 randomized controlled trials to examine the impact of aerobic exercise on markers of glycaemic control in individuals with T2DM. Their pooled data (i.e., irrespective of exercise modality or exercise duration) demonstrated that exercise led to reductions in HbA1c, fasted blood glucose, fasted insulin, and homeostatic model assessment of insulin resistance (HOMA-IR) compared to non-exercise controls. Therefore, these easy to determine measures will be examined in the current study.

Dynamic measures of glucose control

Fasting measures are common in practice and trial settings for their ease of use and low cost. However, they do not take into account the daily fluctuations in glucose homeostasis. Glycaemic variability represents the fluctuations from peaks to nadirs in plasma glucose concentration (18) and has been associated with micro- and macro-vascular diabetic complications (19, 20). Among individuals with T2DM, postprandial hyperglycaemia (the increase in plasma glucose concentrations after consuming a meal) contributes significantly to individual glucose variability (21). Postprandial hyperglycaemia and glucose variability are reported to be strongly correlated in individuals with T2DM (22) and in individuals with normal glucose control (23). Monnier and colleagues (24) demonstrated that postprandial hyperglycaemia makes a significant contribution to the overall hyperglycaemia seen in individuals with T2DM. It is now widely accepted that postprandial hyperglycaemia is an independent risk factor for CVD and mortality in individuals with T2DM (25, 26) and as such researchers have begun to explore the underlying mechanisms that create this link.

The oral glucose tolerance test (OGTT) is a simple test, widely used in clinical practice, to examine the efficiency of the body to dispose of glucose after an oral glucose load or meal. Incremental area under the curve (iAUC) for glucose and insulin have been used to provide a measure of insulin resistance, with elevated insulin and elevated glucose intuitively indicating insulin resistance and giving an idea of pancreatic insulin secretion levels. These are the most common measures derived from an OGTT (12) and will be calculated in the current trial. However, they do not provide an overall measure of insulin resistance. Since the late 90s various indices have been created to examine insulin resistance and beta cell function based on the interrelations between concentrations of insulin and glucose obtained from blood samples in a fasted state and during the OGTT. Three of these were explored in the current study:

1) The matsuda index (ISI) examines the ratio of plasma glucose to insulin concentration during the OGTT. The matsuda index provides a dynamic measure of whole-body insulin sensitivity (hepatic and peripheral tissue). This measure has been validated against the euglycemic insulin clamp technique (27). The measure is considered unitless with increases in the index indicating that the individual is more sensitive to insulin.
2) The insulinogenic index (IGI) provides a measure of insulin secretion, and therefore a measure of beta cell function. The original index computes the ratio of the incremental insulin concentration at 30-minutes to the incremental glucose concentration for the same time interval. It is believed to estimate the early phase insulin release and has been found to be an acceptable measure of beta cell function (28). The total insulinogenic index, calculated as the ratio of the incremental insulin concentration at 120-minutes to the incremental glucose concentration for the same time interval, gives an overall picture of the primary and secondary insulin response (29). The lower the value the IGI the worse the beta cell function is believed to be.
3) The insulin secretion-sensitivity index-2 (ISSI-2) was used to calculate beta cell function, while taking into consideration insulin sensitivity. Given the link between beta cell function and insulin sensitivity some researchers suggest that you cannot accurately assess one without considering the impact of the other. The ISSI-2 calculates the product of insulin sensitivity, using the matsuda index, and the beta cell function (AUCinsulin/AUCglucose) and has been found to correlate with the disposition index calculated from intravenous glucose tolerance test (30). Increases in the ISSI-2 suggest improvements in glucose homeostasis.

PA has been reported to have a positive impact on post prandial glycaemic measures in individuals with T2DM (31). Praet and colleagues (32) reported that a single bout of exercise can reduce hyperglycaemia by up to 40%. Moreover, a single bout of exercise can improve postprandial glucose control individuals with T2DM (33). In a meta-analysis of studies using continuous glucose monitors to assess short term glycaemic control, MacLeod and colleagues (34) reported a pooled effect of short term exercise, regardless of modality, on reducing average glucose concentrations by 0.8(95%CI; -0.9 to -0.7)mmol/L and time spent in hyperglycaemia (-129; 95%CI; -153 to -105, $p<0.01$)minutes. In addition, a lifestyle intervention, incorporating to supervised PA component showed a 40% increase in the disposition index compared to the control group from baseline to 12-month follow-up, while the matsuda index increased by 23% more in the lifestyle group than the control group. Interestingly, no changes in insulin secretion, as measured by the IGI were reported (35). The authors concluded that participants became more sensitive to insulin rather than seeing changes in insulin secretion. Improved glucose variability is seen from a variety of exercise modalities, including moderate activity (33, 36-38). Given that e-cycling represents a mostly moderate intensity activity, these outcomes are important to examine in the current trial.

Lipids

Diabetes is associated with dyslipidaemia. This is high levels of triglycerides, low-density lipoprotein cholesterol (LDL-C), total cholesterol and low levels of high-density lipoprotein cholesterol (HDL-C) (39). These factors have also been associated with coronary heart disease (39). Maintaining normal lipid levels is a key part of diabetes treatment (40). Research examining the impact of exercise on blood lipids has produced various results. Kelley and colleagues (41) meta-analysis revealed that aerobic exercise led to a reduction in LDL-C in programmes that ranged from 10 to 26 weeks, but had no effect on total cholesterol, HDL-C or triglyceride levels. A meta-analysis by Hayashino and colleagues (42) reported an increase in HDL-C and a decrease in LDL-C. While this is less than is seen in response to statins or dietary interventions it suggests that exercise may have a positive impact on lipid profiles among individuals with T2DM. To date one study has examined the impact of e-cycling in blood lipids (43). This study found no change in blood lipid levels after four weeks of pedalling in sedentary individuals. However, these individuals displayed optimal levels of blood lipids prior to e-cycling. As such, there is a need to examine the impact of e-cycling on blood lipid levels in individuals with T2DM.

C-reactive protein

C-reactive protein is a substance produced by the liver in the presence of inflammation in the body. The presence of C-reactive protein in the blood is considered a marker of chronic inflammatory status in the body, which is a predictor of future cardiovascular risk. A 2014 meta-analysis of randomized controlled trials revealed that aerobic exercise was associated with reductions in C-reactive protein in individuals with T2DM (42). As such, C-reactive protein will be measured in the current trial.

Health Related Quality of Life

T2DM, and more specifically glycaemic control, is associated with lower health related quality of life (44-46). Furthermore, poor quality of life, as assessed using health related quality of life measures, maybe a marker of mortality (47-49). In the UK in 2019, approximately 40% of people with diabetes reported reduced psychological well-being (50). As such, ensuring patients quality of life is also a central outcome for diabetes management (51, 52). Among individuals with T2DM, engaging in more PA is positively associated with improved quality of life (44) and specifically health related quality of life (53). However, few studies have examined the impact of cycling on quality of life. DeGeus and colleagues (54) showed that among healthy adults, despite high levels of baseline quality of life, cycling to work for one-year did increase physical functioning for women. Specifically related to e-cycling one study found no change in quality of life following eight weeks of cycling to work (55). However, in this study participants in the active travel group reported high levels of general PA at baseline suggesting the measure experienced ceiling effects. Qualitative findings reveal that e-cycling is associated with high enjoyment (56), while this could have a positive impact of quality of life perceptions more research is needed to examine the psychological health impact of e-cycling (57). As such, health related quality of life will be examined in the current study. While the MOS Short Form-36 has been criticised for not specifically examining the outcomes of importance for individuals with T2DM (58, 59) it enables the comparison to other health conditions and the general population.

Physiological outcomes

Cardiorespiratory fitness

Cardiorespiratory fitness represents the capacity of the respiratory and cardiovascular systems to provide muscles with oxygen during exercise and is a good reflection of overall physiological health and function, especially the cardiovascular system. Cardiorespiratory fitness has been shown to be a predictor of the risk of all-cause mortality even when accounting for traditional risk factors including smoking, hypertension and high cholesterol (60, 61). A recent evidence review found that individuals with T2DM have lower cardiorespiratory fitness than age, weight, comorbidity and activity matched controls (62) and as such the authors recommend that improving functional capacity should be high priority for individuals with T2DM. Engaging in regular PA is associated with increases in functional capacity of individuals with T2DM (63). While there is evidence that e-cycling is associated with increases in physical fitness (57) more work is needed to examine this among individuals with T2DM.

Body composition

While BMI and waist circumference are the most commonly assessed measures in clinical practice and in the assessment of relationship between obesity and T2DM they do not provide insight into the distribution of body fat in the body or for the discrimination of lean mass (also known as fat-free mass) from fat mass (64). DEXA (dual energy X-ray absorptiometry) scanning enables the examination of whole body and regional fat and lean mass and provides an objective, accurate and reliable measure for estimating whole body and regional body composition (64, 65). DEXA-assessed body composition has been found to be associated with T2DM (64, 66). Specifically, in their meta-analysis Gupta and colleagues (64) found that the presence of T2DM is associated with low muscle mass even after controlled for a range of diabetes risk factors, including age, gender, diet, PA, smoking, alcohol, T2DM duration. As such, the authors suggest that lifestyle interventions that increase activity, and muscle mass, are of particular importance for this population.

The impact of exercise, in the absence of dietary intervention, on body composition is varied. Willis and colleagues (67) revealed that, among sedentary obese adults, eight months of aerobic training (equating to approximately 12 miles per week at 65 to 80% VO_{2peak}) led to a significant reduction in whole body fat mass but no significant increase in whole lean body mass. Among individuals with T2DM, Sigal and colleagues (68) showed a decrease in abdominal fat mass following 22 weeks of aerobic training. Similar results have been reported by Jung and colleagues (69) following a 12 week moderate intensity aerobic training intervention amongst women with T2DM and by Mourier and colleagues (70) following an 8-week intervention in obese diabetic individuals. Interestingly, while no increases in whole body lean mass are apparent following aerobic training interventions alone (67, 71) some studies have reported increases in thigh muscle area and reduced fat following aerobic training (68, 71). To our knowledge, examination of body composition specifically following a cycling intervention has not been conducted. Therefore, this measure will be examined in the current trial. Given that cycling mainly engages the quadriceps and hamstrings examination of the leg lean and fat mass will take place. In addition, abdominal fat mass will be examined given the positive previous research examining the impact of aerobic exercise on reductions in abdominal fat. Whole body lean and fat masses will be examined for completeness.

Muscle quality, density and area

The skeletal muscle is key for the uptake of glucose with approximately 90% of peripheral glucose uptake occurs in the skeletal muscle (72). However, adipose tissue in the muscle can negatively impact insulin sensitivity (73). Obese individuals with T2DM have higher amounts of intermuscular adipose tissue than obese individuals with normal glucose tolerance (74). While muscle fat infiltration is associated with ageing, cross-sectional studies reveal that average daily step count is associated with lower intramuscular adipose tissue (IMAT) volume in the calf in individuals with T2DM (75), while Butner and colleagues (76) reported that muscle density was positively related to PA and negatively associated with risk of T2DM. To our knowledge no studies have examined the impact of a cycling intervention on thigh muscle cross-sectional area, IMAT, subcutaneous fat area and muscle density using pQCT. As such, these variables were explored in the current study.

Behavioural outcomes

Travel behaviour

Studies from a range of countries have examined how the provision of an e-bike serves to displace other modes of transportation largely through the collection of survey data (56). Some studies reveal that e-cycling largely displaces traditional cycling or walking (77, 78) while others suggest that e-cycling predominantly displaces car use (79, 80). In the UK, Cairns and colleagues (81) reported that the provision of an e-bike led to a reduction in mileage travelled by car of 20%, with little impact of active travel time as the more time spent cycling was offset by a reduction in time spent walking. This data was collected via interviews and focus groups and the authors report that the area in which the study was conducted had significantly higher rates of walking than the rest of the country. There is a need to objectively measure travel behaviour and transportation displacement following e-bike provision (56). Being able to objectively collect data on travel behaviour will provide understanding of which transportation modes are adopted and for what purposes following introduction of an e-bike. Transport mode displacement is an important outcome to measure as trips made by e-bike instead of motorised transport contribute positively toward the environmental and health benefits associated with cycling. However, trips made by e-bike instead of a conventional bicycle have slightly more negative environmental impact (due to use of a battery), however, the health impact of shifting from conventional bicycle to e-bike is less well understood. Understanding the purpose for which this population use e-bikes will help us understand their potential for mode displacement and give insight in to how to promote e-cycling (56). The impact of e-cycling on the travel behaviour of individuals with T2DM has not been examined.

Transportation CO2 emissions

This measure will provide insight into whether changes in transportation modes (if any) following the provision of an e-bike have an environmental impact through changes in CO_2 emissions at the individual. In Sweden, Winslott Hiselius & Svenssona (79) reported that purchasing an e-bike significantly decreased the CO_2 emissions per person per year. This information will be of interest of town councils.

Physical activity behaviour

It is currently recommended that individuals with T2DM engage in 150-minutes of moderate-to-vigorous intensity PA per week (8). Therefore, the aim of an exercise intervention, such as this, should be to increase PA to this level. E-cycling has been reported to provide PA at an intensity that is high encourage of evoke positive health outcomes (57, 82-84). However, most of these studies have been completed under experimental conditions. Data collected from the current study will provide information on whether a 12-week e-cycling intervention individuals are meeting the PA guidelines. This information will give insight into the feasibility of e-bikes as a potential strategy to increase PA behaviour in individuals with T2DM. Given that e-bikes are a costly investment, this information is key in deciding whether the promotion of e-biking amongst individuals with T2DM is a worthwhile endeavour as a health promotion strategy.

Physical activity due to e-cycling

It is important to understand the extent to which e-cycling contributes to an individual's PA level and the intensity of activity associated with e-cycling to provide insight into whether e-cycling has the potential to evoke positive health benefits among individuals with T2DM. Hip worn accelerometers have been found to have limited ability to determine lower body activities such as cycling (85). As such, they may underestimate the energy expenditure associated with cycling. Heart rate provides a measure of the physiological effect of PA and is less affected by the biomechanics of an activity. This has led some researchers to propose that combining accelerometery and heart rate can provide a better estimate of PA energy expenditure (86). Studies have shown that the use of heart and accelerometery can improve the prediction of energy expenditure in free living activities (87). As such, a combined accelerometers and heart rate monitor will be used to determine the intensity of activity while e-cycling in the current trial.

E-cycling during the intervention

Having a GPS unit attached to the bicycle for the duration of the study will enable the assessment of a) the cumulative e-bike use over the 12-weeks and b) the purpose of e-bike use. The use of a GPS device provides more contextual data about journeys than an in-built bike odometer and as such it will be trailed in the current study. An inbuilt bike odometer will also be used to ensure total e-cycling distance is captured. Knowledge of how an individual uses an e-bike can provide insight on how to target e-bike interventions in a future trial and may give insight into promotion strategies in the future.

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Appendix 7.3 Impact of VO_{2max} verification through use of a supramaximal assessments

To examine the potential utility of implementing a verification phase in this population, participants were classified into one of six categories based on their results (Table 1). The number of participants that fell into each category at baseline and post-testing are provided in Table 2.

Table 1. Classification for the achievement of VO2max

1	True positive	Participants achieved primary criteria for VO_{2max} in the incremental phase and this is confirmed by the verification phase (≤5% as suggested by Moreno-Cabanas et al., 2020). The higher of the two values of VO_{2max} was accepted
2	False positive	Participants achieved primary criteria for VO_{2max} in the incremental phase, but scored a higher VO2 value on the verification phase (<5% difference), the VO_{2max} value from the verification phase was accepted as VO_{2max}
3	Unconfirmed positive	Participants achieved primary criteria for VO_{2max} in the incremental phase, but this is not confirmed in the verification phase, which is >5% lower than the results of the incremental phase. The result from the incremental phase was accepted as VO_{2max}
4	True negative	Participants did not achieve the primary criteria for VO_{2max} in the incremental phase and scored higher on the verification phase. The value from the verification phase was accepted as VO_{2max}
5	False negative	Participants did not achieve the primary criteria for VO_{2max} in the incremental phase, but the verification phase did not produce a higher value of VO_{2max}. The highest of the two values was accepted as VO_{2max}
6	Single test	Participants did not complete the verification phase but achieved the primary criteria for VO_{2max} in the incremental phase, this value was taken as VO_{2max}

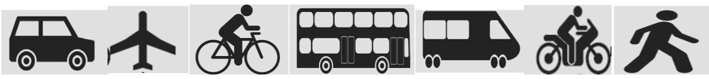
Table 7.2 Categorisation of participants based on VO_{2max} data

Category	Baseline	Post
True positive	12	12
False positive	7	7
Unconfirmed positive	9	1
True negative	3	0
False negative	1	1
Single incremental test	3	3
Did not complete any fitness assessment	5	16

Appendix 7.4 PEDAL2 travel diary

PEDAL-2

TRAVEL DIARY



Please complete the following travel diary for the next seven days starting: [ ]

INSTRUCTIONS

A few points to remember when filling in the travel record:

1. We are interested in **all types of transport**; walks, e-bike and regular bike journeys as well as cars and public transport.

2. Use a new line for each journey (e.g. go to work, go home). From column G use a new line for each method of travel you used for each stage of your journey (e.g. car, train, bus, walk).

Column A: Describe you journey

Please give a simple description such as 'go to work', 'take children to school' or 'go home'. If you went shopping please note whether it was 'food shopping' or 'other shopping'.

Column B: Categorise the purpose of your journey

Please categorize your journey using one of the following categories: Commuting, business, education, escort education (i.e., taking others to a place of education), shopping, visiting friends, entertainment, recreation

Columns C/D: What time did you leave/arrive?

Write in hours and minutes (e.g. 9.15). Please tick in am or pm to show the time of the day.

Columns E/F: Where did you start/go to? (Tick 'Home' or give the name)

Please write down the name of the place where your journey **started** and **finished**. Please give the postcode where possible. If you went to a shopping centre or visitor attraction, please tell us its name. If your journey started or finished at home, you only to tick 'Home'.

Column G: What method of travel did you use for each stage of your journey?

Use a different line for the **method of travel** you used at each **stage** of your journey (e.g. car, train, bus, bike). Please include all walks.

DAY 1 TRAVEL RECORD: DATE:

STAGES These columns are for entering details of **each stage** of your journey

JOURNEYS Please record each journey on a new row. Include very short ones and return ones. Include all walks.

A Describe your journey (e.g., taking children to school, going to work)	**B. What was the main purpose of your journey?** (Commuting, business, education, escort education, shopping, visiting friends, entertainment, recreation)	**B What time did you leave?**	**C What time did you arrive?**	**D Where did you start your journey?** (Provide postcode if know)	**E Where did you go to?** (Provide postcode if know)	**F** What method of travel did you use for each stage of your journey?	
1		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
2		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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3		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
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4		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
5		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
6		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
7		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	

DAY 2 TRAVEL RECORD: DATE:						**STAGES** These columns are for entering details of **each stage** of your journey	
JOURNEYS Please record each journey on a new row. Include very short ones and return ones. Include all walks.							
A Describe your journey (e.g., taking children to school, going to work)	**B. What was the main purpose of your journey?** (Commuting, business, education, escort education, shopping, visiting friends, entertainment, recreation)	**B What time did you leave?**	**C What time did you arrive?**	**D Where did you start your journey?** (Provide postcode if know)	**E Where did you go to?** (Provide postcode if know)	**F** What method of travel did you use for each stage of your journey?	
1		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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2		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
3		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
4		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
5		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
6		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
7		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	

DAY 3 TRAVEL RECORD: DATE:						**STAGES** These columns are for entering details of **each stage** of your journey	
JOURNEYS Please record each journey on a new row. Include very short ones and return ones. Include all walks.							
A Describe your journey (e.g., taking children to school, going to work)	**B. What was the main purpose of your journey?** (Commuting, business, education, escort education, shopping, visiting friends, entertainment, recreation)	**B What time did you leave?**	**C What time did you arrive?**	**D Where did you start your journey?** (Provide postcode if know)	**E Where did you go to?** (Provide postcode if know)	**F** What method of travel did you use for each stage of your journey?	
1		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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3		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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4		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
5		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
6		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
7		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	

DAY 4 TRAVEL RECORD: DATE:

STAGES These columns are for entering details of **each stage** of your journey

JOURNEYS Please record each journey on a new row. Include very short ones and return ones. Include all walks.

A Describe your journey (e.g., taking children to school, going to work)	**B. What was the main purpose of your journey?** (Commuting, business, education, escort education, shopping, visiting friends, entertainment, recreation)	**B What time did you leave?**	**C What time did you arrive?**	**D Where did you start your journey?** (Provide postcode if know)	**E Where did you go to?** (Provide postcode if know)	**F** What method of travel did you use for each stage of your journey?	
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2		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1 2 3	
3		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1 2 3	
4		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1 2 3	
5		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1 2 3	
6		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1 2 3	
7		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1 2 3	

DAY 5 TRAVEL RECORD: DATE:

STAGES These columns are for entering details of **each stage** of your journey

JOURNEYS Please record each journey on a new row. Include very short ones and return ones. Include all walks.

A Describe your journey (e.g., taking children to school, going to work)	**B. What was the main purpose of your journey?** (Commuting, business, education, escort education, shopping, visiting friends, entertainment, recreation)	**B What time did you leave?**	**C What time did you arrive?**	**D Where did you start your journey?** (Provide postcode if know)	**E Where did you go to?** (Provide postcode if know)	**F** What method of travel did you use for each stage of your journey?	
1		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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3		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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4		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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5		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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6		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
						2	
						3	
7		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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DAY 6 TRAVEL RECORD: DATE:

STAGES These columns are for entering details of **each stage** of your journey

JOURNEYS Please record each journey on a new row. Include very short ones and return ones. Include all walks.

A Describe your journey (e.g., taking children to school, going to work)	**B. What was the main purpose of your journey?** (Commuting, business, education, escort education, shopping, visiting friends, entertainment, recreation)	**B What time did you leave?**	**C What time did you arrive?**	**D Where did you start your journey?** (Provide postcode if know)	**E Where did you go to?** (Provide postcode if know)	**F** What method of travel did you use for each stage of your journey?	
1		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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3		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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5		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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6		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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7		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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DAY 7 TRAVEL RECORD: DATE:

STAGES These columns are for entering details of **each stage** of your journey

JOURNEYS Please record each journey on a new row. Include very short ones and return ones. Include all walks.

A Describe your journey (e.g., taking children to school, going to work)	**B. What was the main purpose of your journey?** (Commuting, business, education, escort education, shopping, visiting friends, entertainment, recreation)	**B What time did you leave?**	**C What time did you arrive?**	**D Where did you start your journey?** (Provide postcode if know)	**E Where did you go to?** (Provide postcode if know)	**F** What method of travel did you use for each stage of your journey?	
1		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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3		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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5		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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7		Time: ☐ am ☐ pm	Time: ☐ am ☐ pm	☐ Home	☐ Home	1	
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IS THE TRAVEL BEAHVIOUR RECORDED IN THIS DIARY REPRESENTATIVE OF A TYPCIAL WEEK FOR YOU? ☐ YES ☐ NO

If no, please explain why it was not typical?

What journeys would be completed or not completed on a typical week?

USE THIS SPACE FOR ANYTHING ELSE YOU WANT TO TELL US (e.g., about the journeys you took, safety and quality of the routes etc.)

Appendix 7.5 Estimation of CO2e emissions

Methods

Data from travel diaries and GPS devices were used to calculate CO_2e emissions by transport mode. CO_2e is a metric for quantifying the overall emissions of multiple greenhouse gases. In the most recent UK government 2020 guidelines for greenhouse gas CO2e emissions included carbon dioxide (CO_2), methane (CH_4) and nitrous oxide (N_2O) (1).

For travel by bus, train, underground or taxi the total distance travelled in the past week was multiplied by the mode-specific average emissions factors per kilometres calculated by the UK Government 2020 guidelines for greenhouse gas reporting (1). Data from air travel by one participant was excluded as this was not representative of a typical week and the survey was not designed to capture emissions due to air travel.

For personal vehicles CO_2e emissions were calculated by multiplying the distance travelled (using GPS and travel diary data by mode) by vehicle type (can, van, motorcycle), vehicle size (based on engine size) and fuel type (petrol, diesel, hybrid etc; not available for motorcycle). The vehicle reported as 'most used' by participants in survey data was taken as the reference vehicle for emissions calculations unless stated otherwise. If vehicle details were not reported the average of the unreported variable was taken to calculate emissions. Due to limited detailed data on shared car use, in the current study all CO2e emissions for trips undertaken by the participant, regardless of whether the participant was the driver or passenger, were assigned to the participant. This method provided an estimate of the total CO2e contribution for that specific car journey.

While electric bikes have no direct emissions there are emissions associated with the electricity to charge the e-bikes (indirect emissions). GHG emissions associated with charging the e-bikes were calculated on an individual basis using the following method:

1. The range the e-bike could be ridden on one battery cycle was estimated based on: a) the weight of the rider (kg; based on anthropometric data), b) the average speed of e-bike journeys (based on GPS and travel diary data) and c) an estimated assistance setting of *tour* using the Bosch range assistant (https://www.bosch-ebike.com/en/service/range-assistant./)
2. The total distance ridden during the monitoring week was divided by the estimated range to give the total number of battery cycles used.

3. The number of battery cycles was multiplied by the battery capacity for each bike to give the total electricity consumed for e-bike charging (Watt hours)
4. The total electricity consumed (Watt hours) for e-bike charging was converted in kg CO2e using the UK Government 2020 greenhouse gases conversion factors for UK electricity (1).

The average kilograms of CO2e per week emitted for each participant was calculated by dividing the sum of kg of CO2e for a given participant by the number of valid days of data, multiplied by seven. All calculations were conducted in excel.

Results

At baseline each participant in the control group generated a median of 26.0 kg of CO2e (IQR: 16.8, 74.7) per week. This value decreased at post testing with a median of 20.9 kg of CO2e per week (IQR: 13.7, 36.2). The intervention group had a lower estimated weekly carbon emissions per person than the control group with a baseline median per participant of 19.3 kg of CO2e generated (IQR: 10.4, 43.5), this value increased at post testing to a median of 24.55 (IQR: 14.2, 43.1). These values are in line with median distances reported for groups at baseline and post testing.

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Appendix 7.6. Actigraph accelerometer procedures and settings

Procedure	Settings	Justification
Data collection		
Initialising	Initialized to start recording the day after distribution and to collect data for seven days including a weekend	Used in multiple accelerometery studies with the goal of providing at least four days of valid data.
Sampling frequency	30Hz	For this make of accelerometer this is the only option of sampling frequency.
Protocol	ActiGraph GT3X monitor worn on the right hip	Hip worn found to be superior for measuring locomotion, compared to wrist (1)
Wear time	Waking hours (except when swimming/bathing/showering)	Wearing the accelerometer on the hip during sleeping could be uncomfortable. Therefore, the research team decided to request the accelerometer was only worn for waking hours. This protocol has been used with older adults (2)
Data processing criteria		
Valid length of day	≥ 10 hours (600 minutes in duration)	This length has been recommended as appropriate to capture sufficient data during the day (3) and has consistently been used in other studies with older adults (4, 5)
Days required	≥ 3 days of valid wear time	Hart and colleagues (6) and Dowd and colleagues (7) suggest a minimum of three days of valid data is required. Migueles and colleagues (3) examined the trade-off between amount of data rejected and the study sample size. Given the small sample size in the current study three days of data meant the inclusion of three participants at baseline and five at post testing who would have been excluded if the requirement of four valid days was set
Epoch length	60-seconds	The activity cut-off points developed by Sasaki and colleagues (8) were validated using 60s cut points. Migueles and colleagues (3) argue that it is important to use the same epoch length from which the cut-off activity points were derived as to limit error in activity classification.
Zero counts	≥ 90 minutes of zeros allowing for 2 mins of activity when placed between 2 30min windows (Choi et al)	Time spent in sedentary behaviour increases with age (9) which may lead to increased risk of misclassifying sedentary time as non-wear time. The choi et al (10) algorithm for detection of non-wear time has been proposed for use with older adults (3) and has been used by other studies (5). This algorithm was validated using vector magnitude derived from tri-axial accelerometers. The use of an automated filter method has been found to be as accurate as combining automated filters with activity logbooks (11).
Spurious data	>15000cpm	Used by Audrey and colleagues (5) and by other studies(11)

Missing data	No imputation – only use those with enough days and wear time	It is not considered appropriate to impute missing data (11).
Filter	Normal	Migueles et al (3) recommend using the same filter as was used in the validation study for cut points being employed in the study. Therefore normal frequency filter will be applied to the Sasaki cut points (8).
Activity cut-off points	Light ≤ 2690 MVPA≥2691	Sasaki et al (2011) cut points has been found to be the most appropriate activity cut points for use in adults (3) and will therefore be used in the current study.
Axis of analysis	Vector magnitude (VM)	Triaxial accelerometry has been reported to provide a better estimate of PA than uni-axial with some research suggesting this is particularly important when looking at activities such as cycling (11, 12). The Sasaki et al (8) cut points used in this study were developed using the three axis and so this procedure will be followed in the current trial.

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PEDAL 2 LOG BOOK

Use this space to record all your e-cycling over the next three months. This will help you keep track of what you have done.

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What is your e-cycling goal?

Setting goals can keep us motivated. The best goals are specific, measurable, achievable, realistic and time-based

SMART

RECORD YOUR EXERCISE GOAL IN THE SPACE BELOW

(e.g., ride my e-bike 3 x per week for 60-minutes)

My goal is:

Use the log book to keep track of your e-cycling and re-visit your goal on a regular basis to see if you are achieving your goal or if it needs altering slightly.

Contact us anytime:

Phone: **0117 3534580**

Email: training@ lifecycleuk.org.uk

We are also on **Facebook and Whatsapp**

If you experience is breakdown:
Ring the Life Cycle UK office **Monday to Friday 9am-5pm** at **0117 3534580.** A member of staff will arrange for a taxi to pick you and the bike up and take you home. You will not have to pay for this service. If the bike cannot be transported, please lock the bike securely and inform Life Cycle UK of its location.
For out of hours breakdowns: Please contact Jacqui Wilcox the Life Cycle project manager on 0795 6885000

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E-bike Log Book Instructions

Use this log book to monitor your exercise sessions. Remember there are no right or wrong answers so please be 100% honest with your answers. Be sure to record each and every e-bike session that you complete. You can also use this log to record any other exercise you do.

1. What activity did you do today?

- Examples: e-cycling, walking

2. How many minutes of activity did you do?

3. Rate of Perceived Exertion

While doing physical activity we want you to rate your perception of exertion. This feeling should reflect how heavy and strenuous the activity feels to you, combining all sensations and feelings of physical stress, effort and fatigue

0	Nothing at all
0.5	Very, Very Weak
1	Very Weak
2	Weak
3	Moderate
4	Somewhat strong
5	Strong
6	
7	Very Strong
8	
9	Very, very strong, Maximal
10	

4. If e-cycling, on average, what assistance level did you use?

5. If e-cycling, for what purpose did you e-cycle (i.e., for leisure – just going for a ride, to commute to work, or to go to the shops or meet a friend)

6. Additional thoughts or feelings: Record in box for your reference

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Week 1	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Activity							
Minutes of Activity							
RPE							
Assistance level e-cycling							
Purpose of e-cycle							
Additional Thoughts and Feelings							

Note: Week one is provided as an example. Weeks one to 13 were provided in the original log book

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Appendix 7.8. Baseline descriptive statistics of secondary outcomes, by condition for those included in the analyses (n=35)

Outcomes	**Intervention (n=17)**			**Control (n=18)**		
	N	Mean (*Median)	SD (*IOR)	N	Mean (*Median)	SD (*IOR)
Height, cm	17	169.7	9.0	18	173.3	9.3
Weight, kg	17	96.3	20.6	18	98.4	23.8
BMI, kg/m^2	17	33.5	7.4	18	32.5	5.9
Waist circumferences, cm	17	114.9	17.3	18	113.1	16.9
Biochemical measures						
HbA1c, mmol/mol	17	54.6	11.1	16	57.8	20.1
Fasting glucose, mmol/L	17	7.7	2.2	17	7.5	2.9
Fasting insulin, mIU/mL	17	19.8	16.6	16	18.4	13.3
HOMA-B, %	17	88.7	64.4	16	96.1	58.0
HOMA-IR, unitless	17	2.8	2.6	16	2.6	1.7
C-reactive protein, mg/L	17	2.0	0.9 to 4	17	3.0	2 to 4
Total cholesterol, mmol/L	17	4.0	0.9	17	4.2	0.8
Triglycerides, mmol/L	17	1.7	0.9	17	1.5	0.7
HDL cholesterol, mmol/L	17	1.4	0.5	17	1.1	.03
LDL cholesterol, mmol/L	16	1.8	0.6	17	2.3	0.7
Non-HDL cholesterol, mmol/L	17	2.6	0.8	17	3.0	0.7
iAUC glucose, mmol/L/120mins	15	660.5	185.6	15	521.2	222.3
iAUC insulin, mIU/L/120min	15	6140.9	4619.1	15	4994.4	5146.1
Matsuda Index, unitless	15	3.2	3.5	15	3.0	1.8
$IGI_{original,}$ pmol/mmol	16	49.2	34.2	15	70.4	78.0
$IGI_{total,}$ pmol/mmol	15	61.5	45.9	15	69.7	69.7
ISSI-2, unitless	15	68.1	49.9	15	76.8	57.2
Health related quality of life						
Physical component	17	63.8	21.7	18	73.0	18.4
Mental component	17	68.4	16.5	17	76.3	16.2
Physiological outcomes						
Absolute VO_{2max}, L/min	15	1.9	0.2	15	2.2	0.1
Relative $VO_{2max,}$ ml/kg/min	15	20.2	1.7	15	22.8	1.1

Outcomes	Intervention (n=17)			Control (n=18)		
Max power output, Watts	15	150.2	14.2	15	184.1	8.2
Body Composition						
Body fat, %	17	34.8	10.1	18	33.9	6.9
Fat mass, kg	17	33.1	12.8	18	33.3	12.2
Trunk fat mass, kg	17	17.9	7.4	18	19.0	7.0
Leg fat mass, kg	17	5.3	2.1	18	5.0	2.1
Lean mass, kg	17	58.7	14.2	18	60.6	13.7
Leg lean mass, kg	17	10.2	2.7	18	10.7	2.9
pQCT femur mCSA, cm^2	17	105.5	25.9	16	116.7	30.0
pQCT femur density, mg/cm^3	17	61.6	6.0	16	62.4	6.1
pQCT IMAT area, cm^2	17	20.4	7.2	16	22.4	11.6
pQCT SAT area, cm^2	17	51.3	29.5	16	40.1	24.8
Physical activity						
Daily minutes of MVPA	16	42.9	32.2	17	43.7	24.4
Daily minutes of MVPA10+mins	16	18.1	19.8	17	18.9	17.8
Weekly minutes of MVPA	16	300.6	225.5	17	305.6	170.8
Weekly minutes MVPA10+mins	16	126.8	138.6	17	132.5	124.7

BMI=body mass index; HbA1c=glycated hemoglobin; HOMA-B=homeostasis model assessment of β-cell function; HOMA-IR=homeostasis model assessment of insulin resistance; HDL=high density lipoprotein; LDL=low density lipoprotein; iAUC=incremental area under the curve; IGI=insulinogenic index; ISSI-2=insulin secretion sensitivity index 2; VO_{2max}=maximal oxygen uptake; pQCT=peripheral quantitative computer tomography; IMAT=intramuscular adipose tissue; SAT=subcutaneous adipose tissue; MVPA=moderate to vigorous physical activity

Appendix 8.1 Additional details of the qualitative analysis of participants experiences of e-cycling

Through independent coding of two transcripts by JEB and AS and follow up discussions a total of 39 sub-domains were identified within the 14 domains of the TDF (see Table 1). Sub-domains were further discussed and refined. Refinements including name changes and merging sub-domains of similar content (*e.g., change in riding confidence* and *initial e-cycling confidence* were merged into *confidence to ride the e-bike)*. The final codebook, including sub-domain descriptions are provided in Table 2 (these were termed sub-domains in the current study). In total 35 sub-domains were included in the final codebook.

Table 1. Original code book

	Code Name
1	assistance makes riding possible
2	change in health and fitness
3	change in riding confidence
4	charging and removing the battery
5	confidence cycling on roads or in traffic
6	cost of e-bikes
7	cycle parking infrastructure
8	cycling infrastructure
9	desire for an e-bike
10	desire to keep riding
11	e-bike accessories
12	e-bike as energising
13	e-bike as exercise
14	e-bike handling
15	e-bike storage
16	e-cycling ability
17	enjoyment of riding
18	environmentally friendly
19	experience of e-bike training
20	experience of follow-up sessions
21	goal setting
22	habit formation
23	impact of ex on diabetes
24	impact of weather
25	influence of others on cycling
26	initial confidence level riding on roads
27	initial e-cycling confidence
28	past cycling experience

29	perception of cyclists
30	perception of e-biking from significant others
31	purpose of use
32	remembering e-bike components
33	riding intentions
34	role modelling
35	self as a cyclist
36	theft concerns
37	topography of riding
38	traffic experiences
39	weight of e-bike

Table 2. Final sub-domains and associated descriptions

Sub-domain	Description
Ability to ride further, longer, and hillier terrain	Participants stated how the e-bike enables them to ride further, longer and hillier routes than a conventional bicycle
Ability to ride and manoeuvre the e-bike	Participants report the ease or difficulty they had with moving and riding the e-bike
Access to infrastructure for riding and parking	Participants expressed about how cycling infrastructure supported their riding or reducing their riding. This includes cycle paths and roads as well as safe spaces to lock the bikes
Benefits of physical activity	Participants reported the benefits of e-cycling and physical activity in general. This is often reported in relation to other methods of controlling their diabetes such as diet or medication
Cycling advocacy	Participants talk about encouraging others to try out an e-bike
Concerns about e-bike theft	Participants share their fears of riding the e-bike due to concern that it will be stolen
Confidence riding on roads or in traffic	Participants expressed their confidence level riding on roads and in traffic and how this changed over time.
Decision to engage in e-cycling	Participants shared how they made decisions to ride the e-bike by comparing it to other modes of transport available to them or the impact of environmental factors
Desire to continue riding	Participants reported their intention to continue riding either an e-bike or a conventional bicycle after the study
E-bike training was helpful or insufficient	Participants share their experiences of e-bike training and whether the training was sufficient to encourage riding
E-bike size and design features	Specific features of the e-bike which impacted riding including the weight of the bike and charging the battery are reported
E-bikes are expensive to buy	Participants express how they may not be able to afford an e-bike in the future due to the associated cost of purchasing
E-cycling intentions	Participants reported the intended use of the e-bike when signing up for the study and how this matched with actual behaviour

Environmental and financial impact of e-cycling	Participants expressed the potential environmental and financial impact of e-cycling and the impact these beliefs had engaging with e-cycling
Familiarity with cycle routes	Participants reported the impact that being familiar with the e-bike routes had on their riding
Habit formation	Participants share how/if they got in the habit of e-cycling
Impact of previous cycling experience	Participants report the impact of previous cycling experience on current cycling
Impact of weather and resources	Participants reported the impact that the weather has on their cycling and on the equipment that participants had to enable them to ride in various weather conditions
Increased awareness and empathy for cyclists	Participants stated that riding an e-bike has given them increased empathy or awareness for cyclists. E-cycling has impacted how they behave towards other cyclists when driving a car
Knowledge of riding on roads	Participants shared how the instructors provided them with information on how to ride on roads
Long- and short-term health benefits of e-cycling	Participants shared their beliefs around e-cycling being a form of exercise and the impact of cycling on fitness. The long- and short-term impact of e-cycling on diabetes management is discussed. In the short-term participants discuss how e-cycling can reduce or overcome feelings of fatigue
Optimistic that e-cycling would be a positive experience	Participants share their optimism that e-cycling would be a positive experience that could positively impact health and well-being
Perception of self as a cyclist	Participants share whether they view themselves as a cyclist
Perceived competence riding an e-bike	Participants reported on their general confidence riding an e-bike and how this changed over time.
Personal health issues that impacted riding	Participants share information on their personal health and the impact this had on riding the e-bike
Planning and scheduling e-cycling	Participants reported how they made plans for cycling including how, when and where to cycle
Practical support	Participants talk about the practical support that had riding the e-bike and whether they desired social support
Remembering to charge e-bike or specific equipment	Participants shared the ease or difficulty in remembering the components needed to comfortably ride the e-bike
Riding the e-bike enjoyable and satisfying	Participants share their feelings of enjoyment riding an e-bike, often in the context of riding locations. Participants share how the e-bike can be thrilling to ride
Sense of achievement	Participants express how riding the e-bike was rewarding and they felt they had achieved something
Time constraints	Participants express the impact of time on their use of the e-bike and how the completion of multiple trips impacted riding
Traffic concerns	Participants share their concerns of the traffic and how this impacted their e-cycling

Understanding of how to operate the e-bike	Participants reported on the ease or difficulty operating the e-bike
Using technology to self-monitor rides	Participants reported using technology to monitor their rides including strava, phone distance applications or a garmin GPS etc.
Verbal and emotional support	Participants report on the verbal encouragement they did or did not get as part of the study and the impact this had on riding

Exerts were deductively allocated into one or more of the 14 TDF domains from which five overarching themes were inductively developed. Table 8.2 in the main body of text provides an outline of the themes and sub-domains allocated into the TDF domains.

Appendix 9.1 Findings from Study 3 and suggest future refinements

Finding from Study 3	Suggested future refinements
Recruitment, randomization and retention	
Targeting mail out through primary care practices were the most effective recruitment method. The final sample reflected the ethnic diversity and gender distribution in Bristol	Targeted recruitment through primary care practices can reach a large population. Select primary care practices from different IMD areas to increase diversity in the sample
Study information reached ineligible individuals	Develop databased searches in line with eligibility criteria as much as possible to reduce wasting resources
Participants were motivated to participate in the study to try out an e-bike	Use a waitlist control group to ensure all individuals get the opportunity to try out an e-bike
Participants are curious to complete a variety of measures that are not part of everyday care	Provide participants with individual study reports at the end of the study
Study procedures	
Research staff play an important part in participant retention	Ensure research staff are knowledgeable of the study and procedures and create a relaxed environment for participants
While some flexibility in appointments was available more flexibility may increase the number of individuals that could participate	Offer early morning and weekend appointments to enable more working individuals to participate
Participating in the study involved a significant time commitment	Conduct data collection in one location. Reduce measures completed where appropriate to reduce time burden, while remembering participants are interested in unique assessments
Data collection methods	
Blood sampling and OGTT are acceptable to participants and e-cycling was found to have promise to positively impact these measures	Fasting and dynamic measures of glucose homeostasis should be completed as part of a definitive trial given their sensitivity to change
Measurement of quality of life was not reported to be a burden to participants and was sensitive to change	A measure of quality of life should be included in a definitive trial as it is a key component of diabetes management
Fitness assessments were perceived as hard but manageable. E-cycling showed promise to positively impact fitness with clinically meaningful change	Use of a maximal fitness assessment provides an accurate measure of fitness and should be considered for use in a future trial
Actigraphs are unable to detect cycling, while Actihearts are a significant burden to participants	PA behaviour needs to be accurately measured in a definitive trial. Consider use of a research grade wrist worn accelerometer with integrated HR. Any new measure should be trialled prior to a definitive trial
GPS monitoring was acceptable to participants and provided objective measure of travel behaviour	GPS devices should be used in a future trial to accurately record travel behaviour
Travel diaries were a burden to participants. However, they were a valuable tool for providing contextual trip information	Work with participants to amend the travel diary and potentially design an online app that can be used to record trips
Body composition scans did not show sensitivity to change but the standardised protocol was not followed. These scans were of little burden to participants.	Consider whether this outcome is important for a definitive trial and if the standardised protocol can be following. If the protocol cannot be followed these measures should not be conducted
Intervention implementation	
The intervention was successfully implemented by a community-based organisation and their certified instructors	This method of delivery should be taken forward into a definitive trial
The intervention required high levels of tailoring to meet the needs of participants due to low fitness and balance issues. Instructors were unsure how much they could adapt and tailor the intervention	Ensure instructors are provided with sufficient training to know where and how to implement and adapt the intervention. Use role playing to practice difference scenarios and to increase confidence with delivery

Finding from Study 3	Suggested future adaptations
Some participants were unable to become independent cyclists due to no prior cycling experience before the intervention	Ensure potential participants have a basic level of cycling prior to participating in the intervention to increase chances of intervention success. Individuals who do not know how to ride could be directed to free community 'learn to cycle' initiatives
Sessions during the loan phase were infrequently conducted but were associated with more e-cycling	Ensure e-bike refresher sessions are conducted. Remind instructors of the importance of these sessions so they can encourage engagement and reach out to participants
Intervention fidelity was reported to be high but was only assessed through completion of checklists by instructors	A future trial should incorporate independent assessments of fidelity such as the observation of sessions. Different domains of fidelity should be explored including engagement by participants and receipt of the intervention
Intervention acceptability	
Instructors were comfortable delivering the cycle skills training due to familiarity	Ensure all instructors are national skills level certified instructors
Behavioural counselling was perceived as beneficial however, their confidence delivering this component varied	Provide instructors with more training on behavioural counselling prior to intervention delivery and include role playing activities
Instructors had limited communication with peers during implementation. More interaction was required	Provide opportunities for instructors to meet with each other and share experiences
Six harmful events were reported, two of which required hospitalization. Only three were reported to LCUK and researchers	All harmful events reported to LCUK were reviewed. Ensure that there is a clear system through which participants are encouraged to report harmful events.
The size and weight of the e-bike is hard for individuals to manage potentially due to their fitness level and issues with balance	Instructors should work with participants to test out different size e-bikes and find one that they are comfortable on. This will help to build confidence.
Participants were worried about theft of the e-bike particularly as it did not belong to them	Clearly communicate the implications of e-bike theft for participants.
Determinants of e-cycling	
A range of individual, social and environmental determinants of e-cycling have been identified	Use the current qualitative findings to select appropriate measures that can be used in a future process evaluation to gain greater insight into the determinants of e-cycling