

Improving interventions for physical activity and depression

Submitted by **Jeffrey David Lambert**, to the University of Exeter as a thesis for the degree of **Doctor of Philosophy** in Health and Wellbeing, October 2017.

This thesis is available for Library use on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement.

I certify that all material in this thesis which is not my own work has been identified and that no material has previously been submitted and approved for the award of a degree by this or any other University.

Signature:

Abstract

Background: There is increasing evidence supporting the potential use of physical activity as an intervention for depression. However, effective behavioural interventions which focus on encouraging physical activity in people with depression are needed.

Aim: This thesis reports on the development and pilot evaluation of a web-based intervention based on behavioural activation (BA) and physical activity promotion for people with depression (eMotion). There is also a specific focus on intervention fidelity.

Method: A systematic review was conducted to identify how fidelity is assessed in behavioural interventions promoting physical activity in adults. Findings from the systematic review and the Centre for eHealth and Disease Management (CeHReS) Roadmap informed the development of eMotion. A novel “design fidelity” methodology was devised, which involved using an independent coder to systematically verify the presence or absence of intended and non-intended behaviour change techniques (BCTs). A pilot RCT of eMotion was conducted to provide evidence on the feasibility and acceptability of eMotion, and exploratory data on outcomes. A mixed methods process evaluation of the understanding, feasibility and enactment of the main BCTs used in eMotion, and participant’s perceptions of eMotion was conducted.

Results: The systematic review presents a critical appraisal of the wide range of methods and measures used to assess intervention fidelity. The eMotion intervention consisted of weekly modules designed to re-engage people in routine, pleasurable, necessary or physical activities. Design fidelity of the intervention was excellent with discrepancies between intervention materials and the intended design for 12 out of 221 (AC1 =0.91) and 14 out of 221 (AC1 = 0.88) BCTs relating to BA and physical activity respectively. In the pilot trial, 62 people (≥ 10 on the PHQ-8) were randomised, and the two-month attrition rate was 19% (95% CI: 11 to 30%). Study completers in the eMotion group (n=25) had a significantly larger reduction in depressive symptoms than the waiting list control group (n=25) (Adj Mean Diff -3.6, 95% CI: -6.1 to -1.1). Participants using eMotion also reported significantly higher levels of understanding, ability

Abstract

and enactment of most BCTs compared with controls. Interviews with participants revealed a number of possible mechanisms by which eMotion may have changed behaviour (e.g. increased awareness of the link between mood and activity) and reduced depression (e.g. through distraction).

Conclusion: This thesis has reported on the development and pilot evaluation of a behavioural intervention promoting physical activity for depression while focussing on fidelity. Further insight into a number of methodological and clinical implications for the conduct of future RCTs in this area has also been provided.

Acknowledgements

This work was supported by the Economic and Social Research Council [grant number ES/J50015X/1].

To start, I must thank my supervisors, Colin Greaves, Adrian Taylor, Paul Farrand and Anne Haase. Thank you for giving me this opportunity and for your continued support and encouragement over the last four years. Particularly to you Colin, your help (and patience) throughout the PhD has been enormous, and I look forward to working together more in the future.

Thank you to all the participants who took part in this study, your contribution is greatly appreciated.

I would like to thank all those who proofread chapters or supported me in anyway professionally or personally: Christin Hoffmann, Jane Smith, Jess Bollen, John Campbell, Krystal Warmoth, Lewis Elliott, Lisa Price, Leanne Trick, Mark Tarrant, Ola Borek, Raff Calitri, Richard Pulsford, Samantha Van Beurden, Sarah Dean, Tom Thomson.

Thank you to the 'Febreze Brothers' (Matt, Tom, Darren, Tommy and Ben) for all the laughs along the way and special thanks to Myles for being my best friend and confidant.

To my brothers, David, Simon, Damion and Thomas. Thank you for always being there. I know we don't see each other as frequently as we used to, but I'm proud of you all.

Special thanks go to my mum and dad. Without you, I would not be the man I am today. I consider myself extremely lucky to have had such caring and supportive parents!

To my fiancé, Kayleigh. Thank you for supporting (putting up with) me over the years. You are my rock, and I honestly couldn't imagine life without you. I look forward to being your husband!

I would like to dedicate this thesis to the memory of my uncle Mike.

Table of contents

Abstract	2
Acknowledgements	4
Table of contents	5
List of tables	12
List of figures	13
List of appendices	14
Publications and conference proceedings	15
List of abbreviations	17
Authors declaration	19
Chapter 1 Introduction	21
1.1 Chapter outline	21
1.2 Depression	21
1.2.1 Symptoms of depression	21
1.2.2 Prevalence of depression	22
1.2.3 Causes of depression	22
1.2.4 Consequences of depression	25
1.3 Current provision of care for depression	26
1.3.1 Antidepressants	27
1.3.2 Psychological therapies	29
1.4 Physical activity	32
1.4.1 Physical activity for mental health.....	33
1.4.2 Translation from research to policy and practice	40
1.4.3 Barriers to translation.....	41
1.5 Behavioural interventions promoting physical activity for depression..	44
1.5.1 TRial of Exercise and Depression in the UK (TREAD – UK)	45
1.5.2 Behavioural Activation and Physical Activity (BAcPac)	47

1.5.3	Internet Physical Activity for College Students (IPACS)	48
1.5.4	Internet-delivered therapist-guided physical activity for mild to moderate depression	49
1.5.5	Behavioral activation versus physical activity via the internet.....	50
1.6	Gaps in existing research promoting physical activity for depression .	50
1.6.1	Lack of evidence.....	51
1.6.2	Physical activity measurement.....	51
1.6.3	Intervention fidelity.....	52
1.7	Thesis Aims.....	54
1.8	Thesis structure.....	54
Chapter 2 Assessment of fidelity in individual-level behaviour change interventions promoting physical activity among adults: A Systematic Review.....		56
2.1	Chapter outline.....	56
2.2	The importance of intervention fidelity.....	56
2.3	The NIH Behaviour Change Consortium Framework	57
2.4	Method	59
2.4.1	Searches	59
2.4.2	Study Inclusion/Exclusion Criteria.....	59
2.4.3	Study Selection.....	59
2.4.4	Data extraction and synthesis.....	60
2.5	Results	63
2.5.1	Included studies.....	63
2.5.2	Study Characteristics.....	65
2.5.3	Measurement of Intervention Fidelity.....	66
2.5.4	Intervention Fidelity in Relation to Physical Activity (and Other Study Outcomes)	75
2.5.5	Critical Appraisal of Intervention Fidelity Measurement Practices	75
2.6	Discussion.....	78

2.6.1	Summary of findings	78
2.6.2	Relation to other literature/interpretations	78
2.6.3	Strengths and limitations	81
2.6.4	Implications/Recommendations	82
2.6.5	Conclusion	83
Chapter 3	Development of a web-based intervention based on behavioural activation to promote physical activity for people with depression.....	84
3.1	Chapter Outline	84
3.2	The MRC Framework	84
3.3	Web-based delivery systems	84
3.4	Development and theoretical framework for eMotion	86
3.4.1	Rationale for Behavioural Activation and Physical Activity	86
3.4.2	Self-determination theory and logic model of eMotion	87
3.4.3	Using Intervention mapping to adapt BA	88
3.5	Framework for development of the online platform	90
3.5.1	Using the Centre for eHealth Research and Disease Management (CeHreS) Roadmap	90
3.5.2	Contextual Enquiry: Method	91
3.5.3	Contextual Enquiry: Results	92
3.5.4	Value specification: Method	97
3.5.5	Value specification: Results	97
3.5.6	Design: Method.....	99
3.5.7	Design: Results.....	101
3.6	Intervention description	102
3.6.1	Content	102
3.6.2	Delivery style	108
3.6.3	Delivery mode.....	108
3.7	Discussion.....	109

Chapter 4	Ensuring design fidelity in behavioural interventions: A novel method for assessing design fidelity and its application to the assessment and improvement of the design of a web-based intervention combining behavioural activation and physical activity.....	111
4.1	Chapter Outline	111
4.2	A recap on fidelity.....	111
4.3	How is fidelity currently being assessed?.....	112
4.4	Design Fidelity.....	112
4.5	Current advice on assessing design fidelity	113
4.6	Aims	113
4.7	Method	114
4.7.1	Developing a systematic method for assessing the extent to which BCTs are operationalised.....	114
4.7.2	Test method on the eMotion intervention.....	115
4.8	Results	121
4.8.1	Development of a method to assess design fidelity	121
4.8.2	Agreement of intended techniques	121
4.8.3	Applying the contingency table	124
4.9	Discussion.....	126
4.9.1	Summary of findings.....	126
4.9.2	Relation to other literature	127
4.9.3	Strengths and Limitations	128
4.9.4	Future research	129
4.9.5	Conclusion.....	129
Chapter 5	The eMotion Pilot Trial: Design and Methods.....	131
5.1	Chapter Outline	131
5.2	Chapter aims.....	131
5.3	Trial Design	132
5.4	Participant Flow.....	132

5.4.1	Eligibility criteria	132
5.4.2	Recruitment	133
5.4.3	Sample size	135
5.4.4	Screening	135
5.4.5	Baseline measurement	135
5.4.6	Randomisation and allocation concealment	136
5.4.7	Blinding	136
5.4.8	Two months post-randomisation	136
5.5	Intervention	137
5.5.1	eMotion	137
5.5.2	Support/Facilitation	137
5.6	Control (Waiting list)	138
5.7	Data Collection	138
5.7.2	Primary outcome measures for the main study	140
5.7.3	Secondary outcome measures for the main study	141
5.7.4	Demographic data	143
5.7.5	Data collection for process evaluation	143
5.8	Analysis	143
5.9	Data collection and management	144
5.10	Ethics	144
5.11	Summary of main findings in relation to the thesis	145
Chapter 6	The eMotion Pilot Trial Results	146
6.1	Chapter Outline	146
6.2	Recruitment and attrition rates	146
6.3	Feasibility of accelerometer data collection	148
6.4	Baseline demographic and clinical characteristics	149
6.4.1	Factors influencing trial retention	151
6.5	Intervention fidelity (delivery)	151

6.6	Acceptability	152
6.7	Exploratory analysis	153
6.7.1	Changes in primary outcome	153
6.7.2	Sensitivity analysis.....	156
6.8	Discussion.....	156
6.8.1	Summary of findings.....	156
6.8.2	Relationship to other literature	157
6.8.3	Strengths and Limitations	161
6.8.4	Implications for future research.....	163
6.8.5	Conclusion	164
Chapter 7	Process Evaluation of the eMotion intervention	165
7.1	Chapter Outline	165
7.2	Background.....	165
7.3	Aims	167
7.4	Methods	168
7.4.1	Data Collection	168
7.4.2	Quantitative approach.....	169
7.4.3	Qualitative Approach	172
7.5	Results	175
7.5.1	Quantitative findings	175
7.5.2	Qualitative findings	178
7.6	Discussion.....	193
7.6.1	Summary	193
7.6.2	Relationship to other literature	194
7.6.3	Strengths and limitations	199
7.6.4	Conclusion.....	200
Chapter 8	General Discussion.....	202
8.1	Chapter outline	202

8.2	Recap of overarching thesis aims summary of findings	202
8.3	Summary of findings.....	203
8.3.1	Chapter 2: Assessment of fidelity in individual-level behaviour change interventions promoting physical activity among adults: A Systematic Review.....	205
8.3.2	Chapter 3: Development of a web-based intervention (eMotion) based on behavioural activation to promote physical activity in people with depression.....	206
8.3.3	Chapter 4: Ensuring design fidelity in behavioural interventions: A novel method for assessing design fidelity and its application to the assessment and improvement of the design of eMotion	206
8.3.4	Chapter 5 and 6: The eMotion Pilot Trial: Methods and Results.	207
8.3.5	Chapter 7: Process Evaluation of the eMotion intervention	208
8.4	A discussion of the thesis chapters in relation to the wider literature	209
8.5	Strengths and limitations.....	212
8.5.1	Strengths	212
8.5.2	Limitations	214
8.6	Implications for future research and practice.....	215
8.7	Conclusion	219
	Appendices	220
	References	299

List of tables

Table 1.1: Stepped-care model for treating depression (NICE, 2009).....	27
Table 2.1: Fidelity Assessment and Quality Appraisal Criteria	62
Table 2.2: Summary of Intervention Fidelity Measures	71
Table 3.1: Behavioural objectives and theoretical determinants for eMotion....	89
Table 3.2: Key themes identified from the contextual enquiry and user requirements	99
Table 3.3: Key changes made after user feedback	101
Table 3.4: eMotion intervention structure	104
Table 4.1: Criteria for assessing the extent to which BCTs are operationalised in intervention content.....	115
Table 4.2: Intended BCTs in each eMotion module.....	118
Table 4.3: Contingency table for design fidelity	120
Table 4.4: Amended module content in eMotion after applying contingency table	125
Table 5.1: Schedule of outcome and process measures in the eMotion pilot study.....	139
Table 6.1: Reasons for missing GENEActiv data	148
Table 6.2: Participant demographic and clinical characteristics at baseline ...	150
Table 6.3: Baseline factors influencing trial retention	151
Table 6.4: Module usage by eMotion intervention participants.....	152
Table 6.5: Between-group changes in depression	153
Table 6.6: Between-group changes in secondary outcomes.....	155
Table 7.1: Domains, research questions and methods for evaluating each process.....	169
Table 7.2: Summary of changes in process variables	176
Table 7.3: Participant characteristics (interviews)	178
Table 7.4: Codes, themes and subthemes.....	179
Table 8.1: Description of the eMotion pilot RCT and proposed changes for the main RCT	217

List of figures

Figure 1.1: A framework for understanding physical activity and mental health relationships (taken from Taylor & Faulkner, (2014))	35
Figure 2.1: PRISMA Flow chart of selection process for review (Liberati et al., 2009)	64
Figure 3.1: Logic model of eMotion	88
Figure 3.2: eMotion content (Rationale)	105
Figure 3.3: eMotion content (Identify Activities)	105
Figure 3.4: eMotion content (Rank Activities)	106
Figure 3.5: eMotion Content (Plan Activities)	106
Figure 3.6: eMotion Content (Review Activities)	107
Figure 4.1: Number of modules containing intended techniques for behavioural activation (blue) and physical activity (red)	117
Figure 4.2: Agreement (AC1) of intended techniques for behavioural activation components (blue) and physical activity components (red) before discussion.	123
Figure 4.3: Agreement (AC1) of intended techniques for behavioural activation components (blue) and physical activity components (red) after discussion. .	123
Figure 5.1: Intended participant flow through eMotion	134
Figure 6.1: Flow of participants through the trial	147
Figure 6.2: Participant target and actual recruitment rates	148
Figure 7.1: Process model for eMotion	167
Figure 7.2: Mediation of eMotion process variables	172
Figure 7.3: Results of mediation of eMotion process variables	177
Figure 8.1: Thesis flowchart	204

List of appendices

Appendix 1: Search terms with results	220
Appendix 2: Inclusion/Exclusion Criteria	221
Appendix 3: Data extraction table.....	222
Appendix 4: Search terms with results for intervention development	234
Appendix 5: eMotion Intervention Structure	235
Appendix 6: Design Fidelity Coding Manual	247
Appendix 7 : eMotion Participant Information Sheet.....	251
Appendix 8: eMotion Consent Form	259
Appendix 9: Randomisation list	261
Appendix 10: Questionnaire Items	264
Appendix 11: Suicide Risk Protocol (over the telephone).....	275
Appendix 12: Example histograms for physical activity data	286
Appendix 13: Stata 'Do' file	288
Appendix 14: eMotion Telephone interview Topic Guide	296

Publications and conference proceedings

Publications

Lambert, J. D., Greaves, C. J., Farrand, P. A., Haase, A. M., Cross, R & Taylor, A. H. (2017). Assessment of fidelity in individual level behaviour change interventions promoting physical activity among adults: A Systematic Review. *BMC Public Health*, 17(1), 765.

Publications (under review)

Lambert, J. D., Greaves, C. J., Farrand, P. A., Haase, A. M., & Taylor, A. H. (2017). Development of a web-based intervention (eMotion) based on behavioural activation to promote physical activity in people with depression. *Mental Health & Physical Activity*.

Thompson, T., Lambert, J. D., Greaves, C. J, & Taylor, A. H. (2018). Intervention delivery fidelity assessment of a counselling based intervention for multiple behaviours. *Health Psychology*.

Invited talks

Lambert, J. D., Greaves, C. J., Taylor, A. H. Farrand, P. A & Haase, A. M. The development and pilot evaluation of a web based intervention for physical activity and depression. Oral presentation at the Centre for Clinical and Community Applications of Health Psychology Seminar, University of Southampton Nov 8th 2016.

Lambert, J. D., Greaves, C., Taylor, A., Farrand, P., & Haase, A. A review of fidelity measures used in interventions to increase physical activity. Presented at BPS Seminar 2014, Cardiff University, 9th July, 2014.

Selected conference proceedings

Lambert, J. D., Greaves, C., Taylor, A., Farrand, P., & Haase, A. The development and pilot evaluation of a web based intervention for physical activity and depression. Oral symposia presentation at the British Association of Behavioural and Cognitive Psychotherapies Conference: New innovations in low

intensity CBT: Enhancing engagement and improving outcomes, Manchester University, 26th-28th July 2017.

Lambert, J. D., Elliott, L., Greaves, C., Taylor, A., Farrand, P., & Haase, A. Reducing bias in intervention development: A novel attempt at assessing design fidelity in a behavioural intervention for physical activity and depression. Oral presentation at UKSBM Complex interventions in a complex world: applications of Behavioural Medicine Conference, Hilton, Cardiff, 1st – 2nd Dec 2016.

Lambert, J. D., Greaves, C., Taylor, A., Farrand, P., & Haase, A. A web delivered intervention for depression combining behavioural activation with physical activity promotion: study protocol and intervention development. Poster presentation at 2nd Behaviour Change Conference: Digital Health and Wellbeing, UCL, London, 24th-25th Feb 2016.

Lambert, J. D., Greaves, C., Taylor, A., Farrand, P., & Haase, A. A Web Delivered Intervention for Depression Combining Behavioural Activation with Physical Activity: Study Protocol for a Pilot RCT. Oral presentation at ESRII 3rd Conference, Warsaw, Poland, September 2015.

List of abbreviations

Term/abbreviation	Definition
Affect	A broad psychological construct referring to mental states that involve evaluative feelings (e.g. feeling good or bad, liking or disliking something)
ACTH	Adrenocorticotrophic
BA	Behavioural Activation
BACPAc	Behavioural Activation and Physical Activity
BCT	Behaviour Change Technique
BDI	Beck Depression Inventory
CAR	Cortisol awakening response
CBT	Cognitive behavioural therapy
CHD	Coronary heart disease
CRF	Corticotrophin-releasing factor
FITT	Frequency, intensity, time and type
HAM-D	Hamilton Rating Scale for Depression
HPA	Hypothalamic-Pituitary-Adrenal
IAPT	Improving Access to Psychological Therapies
Light-intensity physical activity	Physical activity with an energetic cost between 1.6 and 2.9 metabolic equivalents of task
LPA	Light intensity physical activity
MAOI	Monoamine oxidase inhibitor
MET	Metabolic Equivalent of task
Metabolic equivalent of task	The ratio of work metabolic rate to the resting metabolic rate. One metabolic equivalent of task is equivalent to a standard resting metabolic rate of 3.5ml O ₂ kg ⁻¹ ·min ⁻¹ (3.5 millilitres of oxygen consumption per kilogram of body weight of the individual per minute engaged in the activity)
MET minutes/hours	The minutes/hours engaged in an activity with consideration to the number of metabolic equivalents of task (METs x duration)

List of abbreviations

Moderate-intensity physical activity	Physical activity with an energetic cost between 3.0 and 5.9 metabolic equivalents of task
MPA	Moderate intensity physical activity
MVPA	Moderate to vigorous intensity physical activity
VPA	Vigorous intensity physical activity
NASSA	Noradrenaline and Specific Serotonergic Antidepressants
NICE	National Institute for Health and Care Excellence
NIH BCC	National Institute of Health Behaviour Change Consortium
NHS	National Health Service
PHQ-8	Patient Health Questionnaire-8 item version
Physical Activity	Any bodily movement produced by skeletal muscles that requires energy expenditure
RCT	Randomised controlled trial
SSRI	Selective Serotonin Reuptake Inhibitors
SMD	Standardised mean difference
SNRI	Serotonin and Noradrenaline Reuptake Inhibitors
TCA	Tricyclic antidepressants
TREAD-UK	Trial of Exercise and Depression
Vigorous-intensity physical activity	Physical activity with an energetic cost above 6.0 metabolic equivalents of task
VPA	Vigorous intensity activity
WHO	World Health Organization

Authors declaration

Throughout the PhD, consistent guidance was provided mainly by the primary supervisor (Prof Colin Greaves) and the secondary supervisors (Prof Adrian Taylor, Prof Paul Farrand and Dr Anne Haase). Two of the four studies contained within this thesis have been written up as manuscripts for publication. One of these has been published and one is currently undergoing revision after its first peer review. As explained below, the substantial contribution to co-authored papers was made by the candidate.

In the thesis, these two chapters have been adapted to better reflect the narrative of the thesis as a whole, and as such are not direct translations of the manuscripts used for publications.

Paper 1: Chapter 2

Lambert, J. D., Greaves, C. J., Farrand, P. A., Haase, A. M., Cross, R & Taylor, A. H. (In Press). Assessment of fidelity in individual level behaviour change interventions promoting physical activity among adults: A Systematic Review. *BMC Public Health*, 17(1), 765.

The first empirical chapter presented in this thesis (Chapter 2) was published in October 2017 in BMC Public Health. The candidate formed the research questions, analysed the data and wrote the manuscript. Colin Greaves, Adrian Taylor, Paul Farrand and Anne Haase advised on the overall research questions, provided assistance with data analysis and edited the manuscript. Rosina Cross is a researcher in process evaluation in Bath and provided double screening for titles/abstract, full texts and data extraction, and made comments on the manuscript.

Paper 2: Chapter 3

Lambert, J. D., Greaves, C. J., Farrand, P. A., Haase, A. M., & Taylor, A. H. (Under Review). Development of a web-based intervention (eMotion) based on behavioural activation to promote physical activity in people with depression. *Mental Health & Physical Activity*.

The second empirical chapter presented in this thesis (Chapter 3) was submitted to Mental Health & Physical Activity in July 2017. It received its

second completed peer review in October 2017. The candidate developed the eMotion intervention based on previous content and work conducted by Farrand et al., 2014 and collaborated with Prof Chris Williams at the University of Glasgow to deliver eMotion via the Living Life to the Full web-based platform. The candidate designed the content, voiced all of the audio and uploaded the content to the platform. Colin Greaves, Adrian Taylor, Paul Farrand and Anne Haase advised on the overall research questions, and edited the manuscript.

.

Chapter 1 Introduction

1.1 Chapter outline

This thesis primarily concerns the development, and evaluation of a web-based behavioural intervention promoting physical activity for depression, with a focus on intervention fidelity. Poor control of intervention fidelity (i.e. the extent to which an intervention was delivered and received as intended), is a crucial methodological factor which can undermine scientific confidence in the interpretation of findings. The thesis aims to (a) understand how “intervention fidelity” is assessed in behavioural interventions to promote physical activity, and (b) describe the development and pilot randomised controlled trial (RCT) of a behavioural intervention intended to promote physical activity and reduce depression.

The specific aim of this chapter is to summarise the literature related to:

- a. The symptoms, causes and consequences of depression
- b. The utility of physical activity as a treatment for depression
- c. The existing problems with trials promoting physical activity for depression

Based on this literature review, key evidence gaps relating to existing behavioural interventions promoting physical activity for depression are identified, followed by a statement of the thesis aims and structure.

1.2 Depression

1.2.1 Symptoms of depression

Depression is a common mental health disorder, mainly characterised by low mood, apathy, reduced enjoyment and energy, leading to inactivity and tiredness for a sustained period (National Institute for Health and Clinical Excellence (NICE, 2009). Other symptoms can include chronic joint pain, limb pain, back pain, gastrointestinal problems, tiredness, sleep disturbances, psychomotor activity changes and appetite changes (Trivedi, 2004). Depression is often considered heterogeneous in nature, and is formally diagnosed when five or more of the following symptoms are present for at least two weeks: low

mood, apathy (anhedonia), significant weight change, change in sleeping patterns or activity, fatigue, guilt, loss of concentration and suicidality (American Psychiatric Association, 2013).

1.2.2 Prevalence of depression

Up to one in five adults in the UK are affected by common mental health problems including depression (Evans, Macrory, & Randall, 2016). Depression has also become the leading cause of disability worldwide, affecting over 300 million people (World Health Organization [WHO], 2012). The prevalence of depression varies depending on a range of sociodemographic characteristics. Epidemiological data suggest an association between increased prevalence of depression and being female, being separated/divorced (Kessler et al., 2003), having a lower educational level (Freeman et al., 2016) and having a lower income (Zimmerman & Katon, 2005).

1.2.3 Causes of depression

The aetiology of depression is currently unclear, and researchers attribute it to a wide range of interacting genetic, biological, psychological and social factors.

1.2.3.1 *Genetics and the environment*

Monozygotic twin studies suggest a 40-50% heritability of depression implying a genetic basis (Sullivan, Neale, & Kendler, 2000). Genome-wide association studies have also indicated that a genetic pre-disposition in conjunction with environmental factors contribute to the development of depression (Malhi, Moore, & McGuffin, 2000). Environmental factors can exert their influence from the prenatal period, and carry on into early childhood and later life. For example, psychological distress experienced by the mother has been shown to affect the neurodevelopment of a foetus and result in long-term changes in subsequent brain development and behaviour across the lifespan (Kinsella & Monk, 2009). Studies also associate early childhood development (e.g. childhood abuse or neglect), and stressful life events (job loss, divorce, bereavement) with the onset of depression (Heim & Binder, 2012). However, the relationship between the environment and genetics is complicated, and genetic factors can also predict the likelihood of exposure to stressful life events (Kendler, Karkowski, & Prescott, 1999).

1.2.3.2 *Neurological basis*

Dysregulation of the Hypothalamic-Pituitary-Adrenal (HPA) axis and hippocampus (caused by chronic stress) provides a biological explanation for the onset of depression. The HPA hypothesis proposes that neurons in the hypothalamus over-secrete corticotrophin-releasing factor (CRF) which stimulates the synthesis and release of adrenocorticotrophic hormones (ACTH). ACTH then results in elevated levels of glucocorticoids (cortisol) which are often seen in people with depression (Nestler et al., 2002). Cortisol has dramatic effects on various brain regions leading to depressive behaviours. For example, a recent study of 109 adult males found that the cortisol awakening response (CAR) correlates with early life stress ($p = 0.007$) and poorer problem-solving ability ($p = 0.046$), factors also associated with depression (Butler, Klaus, Edwards, & Pennington, 2017). Researchers have also linked the neurochemistry of the brain to depression. Neurons are specialised cells located in the brain which transmit information to each other via molecules called neurotransmitters. Three main neurotransmitters are linked to depression; these are dopamine, noradrenaline and serotonin (Nutt, 2008). A deficiency in dopamine predicts psychomotor retardation, diminished motivation and a reduction in pleasure. A lack of serotonin predicts anxiety and compulsive behaviour, and noradrenaline predicts decreased attention, low energy, and reduced cognitive ability (Moret & Briley, 2011). It is, however, important to note that, all the above associations may reflect mechanisms by which depression is manifested rather than represent fundamental causal factors.

1.2.3.3 *Inflammation*

More recent hypotheses suggest that the presence of increased inflammatory cytokines (e.g. c-reactive protein, IL-1, IL-6, IL-10) may contribute to depressive symptoms in a subset of people with depression (Raison & Miller, 2012). Inflammatory cytokines are produced in response to peripheral infection sending signals to the brain (via the HPA axis) resulting in illness behaviours. Illness behaviours are adaptive and are intended to promote healing (e.g. reduced activity) in the presence of possible infection. However, in depressed individuals, an excess of inflammatory cytokines, (as the result of chronic stress) can cause prolonged illness behaviours which can then manifest as depression (Dantzer, O'Connor, Freund, Johnson, & Kelley, 2008). A recent

cross-sectional study (n =14,276) revealed that people with depression had 31% higher levels of c-reactive protein (95% CI, 14% to 50%) than people without depression (Cepeda, Stang, & Makadia, 2016). Furthermore, a recent systematic review of 12 studies found that acute experimental inflammation resulted in negative biases in the processing of social and emotional stimuli (Bollen, Trick, Llewellyn, & Dickens, 2017), factors implicated in the development of depression (Roiser, Elliott, & Sahakian, 2012).

1.2.3.4 *Psychosocial factors*

Depression can also be understood from a psychological perspective including a range of cognitive, social and behavioural factors. Current cognitive neuropsychological models propose that depression is the result of negative information processing biases and deficits in cognitive control (Gotlib, 2010). Negative biases are suggested to be the result of a combination of environmental and genetic factors and over time shift the automatic processing of affective information. This change can then lead to a self-reinforcing cycle of depression due to the development of new negative attentional biases (Roiser et al., 2012). Only attending to adverse stimuli in the environment leads to lower positive affect, which then leads to more depressive symptoms and further reinforces negative schemata (Roiser et al., 2012). Other possible cognitive factors include rumination. A recent review of thirty studies showed that worry or rumination was significantly associated with subsequent depression in people with long-term conditions ($r= 0.23$ to $r = 0.73$) (Trick, Watkins, Windeatt, & Dickens, 2016). Psychosocial factors (e.g. lack of perceived competence or self-esteem) can also influence negative cognitive schemata by leading to negative self-evaluations and rumination (Bandura, 1991). Cognitive behavioural models of depression also emphasise the role of persistent negative thinking in the aetiology of depression and posit that this leads to negative interpretations of the self, the world and the future (i.e. the cognitive triad) (Beck, 1979). Finally, rather than internalising depression (e.g. negative schema or malfunctioning brain chemistry), behavioural models conceptualise depression as a natural consequence of an inability to cope with the daily challenges of day to day life. A behavioural perspective posits that depression is learned and the product of reduced exposure to positive reinforcement and

increased exposure to sources of negative reinforcement (Hopko, Lejuez, Ruggiero, & Eifert, 2003; Jacobson, Martell, & Dimidjian, 2001).

1.2.4 Consequences of depression

Depression has significant implications for individuals, their families and society as a whole, resulting in increased utilisation of health services, reduced quality of life and lower productivity at work (with considerable associated economic costs). In the UK alone, the economic cost of depression to society in 2012 was estimated to be £105 billion (National Health Service [NHS], 2012). Depression is also a major contributor to the global burden of disease and is associated with over one million suicides per year (WHO, 2012).

1.2.4.1 Association between depression and negative health behaviours

In addition to the direct consequences, depression is associated with a range of negative health behaviours, such as smoking, excessive alcohol intake, and physical inactivity. These negative health behaviours can then lead to further disease burden and economic costs. A recent systematic review of 148 studies reported significant associations between mental health and smoking behaviour in over half of the studies reviewed (Fluharty, Taylor, Grabski, & Munafo, 2017). Alcohol problems are also more prevalent in people with depression than in the general population. A systematic review of 35 studies found a median current and lifetime prevalence of 16% (range 5-67%) and 30% (10-60%) of alcohol use problems in people with depression respectively. This prevalence compares to 7% for current and 16-24% for lifetime alcohol problems in the general population (Sullivan, Fiellin, & O'Connor, 2005). Finally, depression has also been associated with leading a less physically active lifestyle (sedentary behaviour). In a systematic review of seven observational and four intervention studies, positive associations were found between sedentary behaviour and depression in adults. However, it is thought that this relationship is bi-directional, as depression could be the result of sedentary behaviour, and vice versa (Teychenne, Ball, & Salmon, 2010).

1.2.4.2 Association between depression and chronic diseases

The prevalence of depression is also higher than for healthy adults in people with many chronic illnesses (e.g. diabetes and coronary heart disease)

(Moussavi et al., 2007; Onyike, Crum, Lee, Lyketsos, & Eaton, 2003). This increased prevalence of depression may also impact on the self-care (and outcomes and subsequent costs) of these diseases. Depression is associated with a range of chronic conditions, including diabetes and coronary heart disease (CHD) (Moussavi et al., 2007; Onyike et al., 2003). A meta-analysis of 42 studies found that the prevalence of depression in people with diabetes was twice that of people without diabetes (OR = 2.0, 95% CI 1.8–2.2) (Anderson, Freedland, Clouse, & Lustman, 2001). In a more recent meta-analysis of ten studies, there were similar findings with a 1.6 higher risk of having depression with diabetes (OR = 1.6, 95% (CI 1.2 - 2.0) (Ali, Stone, Peters, Davies, & Khunti, 2006). The association between depression and CHD is also well established. One review of 11 studies found that the relative risk for the development of CHD in people with depression was 1.64 compared with those without (95% CI: 1.29–2.08) (Rugulies, 2002). Another prospective cohort study of 1017 people with CHD found a 31% higher rate of cardiovascular events in those with depressive symptoms (Whooley, de Jonge, Vittinghoff, & et al., 2008). A more recent review concluded that multiple bi-directional mechanisms might explain this relationship between CHD and depression (e.g. genetic and inflammatory mechanisms) however a key behavioural mechanism could also be lack of physical activity (Dickens, 2015).

1.3 Current provision of care for depression

The National Institute for Health and Care Excellence (NICE, 2009) guidance proposes a four-step model for treating depression (Table 1.1). Table 1.1 shows that treatments for depression range from psychoeducation and support to medication, psychological intervention and even electroconvulsive therapy, depending on the severity.

Table 1.1: Stepped-care model for treating depression (NICE, 2009)

Focus of the intervention	Nature of the intervention
STEP 4: Severe and complex ^a depression; risk to life; severe self-neglect	Medication, high-intensity psychological interventions, electroconvulsive therapy, crisis service, combined treatments, multi-professional and inpatient care
STEP 3: Persistent subthreshold depressive symptoms or mild to moderate depression with inadequate response to initial interventions; moderate and severe depression	Medication, high-intensity psychological interventions, combined treatments, collaborative care ^b and referral for further assessment and interventions
STEP 2: Persistent subthreshold depressive symptoms; mild to moderate depression	Low-intensity psychosocial interventions, psychological interventions, medication and referral for further assessment and interventions
STEP 1: All known and suspected presentations of depression	Assessment, support, psychoeducation, active monitoring and referral for further assessment and interventions

^a Complex depression includes depression that shows an inadequate response to multiple treatments, is complicated by psychotic symptoms, and/or is associated with significant psychiatric comorbidity or psychosocial factors

^b Only for depression where the person also has a chronic physical health problem and associated functional impairment.

1.3.1 Antidepressants

Antidepressants are the most common treatment for depression. In 2015, the NHS dispensed 61 million antidepressant prescription items in England, a rise of 108% since 2005 (NHS Digital, 2016). Antidepressants work by increasing the availability of neurotransmitters responsible for (or at least to be mechanistically involved in) depressive symptoms in the brain (NICE, 2009). There is currently five main type of antidepressant which includes: Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin and Noradrenaline Reuptake

Inhibitors (SNRIs), Noradrenaline and Specific Serotonergic Antidepressants (NASSAs), Tricyclic antidepressants (TCAs) and Monoamine oxidase inhibitors (MAOIs). The increased availability of these neurotransmitters may directly exert an anti-depressive effect, or it may impact on negative cognitive processing, which subsequently relieves depression (Harmer, Goodwin, & Cowen, 2009; Roiser et al., 2012).

1.3.1.1 Effectiveness of antidepressants

Researchers have evaluated the effectiveness of antidepressants in both primary and secondary care settings with varying results. A Cochrane review of 14 RCTs found a relative risk of 1.24 (95% CI 1.11 to 1.38) in favour of TCAs vs placebo and a relative risk of 1.28 (95% CI 1.15 to 1.43) in favour of SSRIs vs placebo on depression recovery (Arroll et al., 2009). However, another meta-analysis of 42 RCTs of antidepressant trials (submitted to the US Food and Drug Administration) found a standardised mean difference (SMD) of 0.32 on improvement in depression in favour of antidepressants over placebo (lower than NICE recommendations) (Kirsch et al., 2008). Furthermore, a study which surveyed 1747 antidepressant users using open-ended questions, found that people used medication as a way of meeting social obligations, a stepping stone to further help and even a lifesaver (Gibson, Cartwright, & Read, 2016).

1.3.1.2 Limitations of antidepressants

Despite their popularity antidepressants may only be effective for specific severities or types of depression. An individual patient-level meta-analysis of six datasets from placebo-controlled RCTs found that the effect of medication for depression varied as a function of baseline depression severity (Fournier et al., 2013). As such, the authors concluded that antidepressants might only be useful for those with more severe depression, and only very mildly effective for mild to moderate depression. Previous RCTs evaluating antidepressants have also been of short duration and funded by pharmaceutical companies which may have biased the findings (Peppone et al., 2015). Kirsch et al., (2008) included all studies submitted to the Food and Drug Administration (including unpublished studies) and found a smaller SMD than previous estimates. Side-effects are also common in antidepressants and include emotional blunting, (Opbroek et al., 2002), sexual dysfunction (Gelenberg et al., 2000) and

medication dependence (Leydon, Rodgers, & Kendrick, 2007). A recent systematic review and meta-analysis of 70 RCTs also found that there was a twofold increase in suicidality and aggression in children and adolescents taking antidepressants (Sharma, Guski, Freund, & Gøtzsche, 2016). Furthermore, users of antidepressants (n=1747) have reported that they are ineffective, undermine emotional authenticity, mask real problems, reduce the sense of control and have unbearable side effects (Gibson et al., 2016).

1.3.2 Psychological therapies

Psychological therapies such as cognitive behavioural therapy (CBT) are designed to help people with depression by reconfiguring /modifying their thoughts, feelings or behaviours (Butler, Chapman, Forman, & Beck, 2006). They offer an effective alternative to people who do not want to take antidepressant medication. A meta-analysis showed that three times as many patients had a preference for psychological therapies over antidepressant medication (McHugh & Whitton, 2013). Furthermore, psychological therapies may offer a useful adjunct to people with depression who are not responding to medication. An RCT of 469 adult patients with treatment-resistant depression (on antidepressants for over six weeks and a BDI >13) compared CBT with usual care, to usual care alone. For 46% of people in the CBT group, depressive symptoms had reduced by 50% compared to only 22% of people in the usual care group (OR 3.26, 95% CI 2.10-5.06) (Wiles et al., 2014). The Improving Access to Psychological Therapies (IAPT) NHS programme, delivers treatment to people with common mental health disorders (depression and anxiety) and received a total 1,399,088 referrals between 2015 and 2016 (NHS Digital, 2016b) making it the largest provider of psychological therapies in the UK. Although many psychological therapies are available, CBT accounted for 32.6% of all referrals (of those who completed treatment) between 2015 and 2016, making it the most prescribed psychological therapy within IAPT.

1.3.2.1 Cognitive behavioural therapy

CBT helps people develop coping strategies to target specific elements of the negative spiral of cognitions, behaviours and emotions that facilitate depression (NICE, 2009). CBT aims to change negative cognitions by getting people to mentally (e.g. using self-talk and planning /rehearsal of thinking

strategies for coping in situations where negative thoughts tend to arise), and objectively (e.g. by conducting behavioural experiments in real life) challenge their automatic thoughts (Roiser et al., 2012). CBT has also proved effective. A recent meta-analysis (N = 40) revealed negligible differences between CBT and antidepressant medication ($g = 0.02$ (95% CI: 20.07 to 0.10) (Cuijpers et al., 2013; Cuijpers, van Straten, Andersson, & van Oppen, 2008). Another meta-analysis found superior effects in favour of CBT when compared to control groups (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012). Another meta-analysis of 28 RCTs found that acute-phase treatment with psychotherapy also protects against the return of depressive symptoms as much as continued treatment with medication, possibly helping people who are dependent on antidepressant medication (Imel, Malterer, McKay, & Wampold, 2008). CBT has also been shown to be more cost-effective in the short term when compared with medication (Knekt, Lindfors, Sares-Jäske, & Laaksonen, 2012).

1.3.2.2 *Limitations of CBT*

Despite the patient preference for CBT alongside encouraging data on effectiveness, CBT requires a high level of training, can be costly to deliver when compared to usual care (Schulberg, Raue, & Rollman, 2002) and can be difficult for patients to access (NHS Digital, 2016). In England, the IAPT programme has gone some way to relieving this pressure (with over 900,000 patients accessing IAPT between 2015 and 2016). However, a survey of people who have either used or tried to access psychological therapies on the NHS in England within the last two years found that one in ten people have been waiting over a year to receive treatment. Furthermore, 40% of patients who receive psychological therapies have had to specifically request them rather than medication (MIND, 2013). Trials of CBT also have limitations. One meta-analysis (n=115) found that higher quality RCTs (e.g. had a larger sample size or were blinded) reported lower effect sizes in favour of CBT ($d=0.22$) than lower quality RCTs ($d=0.74$, $p<0.001$) (Cuijpers, van Straten, Bohlmeijer, Hollon, & Andersson, 2010). Another meta-analysis found negligible differences in effect sizes for trials which compared psychotherapies to 'well-designed placebos' (e.g. same number of sessions/time/therapist) (Baskin, Tierney, Minami, & Wampold, 2003). Dropout is also a problem with CBT, a recent meta-analysis of non-randomised studies of adult outpatients with unipolar

depression, found that a quarter did not complete psychotherapy with 25% dropping out over a six-month period (Hans & Hiller, 2013). A qualitative study investigating why participants dropped out of CBT found that factors such as time and location were key barriers. The 'homework' aspect (i.e. the requirement for patients to use worksheets outside of sessions) was also problematic as it required participants to think about the causes of their depression and to reflect on situations which could not be changed, causing distress (Barnes et al., 2013).

1.3.2.3 Behavioural Activation

Behavioural activation (BA) is an evidence-based psychotherapeutic treatment and is recommended at step 2 as part of the NICE guidelines for treating depression. The theoretical premise of BA proposes that people with depression reduce the frequency and type of their usual behaviours that they may have previously enjoyed (e.g. seeing friends, going out). When a person is under stress/not coping with life's challenges, avoiding such activities provides a sense of immediate relief in the short term. The tendency towards avoiding activity is therefore negatively reinforced, resulting in the increased likelihood of future avoidant behaviour. However, in the longer term, not engaging in activities reduces feelings of well-being/self-worth, resulting in less positive reinforcement leading to a further reduction in activities. Depression can, therefore, be conceptualised as the product of a cycle of reduced positive reinforcement and increased negative reinforcement (Richards 2010). While different theoretical accounts of BA exist, (Hopko et al., 2003; Lejuez, Hopko, & Hopko, 2001) the version of BA delivered by IAPT aims to reduce depressive symptoms by decreasing behavioural avoidance (i.e. negative reinforcement) and increasing rewarding activities (i.e. positive reinforcement).

The recent evidence for the effectiveness of BA for adult depression has shown promise. A recent meta-analysis of 26 RCTs (n=1524) conducted in adults with depression, found BA to be superior to control (i.e. usual care, waitlist, placebo) (SMD -0.74, CI -0.91 to -0.56, k = 25, N = 1088) and medication (SMD -0.42, CI - 0.83 to -0.00, k = 4, N = 283) for reducing depression (Ekers et al., 2014). BA has also been found to be more cost-effective than CBT as it is easier and quicker to train mental health workers to

deliver. For example, a recent randomised non-inferiority trial found that BA delivered by junior mental health workers was no less effective than CBT for treating depression (Rhodes et al., 2014; Richards et al., 2016). As such, BA could potentially be more scalable and accessible than other psychological therapies and less intensive (e.g. time-consuming, complicated) for services and people with depression to implement. BA has also been used in complex interventions which target depression in people undergoing cardiac rehabilitation (Winder et al., 2017). Despite the evidence of the benefits of BA over other more popular treatments, IAPT only delivered it to 8,746 people (compared to 152,452 for CBT) between 2015 and 2016 (NHS Digital, 2016). A recent study that attempted to deliver BA through the IAPT service, also found that providers were resistant to implementing BA alone and may have had biases towards other treatments (e.g. CBT) (Pentecost et al., 2015). Some patients also appeared to find BA too simplistic (especially when compared to CBT) referring to it as simplistic, superficial and restrictive (Finning et al., 2017; Ly et al., 2015).

1.4 Physical activity

Physical activity is defined as any bodily movement produced by skeletal muscles that result in energy expenditure (Caspersen, Powell, & Christenson, 1985) The Chief Medical Officer (CMO) (Department of Health, 2011b) recommends that adults should aim to be active daily, accruing at least 150 minutes of moderate or vigorous physical activity (MVPA) in bouts of 10 minutes or more each week. However, globally in 2010, 23% of adults aged were insufficiently active (men 20% and women 27%) based on self-report measures of physical activity (WHO, 2017). In the UK levels of MVPA are also low, with only 39% of men and 29% of women achieving this target based on self-report measures (Department of Health, 2011b). Physical activity helps to prevent many physical health problems associated with depression such as cardiovascular disease, cancer and diabetes (Gibala, Little, Macdonald, & Hawley, 2012). Lack of physical activity has been implicated as a causal factor in many chronic diseases (Booth, Roberts, & Laye, 2012). Engaging in physical activity has also been shown to be effective in the management and prevention of many chronic conditions also associated with depression, such as diabetes (Helmrich, Ragland, Leung, & Paffenbarger, 1991), CHD, and obesity

(Varghese et al., 2016). Physical activity may also potentially help people who are trying to quit smoking (a behaviour associated with depression). In a systematic review of 20 trials (n = 5870), two trials offered evidence for exercise as an aid to smoking cessation in the long term. However, the authors concluded that further trials with larger sample sizes and sufficiently intense interventions were needed (Ussher, Taylor, & Faulkner, 2014).

1.4.1 Physical activity for mental health

Contemporary treatments seem to have small to moderate effects on depression (Arroll et al., 2009; Cuijpers et al., 2013). However, a 15-year prospective study showed that 85% of patients who had successfully recovered from depression relapsed at least once, and 58% of those who remained well for at least five years after treatment relapsed at least once (Mueller et al., 1999). The level of physical activity necessary to provide life's essential resources (e.g. food, water, shelter), has diminished over the last century due to industrial and technological advances. This lack of opportunity for 'effort based rewards' has been argued as a key contributor to the prevalence of depression in today's society (Lambert, 2006). As such, in addition to its well-established physical health benefits (Gibala et al., 2012), increasing physical activity may also have benefits for depression having the dual benefit of targeting both mental and physical health outcomes (Faulkner & Taylor, 2012). NICE guidance currently recommends supervised exercise programmes, three times a week (45 minutes to one hour) over 10 to 14 weeks at step two (NICE, 2009). Physical activity is often preferred by people with mental health problems (including depression), with many believing in the benefits of exercise for mental health (e.g. working through biochemical pathways or providing a source of distraction) (Searle et al., 2011; Ussher, Stanbury, Cheeseman, & Faulkner, 2007). People with depression have also strongly agreed that they would be more active if advised to do so by a doctor, but reported low self-efficacy for doing so (Ussher et al., 2007). A range of other benefits that do not come with traditional approaches (e.g. anti-depressants and psychological therapy) are also possible with physical activity (e.g. fewer side effects and potentially low cost).

Physical activity may also help to reduce depressive relapse (often associated with anti-depressants and psychological therapies) by building self-regulatory skills. An RCT of structured exercise interventions, randomised

adults with depression ($n = 156$) into three groups; exercise (3 supervised sessions per week consisting of 30 minutes of continuous walking/jogging at 70% to 85% of heart rate reserve), sertraline (an anti-depressant), or a combination of sertraline and exercise (Blumenthal et al., 1999). All groups exhibited statistically and clinically significant reductions in depressive symptoms on the Hamilton Rating Scale for Depression and the Beck Depression Inventory (BDI) (Blumenthal et al., 1999). Six months after study completion (ten months after randomisation), all groups were followed up, revealing significantly lower relapse rates ($p=.01$) than the medication group (Babyak et al., 2000). Exercise behaviour was also associated with reduced probability of meeting diagnostic criteria for depression (OR 0.49, $p = .0009$) suggesting that exercise may provide skills or other benefits that medication does not. However, the study by Babyak et al., (2000) could not provide causal evidence that physical activity was responsible for preventing relapse (i.e. people may have continued to be active after treatment due to reduced depression). Furthermore, the study sample may have been self-selecting as they were recruited from the community.

To summarise, physical activity may be a preferred treatment option for people with depression (Searle et al., 2011; Ussher, Stanbury, Cheeseman, & Faulkner, 2007), may prevent depressive relapse (Babyak et al., 2000), and is less prone to side effects than medication. Furthermore, physical activity provides a host of other physical health benefits that do not come with medication and psychological therapies (World Health Organization [WHO], 2017). However, to fully understand the utility of physical activity as a treatment for depression, researchers need to address the following fundamental questions: a) How effective is physical activity for reducing depression? b) How does physical activity reduce depression? c) What is the optimal dose of physical activity to reduce depression? d) How effective is behavioural support for people with depression? e) What are the psychosocial mediators of behavioural support? f) What is the optimal dose of behavioural support? These questions can be most easily understood using the framework for understanding physical and mental health (Fig 1.1) (Taylor & Faulkner, 2014).

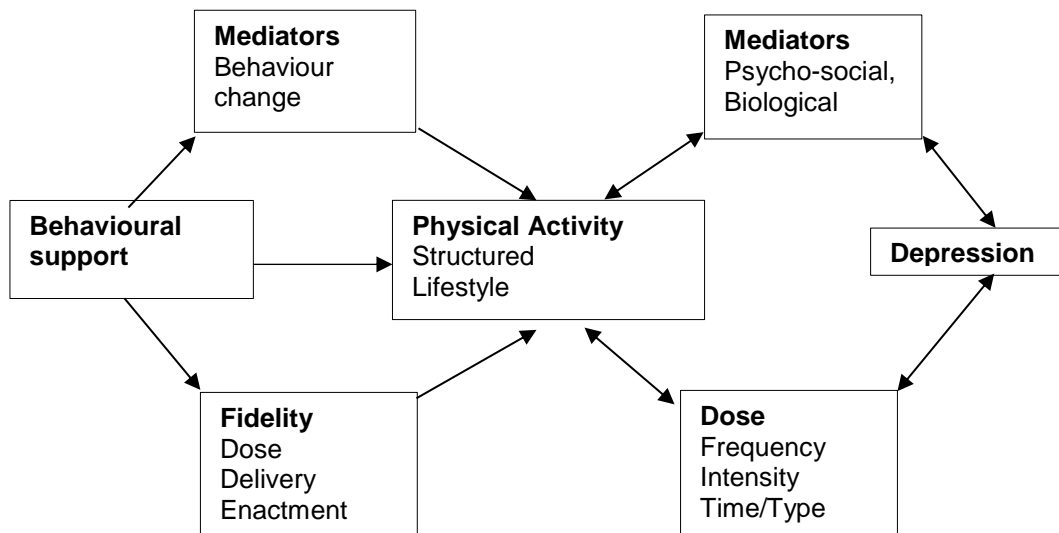


Figure 1.1: A framework for understanding physical activity and mental health relationships (taken from Taylor & Faulkner, (2014))

1.4.1.1 How effective is physical activity for reducing depression?

The first research question in Figure 1.1 relates to the direct effects of physical activity (and sedentary behaviour) on depression. The effectiveness of physical activity for the treatment of adult depression is well studied. A recent Cochrane systematic review and meta-analysis of 39 RCTs, found physical activity to be more effective than control conditions for reducing depressive symptoms (SMD -0.62). Furthermore, physical activity was as effective as pharmacotherapy (SMD -0.11, 95% CI -0.34 to 0.12) and psychological therapies (SMD -0.03, 95% CI -0.32 to 0.26) (Cooney et al., 2013). A meta-analysis of 92 RCTs ($n = 4310$) also found a medium effect (SMD -0.50, 95% CI -0.93 to -0.06) of physical activity on depression compared to control (Rebar et al., 2015). However, Cooney et al., (2013) reported that many trials had a number of methodological limitations (e.g. using self-report scales as a method for post-intervention analysis) which had the potential to bias findings. The SMD reduced considerably when only higher quality studies were analysed.

1.4.1.2 How does physical activity reduce depression?

The next research question (Figure 1.1) concerns the mediators by which physical activity exerts its impacts on the main symptoms of depression. Several physiological and psychological mechanisms have been proposed for the relationship between physical activity and depression (Craft & Perna, 2004; Fox, 1999). However, physical activity can be considered a complex

intervention (Faulkner & Taylor, 2009) and depression is a complex disorder (Malhi et al., 2000). As such, it is likely that the relationship is mediated by a variety of interacting psychological and physiological mechanisms.

Thermogenic Hypothesis

A rise in core body temperature following exercise may be a potential mechanism for reducing depression (thermogenic hypothesis). Increases in temperature of specific brain regions (e.g. brain stem), may lead to an overall feeling of relaxation (Craft & Perna, 2004). However, there is limited research conducted on the thermogenic hypothesis as a mediator for the effects of physical activity for depression (Craft & Perna, 2004).

Monoamine hypothesis

Researchers implicate physical activity in the increase in the availability of dopamine, noradrenaline and serotonin (Meeusen & De Meirleir, 1995), the three primary neurotransmitters linked to the pathophysiology of depression (Nutt, 2008). However, this increase in neurotransmitters has only been found in urine and plasma samples, which may not reflect their presence in the brain. Animal studies have also suggested that physical activity increases serotonin and norepinephrine in the brain. However, many of these animal studies have only been able to measure depression through the use of behavioural proxies (e.g. forced swim test) (Brosse, Sheets, Lett, & Blumenthal, 2002). The research needed to move this hypothesis forward would require invasive tests (e.g. spinal taps) making it hard to conduct in humans (Craft & Perna, 2004).

Endorphin hypothesis

The endorphin hypothesis proposes that physical activity exerts its positive effects on mood through the release of beta-endorphins (Craft & Perna, 2004). Endorphins are peptides that have similar properties to opiates such as heroin or morphine (Dishman & O'Connor, 2009). Studies have shown that endorphins increase after exercise. However, the hypothesis that endorphins are responsible for changes in depression after physical activity remains largely untested (Dishman & O'Connor, 2009). Despite this lack of evidence, endorphins are commonly cited by patients (Searle et al., 2011) and

practitioners (Searle et al., 2012), as a key mechanism by which physical activity reduces depression.

Inflammation

Inflammation has also been recently implicated as a modifiable mechanism that may explain part of the relationship between physical activity and depression. A recent small exploratory RCT with 101 patients with depression compared enhanced CBT emphasising exercise (CBT-E) to CBT without this emphasis (CBT-C), or a passive waiting list control (WL). As compared with WL, CBT-E and CBT-C were both associated with significantly lower depressive symptoms 8 and 16 weeks follow-up but were not significantly different to each other. However, an increase in the anti-inflammatory cytokine IL-10 was observed for CBT-E participants at 8 and 16 weeks follow-up, when compared to CBT-C and WL ($P=0.004-0.018$) (Euteneuer et al., 2017). As previously stated, elevated inflammatory cytokines (including IL-10) have been observed in people with depression (Raison & Miller, 2012). Although an interesting step forward, this study was only exploratory, with a small sample size, meaning that further research is needed to confirm the inflammatory mechanism between physical activity and depression.

Distraction

As previously mentioned, rumination or worry is a significant predictor of subsequent depression (Trick et al., 2016). The distraction hypothesis proposes that physical activity may help to distract people from worrying thoughts and rumination hence ameliorating their depressive symptoms (Craft & Perna, 2004). This hypothesis has received limited attention. However, one study examined whether physical activity moderated the response between laboratory-induced rumination and cortisol reactivity and recovery in 46 post-menopausal women. The authors found that sedentary participants who reported higher levels of rumination in response to the stressor had faster and prolonged reactivity (rapid initial increase and later peak of cortisol) and delayed recovery (delayed return to baseline cortisol). In more active participants, cortisol trajectory was not a function of rumination, regardless of the level of stressor-induced rumination (Puterman et al., 2012). Dysregulation of the HPA axis is also implicated in the pathophysiology of depression (evidenced by the

CAR) (Nestler et al., 2002), so these findings support the notion that physical activity may target depression through a reduction in rumination and HPA reactivity. However, this study had a small sample and was only cross-sectional. Another more recent, experimental pre-post study exposed 52 participants to 30 minutes of meditation and 30 minutes of moderate intensity aerobic exercise two times a week over eight weeks. The researchers found that individuals with depression reported significantly less depressive symptoms and ruminative thoughts and increased cognitive control processes (Alderman, Olson, Brush, & Shors, 2016).

Self-efficacy

People with depression often feel a lack of self-efficacy about their ability to create positive change in their lives and feel unable to cope with many of life's challenges. This lack of control and sense of competence can result in negative self-evaluations and cognitive schemata, also linked to depression (Bandura, 1991). Self-efficacy is closely related to both competence (a person's perceived ability to succeed in specific situations or adapt to new challenges in changing contexts) and autonomy (a person's perceived control over a situation) and increasing it can provide someone with an increased sense of control and ability to cope with life (Deci & Ryan, 1985; Ryan & Deci, 2000). Physical activity may provide people with a meaningful mastery experience which builds their self-efficacy and reduces their depression (Craft & Perna, 2004). A recent systematic review of ten physical activity interventions in youths found an increase in self-efficacy as a result of physical activity (Cataldo, John, Chandran, Pati, & Shroyer, 2013). Furthermore, a longitudinal study of 39 adults also found that self-efficacy was one of the most influential mechanisms for mediating changes in depression after increasing physical activity (White, Kendrick, & Yardley, 2009). Researchers propose that physical activity can, therefore, improve perceptions of competence and autonomy by increasing a person's confidence in their body and its ability. A person's engagement with physical activity may, therefore, provide a source of positive reinforcement (due to improved self-efficacy) and work through similar mechanisms to those proposed for BA (Carlbring et al., 2013; Nyström et al., 2017).

Social support

Social support has also been considered a key mechanism by which physical activity helps depression (Craft & Perna, 2004). One study of 583 community-dwelling adults found that exercise and social support were associated with lower levels of depression. However in infrequent exercisers lower social support predicted higher depression as opposed to frequent exercisers, where social support did not predict depression. As such, although physical activity may work through increasing social support, it may also be protective against the effect that social support has on depression (McHugh & Lawlor, 2012).

1.4.1.3 What is the optimal dose of physical activity?

The final research question concerns the optimal dose of physical activity needed to reduce depression (Figure 1.1). A recent systematic review included 12 RCTs looking at the most effective frequency, intensity, time and type (FITT) of physical activity for treating depression (Nyström, Neely, & Hassmén, 2015). Ten of the included studies reported a significant reduction in depressive symptoms. Concerning the type of activity, ten studies used aerobic activity, one study used anaerobic activity (i.e. any activity generating lactic acid) and one study used both aerobic and anaerobic activity. Walking or jogging was used in eight studies. All the interventions had some element of supervision (e.g. from a fitness instructor), and three were delivered in a group setting. The most common frequency of physical activity was three sessions per week (reported in nine studies), and the most common intensity (used in eight of the studies) was a performance at a heart rate intensity 65-85%. The length of the intervention in all of the studies ranged from 30 to 90 minutes per session and interventions lasted between ten days to 20 weeks. The review found no differences for the type of aerobic activity (e.g. cycling or jogging) or level of supervision (i.e. partially vs fully supervised). However, there was a lack of studies looking at aerobic activity. Finally, no effects were found for the intensity (an approximation of the percentage of maximum heart rate) or duration (i.e. minutes per session) of physical activity on depressed mood, but a positive association was found for frequency (i.e. bouts per week) of physical activity. Overall this review suggested that only the frequency of physical activity may influence depressive symptoms (Nyström et al., 2015). However, it is important

to note that there were only 12 studies included in this review, making the findings very tentative. Furthermore, seven of the control groups included in the studies also performed physical activity (e.g. stretching) and five received medication or psychotherapy. Using active controls could have further clouded the issue of dose, and potentially reduced the effects of physical activity on depression (Ekkekakis, 2015). The authors argued that this lack of dose-response effect may support the hypothesis that energy expenditure is not as crucial for reducing depression, but rather other mechanisms (e.g. self-efficacy). If self-efficacy is a key mediating factor, then the physiological exertion of physical activity may be less important than the meaning a person attributes to it (Nyström et al., 2015). The target population may also influence the type of physical activity which is most effective for depression. For example, a meta-analysis (n =16) on the effects of resistance based exercise programmes (as opposed to aerobic based programmes) in the elderly found a significant reduction in depressive symptoms (SMD = -0.36, 95% CI: -0.64 to 0.08) (Park, Han, & Kang, 2014). The authors concluded that resistance based exercise programmes for the elderly may be more appropriate due to the difficulty older adults can experience in doing aerobic exercise.

1.4.2 Translation from research to policy and practice

There is good evidence to support the proposal that physical activity could be a viable treatment for depression being just as effective as contemporary treatments but with fewer side effects. However, more needs to be done to improve the rigour of existing trials. The evidence also implicates a range of interacting physiological and psychological mechanisms which may explain how physical activity reduces depression. However, due to the limitations of current techniques, much of the physiological data is based on animal studies. Finally, the optimal dose by which physical activity might affect depression symptoms is far from clear. Much of the evidence is focussed on the use of structured exercise programmes, rather than physical activity promotion. Although, understanding dose and mechanisms are pertinent questions for further research, from a pragmatic perspective the research on effectiveness is enough to warrant further investigation into the feasibility of the promotion of physical activity as a treatment for depression in clinical and community settings.

However, a major challenge remains regarding the translation of the research evidence into policy and practice. At a policy level, institutional health bodies still appear to reflect a dualist mental health/physical health philosophy (e.g. tackling physical and mental health as separate entities) (Faulkner & Taylor, 2012). The most recent NICE (NICE, 2009) guidelines appear to reflect this dualism. NICE only endorse physical activity at step 2 and in a structured group-based manner (NICE, 2009). Furthermore, IAPT only promoted to physical activity to 374 people exhibiting mild to moderate depression between 2015 and 2016 (compared to 152,452 for CBT). Qualitative evidence also indicates that despite personally endorsing physical activity for mood, many GPs only prescribe physical activity on an anecdotal basis (i.e. based on their personal endorsement rather than from an evidence base) (Searle et al., 2012). In addition to translational barriers (between research and practice), there are also issues around knowledge transfer between diverse research disciplines such as exercise and clinical psychology. A study by Faulkner & Biddle (2001) interviewed course directors of doctoral training programmes in clinical psychology in England to explore their perceptions of exercise for treating depression. They found that course directors had favourable attitudes towards exercise as a positive lifestyle activity, but not as an adjunctive or alternative treatment for mental health problems.

1.4.3 Barriers to translation

There are many possible reasons for the gap in the translation of evidence into practice. These reasons include a lack of practitioner awareness and perceived reliability of the evidence base, and challenges around engaging and supporting mental health services users to become more physically active.

1.4.3.1 Awareness and reliability of the evidence base

Many GPs' and other practitioners personally endorse using physical activity to treat depression. However, a qualitative study revealed that many GPs are unaware of the evidence base (Searle et al., 2012). This lack of awareness could be due to the paucity of research when compared to other more popular treatments such as CBT and medication. Lack of confidence in the evidence base may be another barrier. In the study by Faulkner and Biddle, (2001), course directors of doctoral training programmes in clinical psychology

perceived a lack of confidence relating to the evidence-based on exercise and depression which is possibly driven by the lack of definitive conclusions provided by systematic reviews on the effects of physical activity for depression.

Cooney et al., (2013) concluded that despite an overall moderate effect size in favour of physical activity for depression, the effect sizes were smaller when only high-quality trials are considered (SMD -0.3, 95% CI -0.6 to -0.00). However, a recent article suggested that recent reviews of physical activity significantly underestimate the effect size of physical activity for depression due to methodical limitations of the reviews themselves (e.g. inclusion of active control groups, the inclusion of non-depressed participants) (Ekkekakis, 2015). A recent study reanalysed the data provided by Cooney et al., (2013) while addressing the specific methodological limitations (i.e. by excluding studies with no/active/exercise control groups, including postnatal depression, and adopting a broader definition of physical activity (e.g. yoga, unstructured physical activity)) (Ekkekakis, 2015). The result was a change in the effect size from moderate (0.6, 95% CI: 0.8 to 0.4) to large (0.9, 95% CI: 1.1 to 0.7). Other studies have added weight to this finding. A recent meta-analysis of 25 RCTs compared exercise with controls whilst adjusting for publication bias and found a large significant effect on depression (SMD = 1.1 (95% CI: 0.8 to 1.4)) (Schuch et al., 2016). Another recent systematic review and meta-analysis explored control group responses in 41 RCTs comparing exercise with antidepressants and found the control group response was nearly double that of antidepressant RCTs (SMD -0.9, 95 % CI: -1.1 to -0.7), reducing the apparent effect size of exercise as a treatment, compared with antidepressants. As such, in traditional trials of exercise and depression, physical activity needs to overcome a large control group effect to demonstrate effectiveness (Stubbs, Vancampfort, Rosenbaum, Ward, Richards, Ussher, et al., 2016).

A recent well publicised multi-centre pragmatic RCT (TREAD-UK) may have also compounded practitioner uncertainty around physical activity as a treatment for depression (Chalder et al., 2012). TREAD-UK assessed the effect of promoting physical activity as an adjunct to usual care, compared with usual care alone on depression but found no evidence of a reduction in depression for participants in the intervention group. As such, the authors concluded that “advice and encouragement to increase physical activity is not an effective

strategy for reducing symptoms of depression” (Chalder et al., 2012). However, TREAD-UK was prone to a number of conceptual and methodological limitations (discussed in section 1.5.1).

The overall lack of research combined with the methodological issues surrounding the evidence base explains why practitioners may lack confidence in routinely prescribing physical activity as a treatment for depression. More research needs to be done to carefully address the methodological limitations of existing trials (e.g. by using inactive/placebo control groups) and more clearly disseminate the findings. Given the varying types of physical activity and the heterogeneous nature of depression, building a precise model of the relationship between physical activity and depression is challenging and requires a more nuanced approach.

1.4.3.2 Challenges around engaging and supporting people with depression to be physically active

Taking medication or receiving psychological therapy (although still prone to adherence issues) may be perceived as less difficult for people with depression. Physical activity requires exertion, and despite the wealth of research investigating the effects of physical activity on depression (Cooney et al., 2013; Nyström et al., 2015; Rebar et al., 2015) there is a paucity of research addressing *how to* increase the physical activity of people with depression. Most of the existing studies investigating physical activity for depression are based on structured exercise (e.g. gym based). Very few studies attempt to change physical activity, and as such do not report physical activity levels of their participants (Cooney et al., 2013; Rebar et al., 2015). Therefore, it is plausible that a selection bias could be present (i.e. that trials are attracting people that are already very active, or who are willing /motivated to enrol in a substantial course of gym-based physical activity). This idea is supported by a study which showed that people with mental health problems had a preference for exercising at home rather than in gym settings (Ussher et al., 2007). Furthermore, behavioural avoidance is a key symptom associated with depression (Ottenbreit & Dobson, 2004) and several RCTs evaluating the effects of physical activity for depression have shown substantial dropout alongside poor exercise adherence rates (Cooney et al., 2013). Conversely, a

recent review of 40 RCTs found a dropout rate was 18.1% (95% CI: 15.0–21.8%), indicating that even structured exercise may be feasible for people with depression (Stubbs, Vancampfort, Rosenbaum, Ward, Richards, Soundy, et al., 2016). However, this low dropout rate could be indicative of the fact that motivated and active people were recruited to these studies in the first place.

The need to ensure that interventions reach beyond those who are attracted or motivated to take part in research and/or exercise has been previously highlighted (Glasgow, 2013). Bridging the translational gap between the evidence on the benefits of physical activity for depression and real-world activity promotion requires a focus on behavioural support for the whole population (especially those with depression). The challenge now is to translate the evidence for physical activity as a treatment for depression into practical interventions that are acceptable and feasible for patients, practitioners and policymakers. Individual level (one to one and group-based) behavioural interventions are a key strategy for increasing physical activity in the general population and may help to close the translational gap by exploring whether physical activity can be cost-effectively used to generate improvements in people with depression, especially in those who are relatively inactive. However, there is considerable variation in their reported effectiveness (Foster, Hillsdon, Thorogood, Kaur & Wedatilake, 2005; Foster, Richards, Thorogood & Hillsdon, 2013; Greaves et al., 2011; Orrow, Kinmonth, Sanderson, & Sutton, 2012; Richards, Hillsdon, Thorogood & Foster, 2013). There is also a lack of understanding about the effectiveness of physical activity promotion strategies in populations with depression and the subsequent effect on depression outcomes. Therefore the challenge concerns getting people with depression to engage in and maintain physical activity. Researchers need to develop pragmatic interventions which are easily implementable on already overstretched health services and avoid the issue of self-selection and possible ceiling effects.

1.5 Behavioural interventions promoting physical activity for depression

Individually delivered behaviour change interventions using theory and evidence are a key strategy for increasing physical activity, but have shown mixed results in other populations (e.g. weight loss) (Foster et al., 2005;

Greaves et al., 2011; Orrow et al., 2012). Various theories of behaviour change exist such as the trans-theoretical model (TTM) (Prochaska & Velicer, 1997) or the theory of planned behaviour (TPB) (Ajzen, 1991; Ajzen, 2017). However, most theories of behaviour change assume that people are rational decision makers. For example, the TPB proposes that the culmination of attitudes, subjective norms and perceived behavioural control will predict intention which will subsequently predict behaviour (Ajzen, 1991; Ajzen, 2017). Although partially predictive of physical activity, there is still a large gap between what people 'intend' to do compared to what people *actually* do (Sheeran, 2002). Self-determination theory (SDT) is a theory of motivation which proposes that people are more likely to engage in behaviours they enjoy or find intrinsically motivating (Deci & Ryan, 2000). Intrinsic motivation comes when a person feels a sense of autonomy, competence and relatedness. Fostering these needs in people with depression could, therefore, be a core way of increasing their physical activity (not often done in previous studies) which may then alleviate their depression. For example, in earlier studies evaluating physical activity for depression (e.g. Cooney et al., (2013), a person may not feel competent about engaging in a 30-minute bout of MVPA. However, behavioural support could aim to foster a person's competence and autonomy by suggesting a gradual increase in MVPA (e.g. why not start with a 10-minute walk?) making them more likely to adopt and sustain in their everyday lives. The challenge now is to build an evidence base that shows not only that it is possible to increase the uptake of physical activity in people with depression, but that increased activity will also lead to therapeutic effects. However, at present, there are few trials which have tried to evaluate the promotion of physical activity as a treatment for depression.

1.5.1 Trial of Exercise and Depression in the UK (TREAD – UK)

As previously mentioned (in section 1.4.3.1), TREAD-UK was large multi-centre pragmatic RCT which assessed the effect of physical activity promotion as an adjunct to usual care, compared with usual care alone (Chalder et al., 2012). TREAD-UK recruited 361 adults with a diagnosis of depression (as assessed by the clinical interview schedule) and a score of at least 14 on the revised Beck Depression Inventory (BDI-II). Those randomised to the intervention group were offered usual care in addition to an intervention based

on Self-Determination Theory (SDT) (Ryan & Deci, 2000) delivered by a physical activity facilitator (PAF) over eight months (face-to-face and by phone). At baseline, 26% of participants reported achieving >1000 metabolic equivalent task (MET) minutes (equal to 150 minutes of MVPA) per week, and 48% reported being physically active for at least one day a week (Chalder et al., 2012). A (non-significant) increase in the percentage of people achieving >1000 MET minutes of physical activity per week was found in favour of the intervention group (adjusted odds ratio 1.58, CI: 0.94 to 2.66; $p=0.08$) at four months post-randomisation (Chalder et al., 2012). At four months, follow up data (gathered from 80% of those randomised) revealed no significant difference in depressive symptoms with an adjusted mean difference of -0.54 in depressive symptoms (95% CI: -3.06 to 1.99; $P=0.68$). These findings were also similar at eight and twelve months follow-up. TREAD-UK was one of the first full-scale RCTs to address the pragmatic question regarding the utility of prescribing physical activity (using a well-developed and described intervention (Haase, Taylor, Fox, Thorp, & Lewis, 2010)) in a primary care setting. However, the TREAD-UK study suffered from a range of conceptual and methodological limitations.

First, physical activity was measured using the seven-day physical activity recall (7 day PAR)) which is a self-report measure. Self-report involves participants reporting their physical activities through paper or online questionnaires. They are the most common, and practical measures and allow the collection of mode, duration, frequency, and type of physical activity. Self-report measures may, however, lead to the misclassification of physical activity levels (Foster et al., 2005). Validation studies have shown self-report measures to show low correlations when compared to gold standard measures such as doubly labelled water (Sylvia, 2015), and prone to systematically overestimating or underestimating actual physical activity levels (Westerterp, 2009). Accelerometers were used in TREAD-UK and are considered to be more objective than self-report data. Accelerometers measure acceleration (counts) continuously, and the data can be converted, using validated algorithms, into key metrics of interest (e.g., minutes of MVPA, steps per day, energy expenditure). Commonly worn on the wrist or hip, accelerometers demonstrate better concurrent validity with gold-standard measures (e.g., doubly labelled

water) than self-report measures (Sylvia, 2015). However, in TREAD-UK, accelerometers were only given to a subsample of 84 participants at the four month follow-up point to validate self-report data.

Second, the baseline physical activity levels in TREAD-UK suggested that at least twenty-six percent of participants were achieving at least 150 minutes of MVPA per week (suggesting a selection bias). This means that the trial may have recruited a more active population than intended.

Third, it has been argued that, because many participants within the TREAD-UK control condition received antidepressants and other therapies, many of the psychological and biological effects of physical activity may have been overshadowed (Ekkekakis, 2015). For example, physical activity and antidepressant medication are hypothesised to work through similar neural and psychological mechanisms (Craft & Perna, 2004).

Fourth, TREAD-UK reported a mean of 7.2 (SD 4.1) out of a possible 13 sessions completed, with 56% of participants. However, there was a lack of information regarding how well the providers adhered to the intervention manual (Chalder et al., 2012). Without this information, it is hard to determine if the lack of effects found in TREAD-UK were due to an ineffective intervention or poor delivery.

1.5.2 Behavioural Activation and Physical Activity (BAcPac)

Another more recent pilot RCT (Farrand et al., 2014; Pentecost et al., 2015) explored the feasibility of delivering a supported, written self-help programme based on either BA or BA plus physical activity promotion (BAcPac) through the IAPT service. They included 60 adults with depression as assessed by the clinical interview schedule and a minimum score of 10 on the Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001). The baseline physical activity level of participants was a mean of 19.7 (SD = 43.1) minutes of MVPA per day (140 mins per week) in the intervention group and 9.8 (SD = 13.2) minutes for the control group (Pentecost et al., 2015). At four months post-randomisation, a mean of 9.1 (SD = 10.2) minutes of MVPA per day was reported in the intervention group and 18.8 (SD = 24.0) minutes in the control group. The authors had a retention rate of 73% and did not report any inferential statistics. However, the authors found a mean PHQ-9 score of 10.7

(5.7) for the intervention group (N = 21) and 10.1 (5.8) for the BA comparison group (N = 23) suggesting a pre-post change in depression for both groups.

Conceptually, BAcPac had a number of strengths. BAcPac was theoretically informed, combining BA (an existing evidence-based treatment for depression) with self-determination theory (SDT) (Farrand et al., 2014) and qualitative data indicated good intervention acceptability (Pentecost et al., 2015). However, BAcPac was only a pilot trial and was not powered to detect between-group effects. Furthermore, like TREAD-UK, BAcPac used the 7 day PAR as the primary measure of physical activity and had only managed to collect usable data from a few participants (28 out of 60 at four-month follow-up point). Finally, possibly the most significant limitation is the fact that BAcPac reported that only ten participants received at least one intervention session (out of a possible 12 sessions) from both the intervention and comparison group (with 40 not receiving anything) (Pentecost et al., 2015). Furthermore, despite the authors intending to conduct a more thorough fidelity assessment (Farrand et al., 2014), due to lack of data, this was not possible.

1.5.3 Internet Physical Activity for College Students (IPACS)

The IPACS study randomised 51 college students who were registered for mental health counselling to a web-based physical activity intervention or usual care (Mailey et al., 2010). IPACS was a ten-week modular web-delivered intervention based on social cognitive theory and supported by a physical activity counsellor. Physical activity counts were measured using Actigraph Accelerometers with baseline counts of 243421.81 (62414.56) for the intervention group and 247753.55 (69613.96) for the control group (Mailey et al., 2010). However, the authors did not give any reference as to how these units translated to MVPA. Mean depression (as measured using the Beck Depression Inventory (BDI)) was 15.7 (11.1) for the intervention group and 16.0 (6.3) for the control group. 92% were followed up for ten weeks and a significant time by group interaction effect for physical activity was found with a significantly larger increase in the intervention condition (0.68) than the control condition (0.05). However, the authors found no main or between-group differences in depression.

The IPACS study had significant strengths. Validated measures for assessing depression were used, along with objective measures for assessing physical activity. Furthermore, they had a reasonable retention rate (92%) and used therapist support. However, the IPACS failed to find an effect for depression. Reasons for this could have been due to the small sample size ($N = 51$) and the fact that no inclusion criteria relating to depression were specified. Furthermore, the standard deviations reported for the mean baseline score on the BDI were quite large, indicating that some people may not have fulfilled the cutoff criteria for depression. There was also no information regarding the fidelity of the intervention.

1.5.4 Internet-delivered therapist-guided physical activity for mild to moderate depression

Ström et al., (2013) compared an online clinician-guided physical activity intervention (based on SDT and motivational interviewing) with a waitlist control group. A sample of 48 people in the community with mild to moderate depression (as indicated by the Montgomery-Asberg Depression Rating Scale (MADRS-S) and a structured clinical interview) were recruited. Baseline physical activity (as measured using the International Physical Activity Questionnaire (IPAQ)) was a mean of 778 (SD = 695) MET-minutes per week for the intervention group and 953 (SD = 670) for the control group (Ström et al., 2013). All participants were followed up after nine weeks, and the authors found no significant between-group differences in physical activity. However, for change in depression, there was a moderate between-group effect in favour of the intervention group (Cohen's $d = 0.67$) (which was maintained at six months follow up ($N = 21$)).

The study by Ström et al., (2013) had many strengths, it used a theoretically informed intervention (based on the TREAD-UK intervention (Haase et al., 2010)) and reported good fidelity data regarding usage with 58.3% of participants completing all nine modules. However, as with previous studies (Mailey et al., 2010; Pentecost et al., 2015), the sample size was small, reducing the confidence in the effects. Furthermore, physical activity was measured using self-report, and there was no information taken regarding how participants engaged with the core intervention components outside of the website (i.e. did they use the skills taught in day-to-day settings?)

1.5.5 Behavioral activation versus physical activity via the internet

Nyström et al., (2017) compared the effect of four therapist supported, internet administered treatments (promoting BA and physical activity (with and without providing a treatment rationale) with a waiting list control over twelve weeks on a sample of 312 Swedish adults from the community. People were included based on diagnoses from a structured clinical interview combined with elevated symptoms of depression on the PHQ-9 (≥ 10). The authors did not report levels of baseline physical activity and just stated that they excluded participants who exercised more than once a week as indicated by the IPAQ. At 12 weeks, the study had a retention rate of 92% and a significant reduction in depressive symptoms was found when all four treatment groups were pooled and compared with the control group (except physical activity promotion without treatment rationale). The lack of findings for treatment rationale for physical activity supports the theoretical premise of SDT, which suggests that providing a treatment rationale fosters intrinsic motivation.

This study was a large, multifactorial trial and had many strengths. The first most notable strength was the sample size of the study and good retention rate. Furthermore, the intervention adopted an evidence-based approach for depression (BA) and provided further evidence that physical activity may also be a form of BA in its own right. However, the study had some limitations. Firstly, despite using the IPAQ-SF to include less active participants, the authors did not attempt to measure physical activity or report baseline values. Baseline physical activity levels could have provided further insight into the different mechanisms the interventions worked through. In terms of fidelity, there was no association between the number of completed treatment modules and symptom improvement ($B = 0.011$, $SE = 0.035$, $p = 0.747$, 95% CI: -0.057, 0.080). However, the authors did not measure participant receipt or enactment. Such measures could have provided further insight into how participants engaged with the core intervention components in day-to-day settings.

1.6 Gaps in existing research promoting physical activity for depression

The trials mentioned above are some of the few to attempt to investigate behavioural interventions promoting physical activity for depression and have many strengths. Unlike previous research (Cooney et al., 2013) the trials above

have mostly reported baseline physical activity levels in the people they recruited. Knowing how active people are when they join trials allows researchers to more successfully attract those with depression who are less active and attempt to increase their physical activity levels. However, the move into behavioural interventions opens a whole new field of enquiry and creates some new gaps in the literature which this thesis intends to address.

1.6.1 Lack of evidence

The crucial first gap in the literature concerns the lack of studies evaluating interventions that promote physical activity as a treatment for people with depression. This lack of research pales in comparison to the larger number of studies investigating the effects of structured exercise, psychological therapies and antidepressants on depression (Cooney et al., 2013; Cuijpers et al., 2008). To date, it appears that only one study has been conducted which was pragmatic, multi-centred and powered to detect differences in depression (with 361 people randomised) (Chalder et al., 2012). Due to the small number of trials, it is hard to draw definitive conclusions about the effects of interventions promoting physical activity for depression. Furthermore, it is hard to get a sense of the acceptability and feasibility of delivering behavioural interventions promoting physical activity in clinical practice. This is a major issue, as the current delivery of depression services focuses very little on promoting physical activity. As such, more trials investigating the feasibility, acceptability and effectiveness of interventions to promote physical activity as a treatment for depression are needed.

1.6.2 Physical activity measurement

The second key gap refers to the measurement of physical activity in trials promoting physical activity for depression. The utility of physical activity as a treatment for depression diminishes if researchers are unable to recruit those who are not already active. Research suggests a negative association between physical activity and depression (S. Park et al., 2011). However, it is plausible that trials evaluating the effects of physical activity on depression may attract a subset of people with depression who are more motivated to do structured exercise sessions with intensive support (Taylor & Faulkner, 2014).

Behavioural interventions which focus on promoting gradual increases in physical activity and reducing sedentary time (rather than prescribing structured exercise) could be a way to recruit people with depression who are less active and motivated. Hence, it is critical for researchers to design studies that include representative samples regarding baseline physical activity and use accurate measures to assess and check baseline activity levels. However, the heterogeneity of assessment measures used in the existing evaluation studies promoting physical activity for depression makes it hard to interpret whether or not they recruited more or less active populations (Chalder et al., 2012; Mailey et al., 2010; Nyström et al., 2017; Pentecost et al., 2015; Ström et al., 2013).

Accelerometers are currently considered the most reliable method for assessing physical activity and have been advocated for use in people with severe mental health problems (Soundy, Taylor, Faulkner, & Rowlands, 2007). Few studies have used accelerometers with depressed populations, and we need more studies which accurately measure physical activity levels in trials of activity-based treatments for depression. However, it is important to note that accelerometers are resource intensive, requiring funding and technical expertise to process the complex data generated. Furthermore, beyond step-counting, accelerometers do not provide information on the type of physical activity (e.g., they cannot distinguish between swimming and doing tai chi) and are not sensitive to some types of activity (e.g., cycling) which may be key mechanisms at play in depression. Despite, their limitations, wearable devices represent a step forward in more accurate physical activity measurement, however, feasibility questions remain about whether they can be used to measure physical activity in trials promoting physical activity for depression.

1.6.3 Intervention fidelity

The third key gap concerns the varying quality of descriptions of intervention content and fidelity in previous studies making it difficult for researchers to identify the active components, replicate interventions and build on the existing research findings (Abraham & Michie, 2008; Hoffmann et al., 2014). Despite many studies citing a theoretical basis for informing development (e.g., Self-Determination Theory), a lack of transparency as to how these theories were operationalised is missing. Only one study has provided a more thorough intervention description (Haase et al., 2010).

Furthermore, there is a lack of reporting of the fidelity of interventions promoting physical activity for depression, making it difficult to attribute observed effects (or lack of effects) to the intervention.

Intervention fidelity refers to the extent to which a behavioural intervention was designed and delivered as intended. The National Institute for Health Behaviour Change consortium (NIH BCC) proposes that fidelity should be measured across five domains. These are design, training, delivery, receipt, and enactment (Bellg et al., 2004; Borrelli, 2011). Study Design is concerned with whether a study adequately tests its hypotheses about its underlying theoretical and clinical processes. Provider Training involves standardising training between providers and ensuring they are trained to clear criteria and monitored over time. Intervention Delivery involves assessing and monitoring differentiation (differences between the intervention and any comparison treatments), competency (skills set of provider), and adherence (delivery of intended components). Intervention Receipt refers to whether the intervention was understood and therefore 'received' by participants and enactment refers to whether participants used intervention related skills in day to day settings (Bellg et al., 2004; Borrelli, 2011).

Previous studies provide information relating to number of sessions or modules completed, however, even with this very basic information on delivery /receipt, some studies had low adherence to sessions or modules. No studies provided data regarding quality of intervention delivery and receipt /enactment of specific treatment components or behaviour change techniques (BCTs). Furthermore, there was a lack of attention to design fidelity. Without design fidelity, there is no way of scrutinising the extent to which proposed processes of change were fully operationalised in intervention protocols and manuals. As such, there is a need for more studies which both seek to enhance intervention fidelity and more accurately measure fidelity.

1.7 Thesis Aims

The overall aim of this thesis is to improve the integrity of the evidence base for interventions promoting physical activity for depression. More specifically the thesis aims were: 1) to add to the evidence base relating to interventions promoting physical activity for the treatment of depression (whilst improving on previous methodological limitations) and 2) specifically focus on issues relating to fidelity to ensure the intervention is fully operationalised, delivered and received as intended. The specific objectives were as follows:

Objective 1: *To develop and pilot a behavioural intervention promoting physical activity for the treatment of depression.*

Objective 2: *To use the BCC framework to focus on issues relating to fidelity throughout the development and pilot/feasibility of a behavioural intervention promoting physical activity for depression*

1.8 Thesis structure

Six empirical chapters address the above objectives. This section outlines the content of the remaining chapters:

Chapter 2: Assessment of fidelity in individual-level behaviour change interventions promoting physical activity among adults: A Systematic Review

Chapter 2 explores how intervention fidelity was assessed in interventions promoting physical activity and critically appraises them. Methods used to assess intervention fidelity are categorised, narratively synthesised and critiqued using assessment criteria from the NIH Behaviour Change Consortium (BCC) Treatment Fidelity Framework (design, training, delivery, receipt and enactment).

Chapter 3: Development of a web-based intervention (eMotion) based on behavioural activation to promote physical activity in people with depression

Chapter 3, uses findings from the systematic review (and other prior research evidence /development work) to inform the development of a web-

based BA intervention, which specifically promotes physical activity for depression (eMotion).

Chapter 4: Ensuring design fidelity in behavioural interventions: A novel method for assessing design fidelity and its application to the assessment and improvement of the design of a web-based intervention combining behavioural activation and physical activity

Chapter 4, uses findings from the systematic review to propose a novel method for assessing the extent to which intended active ingredients (stated in chapter 3) appeared in the eMotion intervention.

Chapter 5: The eMotion Pilot Trial: Design and Methods

Chapter 5 outlines the methods of a mixed methods pilot RCT and parallel process evaluation of the eMotion intervention that forms the basis of the remaining chapters. Specific hypotheses are stated in the remaining results chapters.

Chapter 6: The eMotion Pilot Trial: Results

Chapter 6 presents the results of the eMotion pilot trial. Data relating to feasibility (including accelerometer data) and exploratory analyses relating to changes in depression, and physical activity are reported.

Chapter 7: Process Evaluation of the eMotion intervention

Chapter 7 presents the results of a parallel, mixed methods process evaluation of the eMotion pilot trial. Quantitative and qualitative data relating to acceptability, fidelity, and mechanisms of effects on behaviour and mood are reported.

Chapter 8: General discussion

Chapter 8 provides a brief recap of findings relating to the aims of the thesis, gaps in the literature filled, strengths and limitations and a discussion of the relevance of the thesis in the context of the wider literature. Implications and recommendations for future research are made.

Chapter 2 Assessment of fidelity in individual-level behaviour change interventions promoting physical activity among adults: A Systematic Review

2.1 Chapter outline

As highlighted in chapter 1, there is lack of attention to fidelity in behavioural interventions promoting physical activity as a treatment for depression. The present chapter explores how intervention fidelity was assessed in interventions promoting physical activity and critically appraises them. Methods used to assess intervention fidelity were categorised, narratively synthesised and critiqued using assessment criteria from the NIH Behaviour Change Consortium (BCC) Treatment Fidelity Framework (design, training, delivery, receipt and enactment). The aim was to identify a range of methods to inform the development and pilot evaluation of a behavioural intervention promoting physical activity for as a treatment for depression.

2.2 The importance of intervention fidelity

Individual level (one to one and group-based) behavioural interventions are a key strategy for increasing physical activity, however, there is considerable variation in their reported effectiveness (Foster et al., 2005; Greaves et al., 2011; Orrow et al., 2012). This may be due to the fact that behavioural interventions for physical activity are often complex (with many interacting factors), and are therefore challenging to design and implement (Mars et al., 2013). These interacting factors moderate and mediate study outcomes, and include theoretical mechanisms (e.g. motivation or confidence) and contextual factors (e.g. participant demographics) (Craig et al., 2008). Another, key moderator of study outcomes is intervention fidelity - the extent to which a behavioural intervention was designed, implemented and received as intended (Bellg et al., 2004; Moncher & Prinz, 1991). Inadequate attention to the assessment of intervention fidelity can increase the risk of type 1 and type 2 errors and result in spurious conclusions about intervention effectiveness (Bellg et al., 2004). As well as allowing more accurate judgements about effectiveness (Borrelli, 2011), assessing fidelity can also facilitate easier replication and implementation of behavioural interventions in real-world settings (Mars et al.,

2013). The UK, Medical Research Council (MRC) guidelines emphasise the importance of fidelity assessment when interpreting outcomes (Hoffmann et al., 2014; Moore et al., 2014).

2.3 The NIH Behaviour Change Consortium Framework

One framework specifically developed for individual-level behaviour change interventions was developed by the NIH Behaviour Change Consortium (BCC). The BCC conceptualised fidelity across five core domains: Study Design, Provider Training, Intervention Delivery, Intervention Receipt and Enactment. Study Design is concerned with whether a study adequately tests its hypotheses in relation to its underlying theoretical and clinical processes. Provider Training involves standardizing training between providers and ensuring they are trained to clear criteria and monitored over time. Intervention Delivery involves assessing and monitoring differentiation (differences between the intervention and any comparison treatments), competency (skills set of provider), and adherence (delivery of intended components). Intervention Receipt refers to whether the intervention was understood and 'received' by participants and enactment refers to whether participants used intervention related skills in day to day settings (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005). The NIH BCC framework provides guidance for the assessment, enhancement and monitoring of fidelity. However, the focus of the present review is on assessment. Focussing on assessment is important to ensure proposed strategies to enhance fidelity (e.g. those recommended by the NIH BCC) have indeed been successful (e.g. did the provision of a treatment manual result in adequate adherence to treatment components?) and also facilitates accurate monitoring of fidelity over time.

If the assessment of intervention fidelity is important, then agreement on what constitutes fidelity in physical activity interventions is clearly needed. In addition, recommendations for good practice could help to reduce the risk of bias when assessing fidelity (Schoenwald & Garland, 2013; Schoenwald, Garland, Chapman, Frazier, & Sheidow, 2012). Despite this, reviews investigating fidelity assessment in health behaviour research (Borrelli et al., 2005; Shea et al., 2016) self-management (Schinckus, Van den Broucke, & Housiaux, 2014; Toomey, Currie-Murphy, Matthews, & Hurley, 2015), mental health (Gearing et al., 2011) school-based drug abuse prevention (Dusenbury,

Brannigan, Falco, & Hansen, 2003) and physical activity (Breckon, Johnston, & Hutchison, 2008; Quested, Ntoumanis, Thøgersen-Ntoumani, Hagger, & Hancox, 2017) have revealed that there is considerable variability in the conceptualisation and measurement of intervention fidelity. For example, in a review of diabetes self-management interventions, it was reported that intervention fidelity was assessed inconsistently, using a range of different concepts, including adherence to intervention content, duration, coverage and quality of programme delivery. There was also heterogeneity in measurement, with a variety of approaches such as participant self-report, researcher observation, and provider self-report (Schinckus et al., 2014).

A variety of ways to conceptualise (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005; Carroll et al., 2007) and measure (Gearing et al., 2011; Perepletchikova & Kazdin, 2005) fidelity in behavioural interventions have been suggested. Previous studies have also reviewed the theoretical basis of physical activity counselling interventions, and competency level of the interventionists (Breckon et al., 2008) and highlighted the importance of assessing fidelity in physical activity interventions based on motivational theories (Quested et al., 2017). However, to the best of our knowledge, a review of whether and how fidelity has been assessed (using the NIH BCC framework) in physical activity interventions, along with an appraisal of the quality of these approaches and association to outcomes is lacking. An overview of this field would provide intervention developers with a foundation to improve fidelity assessment of their own interventions, and provide researchers and reviewers with a means to assess the extent to which reported intervention processes are a) delivered and b) responsible for study outcomes.

The current review has four key aims. Firstly, to identify and summarise (using the NIH BCC framework) how behavioural interventions to promote physical activity in adults have conceptualised and measured fidelity. Second, to summarise the reported results of fidelity assessments. Third to summarise any reported associations of fidelity and other intervention outcomes. Fourth, to critically appraise the methodological approaches identified.

2.4 Method

2.4.1 Searches

A search of the databases PsychInfo, PsychArticles, MEDLINE, Embase, and Google Scholar, was undertaken in March 2017 for all studies published in English up to that date. Searches were carried out on titles, abstracts and keywords using proximity and wildcard operators to maximise the range of potential studies. Search terms for intervention fidelity (Appendix 1) were informed by previous reviews (Borrelli et al., 2005; Richards et al., 2013; Schinckus et al., 2014) and consisted of synonyms for intervention fidelity (e.g. treatment integrity) combined with those for 'exercise' (e.g. physical activity). Additional searches were carried out by citation searching of included papers.

2.4.2 Study Inclusion/Exclusion Criteria

Retrieved studies were included based on the following criteria: (1) Mentioning fidelity (or related term) in the title, abstract or keywords either as a main focus of the study or as a nested study (e.g. as an analysis conducted within a trial or feasibility study); (2) Individual level behavioural interventions (NICE, 2014) designed to increase any type of physical activity; (3) Study focussed only on physical activity and no other behaviours (e.g. diet, smoking) ; (4) Study involving adults aged 18 or over; (5) Peer-reviewed publications in English published up to March 2017 (no time frame imposed) (6) RCTs, observational studies pre-post studies, case-controlled or other quasi-experimental studies. Comparison groups could include usual care, no intervention or other interventions as the present study was only interested in the main intervention group. Studies were excluded if the intervention consisted of structured exercise alone or behavioural support plus structured physical activity (e.g. exercise classes) (Appendix 2).

2.4.3 Study Selection

All titles and abstracts were screened by the lead author (JL) with 10% independently screened by another co-author (RC). All full texts were also screened independently by JL and RC. Inter-rater reliability was calculated using the AC1 statistic (Wongpakaran, Wongpakaran, Wedding, & Gwet, 2013) and disagreements were resolved by discussion and, if necessary, mediated by a third author (CG).

2.4.4 Data extraction and synthesis

Data extraction and synthesis were guided by previous recommendations on the conduct of narrative synthesis in systematic reviews. Narrative synthesis is an approach used in systematic reviews to textually summarise findings from the included studies (Popay et al., 2006). Characteristics of the main intervention study (i.e. study design, population, intervention, and physical activity outcome) were extracted in addition to fidelity data. Borrelli (2011) provides the latest iteration of the NIH BCC treatment fidelity checklist (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005) (now referred to as the 'treatment fidelity assessment and implementation plan'). Items pertaining only to fidelity assessment (within the domains of design, training, delivery, receipt and enactment) were used to organise and summarise the descriptions of author attempts at assessing fidelity, methods used to collect data and fidelity outcomes (table 2.1). All items from the treatment fidelity assessment and implementation plan were not used as they referred to aspects not related to assessment (e.g. use of a treatment manual). Although important, these items relate to 'enhancing' as opposed to 'assessing' fidelity. Nvivo (version 11) was used to organise the data.

As no specific criteria for appraising the quality of fidelity assessment exist, studies were critically appraised based on criteria suggested in previous studies to represent good practice when assessing fidelity (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005; Gearing et al., 2011; Schoenwald et al., 2012). The more general recommendations made in the NIH BCC papers were used to create a checklist by the study authors. This aimed to provide a sense of the 'quality' of the application of each method. The checklist items assessed the presence or absence of good practice methods for each study and confirmed how robust the fidelity measures were (table 2.1). There were eleven criteria overall, with two for design, one for training, six for delivery, one for receipt, and one for enactment and one applied to all domains. A previous checklist has been developed (i.e. the treatment fidelity assessment and implementation plan) to quantify the extent to which studies have assessed monitored and enhanced fidelity according to the five domains of the BCC framework (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005). However, this checklist was not appropriate for the purpose of appraising the quality of the

assessment measured, as they did not include more specific items relating to the methodological quality of the fidelity measures themselves (e.g. method used to collect fidelity data). Data from all included studies were independently extracted and appraised by two authors and compared. Discrepancies were resolved by discussion with a third author.

Table 2.1: Fidelity Assessment and Quality Appraisal Criteria

NIH BCC Domain	Assessment Method ¹	Quality criteria ²
Treatment Design	Assess whether intervention protocol/manuals reflect the underlying theoretical model or clinical guidelines	Prior to study implementation, investigators, and optimally a protocol review group or panel of experts should review their protocols or treatment manuals to ensure that the active ingredients of the intervention are fully operationalized The degree to which the measures reflect the hypothesized theoretical constructs and mechanisms of action should be assessed
Training providers	Assess provider skills acquisition	Ensure providers are trained to a well-defined, a priori performance criterion. Provider role-plays with standardized patients should be evaluated for both adherence to treatment components and adherence to process (e.g., interactional style)
Delivery of treatment	Assess and monitor provider skills maintenance Assess if provider adhered to intervention plan, or in the case of computer-delivered intervention, method to assess participants contact with information Assess non-specific treatment effects Assess whether or not the active ingredients were delivered Assess whether or not proscribed components were delivered (e.g. components that were unnecessary or unhelpful)	Adherence to treatment components and competence to deliver the treatment in the manner specified Direct observation evaluated according to criteria developed a priori Raters of the audiotapes or videotapes should be skilled in treatment delivery as well as in more subtle aspects of the intervention and the treatment manual. Raters of the audiotapes or videotapes should be independent of the study Raters of the audiotapes or videotapes should be blind to treatment assignment, participant progress and outcomes, and provider identity. Interrater reliability of raters of the audiotapes or videotapes should be conducted
Receipt of Treatment	Assess degree to which participants understood intervention	Assessment of treatment receipt involves verifying the participants' understanding of the information provided in the treatment and verifying that they can use the skills and recommendations discussed. This could include written verification (pre–post-tests), using audiovisuals (repeat information orally and visually), and behavioural strategies (role-plays skills with feedback).
Enactment of treatment skills	Assess participants ability to perform the intervention skills Assess participant performance of intervention skills in setting in which the intervention is applied	Objective observation to determine if participants were using behaviour change techniques in relevant day to day settings
All		Psychometric properties

¹Only items relating to fidelity assessment were taken from the Treatment fidelity assessment and implementation plan, ²Quality criteria informed by recommendations from previous studies to represent good practice when assessing fidelity (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005; Gearing et al., 2011; Schoenwald et al., 2012).

2.5 Results

2.5.1 Included studies

As highlighted in the PRISMA flow chart (Figure 2.1), the search identified 11464 records. Once duplications were removed, 8262 records remained. After title and abstract screening, 47 full texts were examined further with 28 articles describing 21 physical activity interventions included in the review. Inter-rater reliability for titles and abstracts was excellent (AC1 = 0.99) but poor for full text (AC1 = 0.23). However further discussion revealed a systematic difference in the way that one inclusion criterion was being applied (focussing on physical activity as an outcome rather than as a focus of the intervention). After clarification, the full-text screening yielded perfect agreement (AC1 = 1).

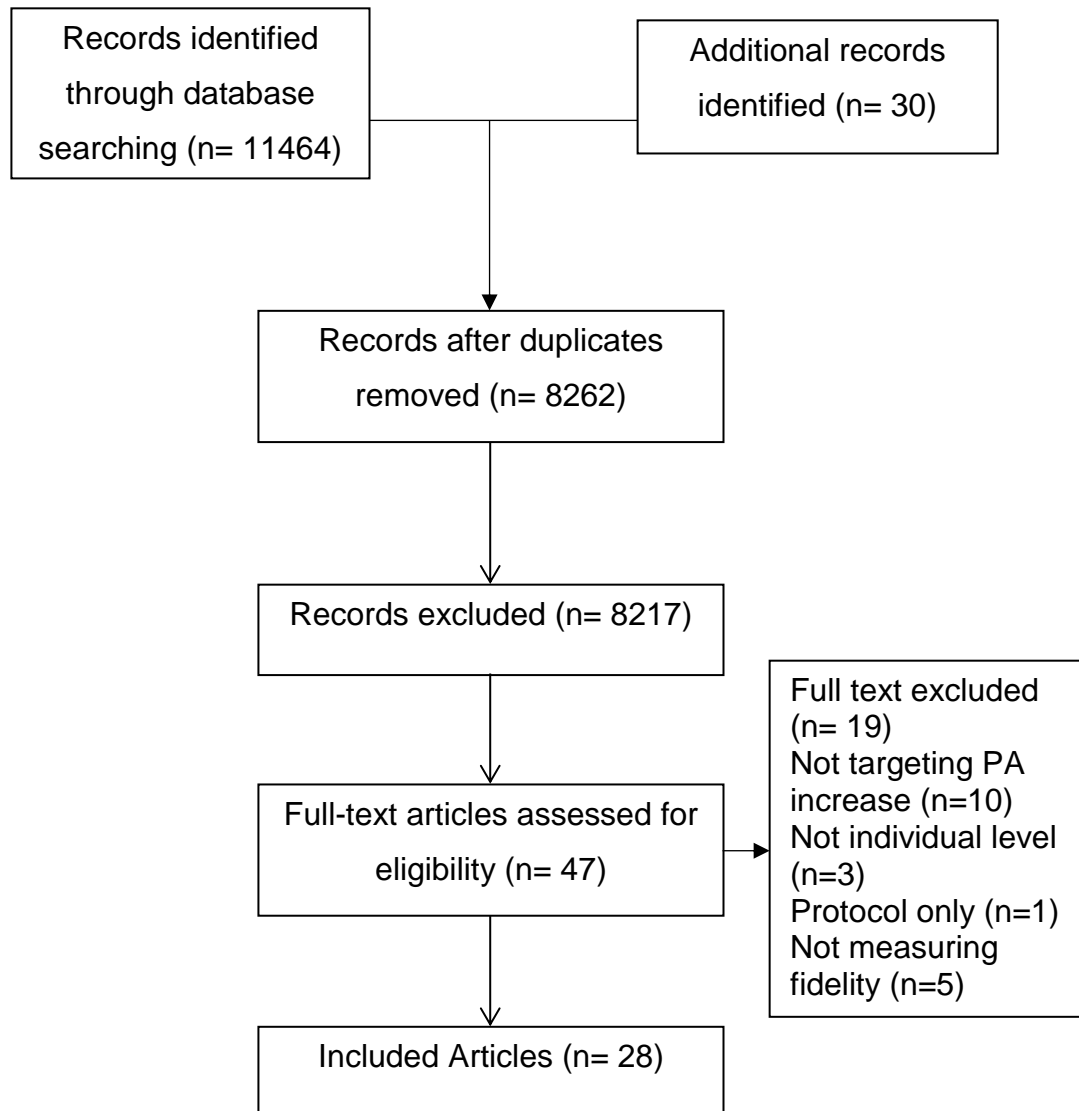


Figure 2.1: PRISMA Flow chart of selection process for review (Liberati et al., 2009)

2.5.2 Study Characteristics

16 studies were RCT's (Aittasalo, Rinne, Pasanen, Kukkonen-Harjula, & Vasankari, 2012; Albright, Saiki, Steffen, & Woekel, 2015; Bombardier et al., 2013; Carr, Karvinen, Peavler, Smith, & Cangelosi, 2013; Castro, Pruitt, Buman, & King, 2011; Goyder et al., 2014; Hardeman et al., 2008; Kolt et al., 2006; Leslie, Marshall, Owen, & Bauman, 2005; Levy & Cardinal, 2004; Pinto, Goldstein, DePue, & Milan, 1998; Quinn et al., 2016; Soetens, Vandelanotte, de Vries, & Mummery, 2014; Steele, Mummery, & Dwyer, 2007; Wilbur et al., 2016; Williams, Michie, Dale, Stallard, & French, 2015) and five were one arm (pre-post) trials (Avery et al., 2016; Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012; Brawley, Arbour-Nicitopoulos, & Martin Ginis, 2013; Bull & Milton, 2010; McCarthy, Dickson, Katz, Sciacca, & Chyun, 2015). All studies reported some form of behavioural support which aimed to increase the uptake of physical activity (e.g. information about health benefits, goal setting, self-monitoring, and pedometers). Studies used motivational interviewing (MI) (Bombardier et al., 2013; Bull & Milton, 2010; Goyder et al., 2014; Kolt et al., 2006; McCarthy et al., 2015; Wilbur et al., 2016), Cognitive Behaviour Therapy (CBT) (Kolt et al., 2006), and guided self-management based on a range of theoretical approaches including social cognitive theory (SCT) (Avery et al., 2016; Brawley et al., 2013; Castro et al., 2011; Steele et al., 2007; Wilbur et al., 2016), theory of planned behaviour (TPB) (Avery et al., 2016; Soetens et al., 2014), self-determination theory (SDT) (Goyder et al., 2014; Levy & Cardinal, 2004; Quinn et al., 2016), the trans-theoretical model (TTM) (Castro et al., 2011; Kolt et al., 2006; Leslie et al., 2005; Pinto et al., 1998; Soetens et al., 2014) and self-regulation theory (Hardeman et al., 2008; Williams et al., 2015). Physical activity was assessed using self-report (Aittasalo et al., 2012; Albright et al., 2015; Bombardier et al., 2013; Brawley et al., 2013; Bull & Milton, 2010; Castro et al., 2011; Goyder et al., 2014; Kolt et al., 2006; Leslie et al., 2005; Levy & Cardinal, 2004; Soetens et al., 2014; Steele et al., 2007; Wilbur et al., 2016), or objective measures of physical activity (e.g. pedometers or accelerometers, pedometers or heart rate monitors) (Carr et al., 2013; Hardeman et al., 2008; Wilbur et al., 2016; Williams et al., 2015). Of the studies that reported outcomes relating to physical activity, nine reported an increase (Aittasalo et al., 2012; Bombardier et al., 2013; Brawley et al., 2013; Carr et al.,

2013; Castro et al., 2011; Hardeman et al., 2008; Levy & Cardinal, 2004; Soetens et al., 2014; Wilbur et al., 2016), and three reported no increase in physical activity (Goyder et al., 2014; Leslie et al., 2005; Williams et al., 2015). Studies included participants with a range of ages (36 to 81) and consisted of inactive employees (Aittasalo et al., 2012), university staff (Leslie et al., 2005) inactive post-partum women (Albright et al., 2015), African American women (Wilbur et al., 2016) patients recovering from spinal cord injury (Brawley et al., 2013), people with comorbid depression and multiple sclerosis (Bombardier et al., 2013), people aged over 50 (Castro et al., 2011; Kolt et al., 2006; Pinto et al., 1998), people from deprived communities (Goyder et al., 2014), people with type 2 diabetes (Avery et al., 2016; Hardeman et al., 2008), people with intellectual disabilities (Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012), primary care patients (Bull & Milton, 2010; Williams et al., 2015) overweight adults (Carr et al., 2013), inactive adults (Levy & Cardinal, 2004; Soetens et al., 2014; Steele et al., 2007), people with heart failure (McCarthy et al., 2015) and people Huntington's disease (Quinn et al., 2016). The mode of intervention delivery included face-to-face (Aittasalo et al., 2012; Avery et al., 2016; Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012; Bombardier et al., 2013; Brawley et al., 2013; Bull & Milton, 2010; Castro et al., 2011; Goyder et al., 2014; Hardeman et al., 2008; McCarthy et al., 2015; Pinto et al., 1998; Quinn et al., 2016; Steele et al., 2007; Wilbur et al., 2016; Williams et al., 2015), online (Albright et al., 2015; Avery et al., 2016; Carr et al., 2013; Leslie et al., 2005; Soetens et al., 2014; Steele et al., 2007), email (Aittasalo et al., 2012; Leslie et al., 2005) post (Levy & Cardinal, 2004) and by telephone (Albright et al., 2015; Bombardier et al., 2013; Castro et al., 2011; Kolt et al., 2006; McCarthy et al., 2015; Wilbur et al., 2016), with both individual (one to one) and group based intervention formats. A more detailed description of each included study can be found in Appendix 3.

2.5.3 Measurement of Intervention Fidelity

Overall, 66 approaches to measuring fidelity were identified across the 21 studies with 52 approaches measuring delivery fidelity, eight measuring enactment, four measuring receipt, two measuring training fidelity and no approaches assessing design fidelity. Table 2.2 provides an overview of the

fidelity measures identified. It is important to note that many studies contained multiple concepts or measurement approaches.

2.5.3.1 Design and Training

No studies reported assessing design fidelity (the extent to which the intervention content reflected the underlying theory or logic model) and only two studies reported assessing training fidelity (the level of provider competence to deliver the intended intervention content before delivery). Training fidelity was assessed in one study by measuring provider competence using a 20 point checklist to assess whether or not providers adhered to the intervention protocol during practice sessions (Williams et al., 2015). In the other study, it was measured using an eight item self-report scale to assess perceived provider confidence to deliver the intended intervention content (Pinto et al., 1998). One study reported an increase in provider confidence (training fidelity) in delivery of the intervention (Pinto et al., 1998) the other study did not report the fidelity outcome, but stated that a minimum level of competence was required before delivering the intervention (Williams et al., 2015).

2.5.3.2 Delivery (human provider)

20 Studies measured delivery of human providers. These included using self-report by providers to measure the presence or absence (Bull & Milton, 2010; Hardeman et al., 2008; Pinto et al., 1998; Quinn et al., 2016), frequency (Castro et al., 2011), or delivery quality (Quinn et al., 2016) of intervention components, or using observation by researchers to assess the presence or absence (Albright et al., 2015; Avery et al., 2016; Wilbur et al., 2016), frequency, (Bombardier et al., 2013; Goyder et al., 2014; Hardeman et al., 2008; McCarthy et al., 2015; Wilbur et al., 2016) or delivery quality (Quinn et al., 2016) of intervention components. Two studies reported measuring the provider's satisfaction with his or her own intervention delivery (Brawley et al., 2013; Bull & Milton, 2010) and two studies reported measuring the participants' satisfaction with intervention delivery (Castro et al., 2011; Kolt et al., 2006). Four studies reported measuring researcher observed rating of provider competence/spirit (i.e. the interpersonal skills of the provider) (Bombardier et al., 2013; Goyder et al., 2014; McCarthy et al., 2015; Wilbur et al., 2016) and two studies reported using researcher assessment of the number of proscribed

behaviours used (e.g. arguing/giving advice without permission) (Bombardier et al., 2013; Goyder et al., 2014; Wilbur et al., 2016). Seven studies assessed the treatment dose delivered (i.e. length of time or number of sessions) (Albright et al., 2015; Bombardier et al., 2013; Bull & Milton, 2010; Castro et al., 2011; McCarthy et al., 2015; Quinn et al., 2016; Wilbur et al., 2016). One study assessed provider adherence to an intervention script, although it was not clear how this was measured (Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012). Data relating to delivery was obtained using provider (Brawley et al., 2013; Bull & Milton, 2010; Goyder et al., 2014; Hardeman et al., 2008; Pinto et al., 1998; Quinn et al., 2016), and participant self-report (Aittasalo et al., 2012; Castro et al., 2011; Kolt et al., 2006; Leslie et al., 2005; Levy & Cardinal, 2004; Steele et al., 2007), as well as audio recordings (Bombardier et al., 2013; Goyder et al., 2014; Hardeman et al., 2008; McCarthy et al., 2015; Quinn et al., 2016; Wilbur et al., 2016), video recordings (Avery et al., 2016), and direct observations (Albright et al., 2015; Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012) by researchers. Provider interviews (Bull & Milton, 2010) were also used. Approaches to sampling varied with some studies taking a sample of sessions from the trial population (Bombardier et al., 2013; Goyder et al., 2014; Hardeman et al., 2008; Wilbur et al., 2016) and others sampling the whole trial population (Aittasalo et al., 2012; Brawley et al., 2013; Bull & Milton, 2010; Carr et al., 2013; Castro et al., 2011; Hardeman et al., 2008). All studies using observational methods opted to apply coding procedures to a selected sample of recordings (or transcripts), rather than using data from all possible intervention sessions. Overall, of the studies reporting fidelity outcomes, many reported adequate intervention delivery (Aittasalo et al., 2012; Bombardier et al., 2013; Bull & Milton, 2010; Carr et al., 2013; Castro et al., 2011; Goyder et al., 2014). One study found adequate levels of fidelity for checklist of intervention components (>70%) and rating of competence measured by researchers. For the same study, less than adequate fidelity was found for an MI intervention measured by trained researchers using a ratio of number of 'adherent' vs 'not-adherent' intervention components (Wilbur et al., 2016). Two studies contrasted delivery assessments made using different methods. One reported low levels of delivery fidelity using objective rating of audio transcripts (with 44% of intervention components delivered as intended), but with provider self-reports indicating high delivery fidelity (100% of intervention components

delivered as intended) (Hardeman et al., 2008). Another study found that provider self-assessment scores were higher than those assigned by an independent rater (Quinn et al., 2016).

2.5.3.3 *Delivery (web-based)*

For web-based interventions, automatically tracked website log ins (Albright et al., 2015; Carr et al., 2013; Leslie et al., 2005; Steele, Mummery, & Dwyer, 2007), time spent on the website (Leslie et al., 2005; Soetens et al., 2014) automated telephone calls sent (Wilbur et al., 2016) or number of pages viewed (Albright et al., 2015; Leslie et al., 2005) were recorded electronically, with one study reporting 'modules used' with participant self-report (Leslie et al., 2005). Three studies also measured self-reported receipt of emails (Aittasalo et al., 2012; Leslie et al., 2005; Levy & Cardinal, 2004).

2.5.3.4 *Receipt*

There were three approaches to assessing intervention receipt, these included; participant demonstration of knowledge or skills acquired (Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012), perceived understanding of intervention content (Brawley et al., 2013), and participant confidence (self-efficacy) to perform skills taught by the intervention (Brawley et al., 2013; Hardeman et al., 2008). Approaches to sampling for assessment of intervention receipt included sampling the whole trial population at the end of each session and ten days later (Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012) and assessing the whole trial population at the end of the trial (Brawley et al., 2013; Hardeman et al., 2008). One study reported a small increase (from 86.2% to 89.4%) in perceived ability to carry out intervention skills (Brawley et al., 2013). Another study found that 73.5 to 100% of participants achieved the learning objectives of any given session (Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012).

2.5.3.5 *Enactment*

Enactment measures included participant self-reports or automatic tracking of using the intervention materials (e.g. log books, worksheets, pedometers) (Aittasalo et al., 2012; Levy & Cardinal, 2004; McCarthy et al., 2015; Wilbur et al., 2016) or of using specified intervention techniques (e.g. action planning/self-monitoring) (Brawley et al., 2013; Carr et al., 2013;

Hardeman et al., 2008). One study also measured participant use of self-monitoring using electronically recorded data from the intervention website (Carr et al., 2013). All studies that measured enactment collected data from the whole trial population. Studies that assessed enactment reported a range from 35.3% to 60% (Aittasalo et al., 2012; Levy & Cardinal, 2004) of participants regularly using intended intervention techniques post intervention. One study found a non-significant increase in the self-reported use of action planning techniques from pre to post intervention (4.6 to 6.8 on a 9 point scale) (Brawley et al., 2013) and one study reported that all participants used intervention techniques as intended at 6 and 12 months follow up (Hardeman et al., 2008). Finally, another study reported 71.9% of participants using intervention materials (accelerometers) (Wilbur et al., 2016)

Table 2.2: Summary of Intervention Fidelity Measures

NIH BCC Domain	Assessment Criteria (n)	What measured (n)	How Measured (n)	Study ¹
Treatment Design (0)	Assess whether intervention protocol/manuals reflect the underlying theoretical model or clinical guidelines (0)	N/A	N/A	N/A
Training providers (2)	Assess provider skills acquisition (2)	Provider confidence to deliver intervention (1)	Provider self-report (1)	(Williams et al., 2015)
		Provider competence to deliver intervention (1)	Assessment of provider (1)	(Pinto et al., 1998)
Delivery of treatment (52)	Assess and monitor provider skills maintenance (0) Assess if provider adhered to intervention plan, or in the case of computer delivered intervention, method to assess participants contact with information (28)	N /A	N/A	
		Number of email messages delivered (1)	Researcher observation (1)	(Aittasalo et al., 2012)
		Number of email messages/intervention materials read/received (3)	Participant self-report (3)	(Aittasalo et al., 2012; Leslie et al., 2005; Levy & Cardinal, 2004).
		Number of website log ins (4)	Automatically tracked (4)	(Albright et al., 2015; Carr et al., 2013; Leslie et al., 2005; Steele et al., 2007)
		Number of automated calls (1)	Automatically tracked (1)	(Wilbur et al., 2016)
		Time spent on website (2)	Automatically tracked (2)	(Leslie et al., 2005; Soetens et al., 2014)
		Number of pages viewed (2)	Automatically tracked (2)	(Albright et al., 2015; Leslie et al., 2005)
Number of website modules read (1)	Participant self-report (1)	(Leslie et al., 2005)		
	Provider rating of satisfaction with delivery (2)	Provider self-report (2)	(Brawley et al., 2013; Bull & Milton, 2010)	

Table 2.2: Summary of Intervention Fidelity Measures (cont'd)

NIH BCC Domain	Assessment Criteria (n)	What measured (n)	How Measured (n)	Study ¹
		Number of intervention sessions delivered (5)	Audio observation (3)	(Albright et al., 2012, 2015; Bombardier et al., 2013; McCarthy et al., 2015)
			Researcher observation (1)	(Wilbur et al., 2016)
		Time of intervention sessions delivered (6)	Provider self-report (1)	(Wilbur et al., 2016)
			Audio observation (3)	(Albright et al., 2012, 2015), (Bombardier et al., 2013) (McCarthy et al., 2015)
			Provider self-report (3)	(Bull & Milton, 2010) (Castro et al., 2011) (Quinn et al., 2016)
		Percentage of intervention script adhered to (1)	Researcher observation (1)	(Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012).
	Assess non-specific treatment effects (6)	Rating of provider spirit/competence (4)	Audio observation (4)	(Bombardier et al., 2013; Goyder et al., 2014; McCarthy et al., 2015; Wilbur et al., 2016)
		Participant rating of provider support (2)	Provider self-report (2)	(Castro et al., 2011; Kolt et al., 2006)
	Assess whether or not the active ingredients were delivered (15)	Rating of intervention components delivered (2)	Audio observation (1)	(Quinn et al., 2016)
		Checklist of intervention components delivered (7)	Provider self-report (1)	(Quinn et al., 2016)
			Researcher observation (2)	(Albright et al., 2015; Avery et al., 2016)
			Audio observation (1)	(Wilbur et al., 2016)

Table 2.2: Summary of Intervention Fidelity Measures (cont'd)

NIH BCC Domain	Assessment Criteria (n)	What measured (n)	How Measured (n)	Study ¹
			Provider self-report (4)	(Bull & Milton, 2010; Hardeman et al., 2008; Pinto et al., 1998; Quinn et al., 2016),
		Number of intervention components delivered (6)	Audio observation (5),	(Bombardier et al., 2013; Goyder et al., 2014; Hardeman et al., 2008; McCarthy et al., 2015; Wilbur et al., 2016)
	Assess whether or not proscribed components were delivered (e.g. components that were unnecessary or unhelpful) (3)	Number of proscribed intervention components delivered (3)	Provider self-report (1) Audio observation (3)	(Castro et al., 2011) (Bombardier et al., 2013; Goyder et al., 2014; Wilbur et al., 2016)
Receipt of Treatment (4)	Assess degree to which participants understood intervention (1)	Participant perceived understanding of intervention skills (1)	Participant self-report (1)	(Brawley et al., 2013)
	Assess participants ability to perform the intervention skills (3)	Participant demonstration of knowledge or skills acquired (1)	Researcher observation (1)	(Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012)
		Participant perceived efficacy to perform intervention skills (2)	Participant self-report (2)	(Brawley et al., 2013; Hardeman et al., 2008)
Enactment of treatment skills (8)	Assess participant performance of intervention skills in setting in which the intervention is applied (8)	Number of participants using intervention materials (e.g. log books, worksheets, pedometers) (3)	Participant Self report (2)	(Aittasalo et al., 2012; Levy & Cardinal, 2004)
			Automatically tracked (1)	(Wilbur et al., 2016)

Table 2.2: Summary of Intervention Fidelity Measures (cont'd)

NIH BCC Domain	Assessment Criteria (n)	What measured (n)	How Measured (n)	Study ¹
		Number of times intervention materials used (e.g. log books, worksheets, pedometers, online self-monitoring) (2)	Automatically tracked (2),	(Carr et al., 2013; McCarthy et al., 2015)
		Checklist of participant use of specified intervention techniques (e.g. action planning, self-monitoring) (2)	Participant Self report (2)	(Carr et al., 2013; Hardeman et al., 2008)
		Participant rating of agreement with using intervention techniques (1)	Participant Self report (1)	(Brawley et al., 2013)

¹Some studies contain multiple measurement approaches

2.5.4 Intervention Fidelity in Relation to Physical Activity (and Other Study Outcomes)

2.5.4.1 *Delivery in relation to Physical Activity*

Only three studies assessed the relationship between delivery fidelity and physical activity. One study found a positive association between MI fidelity (counts of adherent (and non-adherent) components of intervention components and spirit of delivery) with objectively measured total energy expenditure (TEE) ($p=0.027$) (Goyder et al., 2014). Two studies found no significant relationship between the number of intervention components delivered (based on coding of audio observations) and levels of self-reported and objective physical activity (Hardeman et al., 2008; Wilbur et al., 2016).

2.5.4.2 *Delivery in relation to other outcomes*

Only one study looked at the relationship between number of intervention components delivered and participant confidence in using intervention strategies, intention to be physically active and affective attitude towards physical activity (Hardeman et al., 2008).

2.5.5 Critical Appraisal of Intervention Fidelity Measurement Practices

A summary of critical appraisal criteria for each dimension of the BCC framework, and the number of studies meeting the criteria can be seen in table 3). No studies assessed design fidelity, so by default none met these criteria. Of the two studies that assessed training, only one met this criterion (Williams et al., 2015) by getting providers to do a practice role play and marking it against a checklist of intervention techniques. Of the 20 studies that assessed delivery fidelity, only four measured adherence to treatment components and competence to deliver the treatment in the manner specified (Bombardier et al., 2013; Goyder et al., 2014; McCarthy et al., 2015; Wilbur et al., 2016). This was done using the Motivational Interviewing Treatment Integrity Scale (MITI) which measures both usage of MI techniques and 'spirit' of delivery (i.e. use of a person-led, empathy-building interactive style). This is important to ensure effects are due to treatment rather than to different interactional styles (Borrelli, 2011). Some form of direct observation to evaluate delivery against a priori criteria (e.g. using audio/video tapes) was reported in eight studies (Albright et al., 2015; Avery et al., 2016; Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck,

2012; Bombardier et al., 2013; Goyder et al., 2014; Hardeman et al., 2008; Quinn et al., 2016; Wilbur et al., 2016), enhancing the reliability of the data. Of the eight studies that used direct observation, credible data supporting the competence of the raters used to assess delivery fidelity (e.g. previous training in the intervention) was evident in six. Such evidence included mentions of having expertise in health behaviour change (Avery et al., 2016), being trained in MI (Bombardier et al., 2013; Goyder et al., 2014; Wilbur et al., 2016) and being the 'intervention director' (Castro et al., 2011; McCarthy et al., 2015). Rater independence was only present in three studies (Goyder et al., 2014; Hardeman et al., 2008; McCarthy et al., 2015) where external raters who were not otherwise involved in the study were employed to provide a more objective rating of fidelity. Evidence of rater blinding from providers, participants or outcomes was not reported in any of the studies and interrater reliability of raters was only reported for three studies, one reporting a Cohens Kappa of 0.60 (Avery et al., 2016) and the other two reporting percentage agreement scores ranging from 75% and 100% agreement (Hardeman et al., 2008; Quinn et al., 2016). No studies met all six of these criteria and only 2 studies met at least four out of the six (11%). Of the three studies which measured receipt, only one study made use of knowledge tests by providing multiple choice tests as well as free text questions (Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012). Finally, for the six studies which measured enactment, only one study met the criterion of 'objective observation to determine if participants were using behaviour change techniques in relevant day to day settings' by counting the amount of times steps were logged by participants on a website (Carr et al., 2013). Across all 21 identified studies, the psychometric properties of instruments used to measure any type of intervention fidelity were only reported for six studies. This involved either reporting internal consistencies (Brawley et al., 2013; Castro et al., 2011), intraclass correlations (Wilbur et al., 2016) or referencing the use of previously validated and reliable scales (Bombardier et al., 2013; Goyder et al., 2014; McCarthy et al., 2015; Wilbur et al., 2016).

Table 2.3: Critical appraisal of fidelity measures

BCC (number of studies identified)	Criteria (Bellg et al., 2004; Borrelli, 2011b; Borrelli et al., 2005)	No of studies meeting criteria	
Design (0)	Prior to study implementation, investigators, and optimally a protocol review group or panel of experts, should review their protocols or treatment manuals to ensure that the active ingredients of the intervention are fully operationalized.	N/A	
	The degree to which the measures reflect the hypothesized theoretical constructs and mechanisms of action should be assessed.	N/A	
Training (2)	Ensure providers are trained to a well-defined, a priori performance criterion. Provider role-plays with standardized patients should be evaluated for both adherence to treatment components and adherence to process (e.g., interactional style).	1	(Williams et al., 2015)
Delivery (19)	Adherence to treatment components and competence to deliver the treatment in the manner specified	4	(Bombardier et al., 2013; Goyder et al., 2014; McCarthy et al., 2015; Wilbur et al., 2016).
	Direct observation evaluated according to criteria developed a priori	8	(Albright et al., 2015; Avery et al., 2016; Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012; Bombardier et al., 2013; Goyder et al., 2014; Hardeman et al., 2008; Quinn et al., 2016; Wilbur et al., 2016)
	Raters of the audiotapes or videotapes should be skilled in treatment delivery as well as in more subtle aspects of the intervention and the treatment manual.	6	(Avery et al., 2016; Bombardier et al., 2013; Castro et al., 2011; Goyder et al., 2014; McCarthy et al., 2015; Wilbur et al., 2016)
	Raters of the audiotapes or videotapes should be independent of the study	3	(Goyder et al., 2014; Hardeman et al., 2008; McCarthy et al., 2015)
	Raters of the audiotapes or videotapes should be blind to treatment assignment, participant progress and outcomes, and provider identity.	0	
	Interrater reliability of raters of the audiotapes or videotapes should be conducted	3	(Avery et al., 2016; Hardeman et al., 2008; Quinn et al., 2016)
Receipt (3)	Assessment of treatment receipt involves verifying the participants' understanding of the information provided in the treatment and verifying that they can use the skills and recommendations discussed. This could include written verification (pre–post-tests), using audio visuals (repeat information orally and visually), and behavioural strategies (role-plays skills with feedback).	1	(Bodde, Seo, Frey, Lohrmann, & Van Puymbroeck, 2012)
Enactment	Objective observation to determine if participants were using behaviour change techniques in relevant day to day settings	1	(Carr et al., 2013)
All (21)	Psychometric properties	6	(Bombardier et al., 2013; Brawley et al., 2013; Castro et al., 2011; Goyder et al., 2014; Hardeman et al., 2008; McCarthy et al., 2015)

2.6 Discussion

2.6.1 Summary of findings

This review systematically identified and summarised the range of concepts and methods used to assess intervention fidelity in interventions to increase physical activity and critically appraised the methods used. Only twenty eight articles reporting twenty one studies were identified which had explicitly examined intervention fidelity, suggesting an overall lack of attention to this issue in the field.

A range of different ways to assess intervention fidelity were identified, with delivery of intervention components being the most frequent. The concepts measured often deviated from those identified by the BCC Framework (Borrelli, 2011). For example, there was a lack of clear distinction between fidelity of training and fidelity of delivery and no studies assessed every aspect of fidelity.

A wide range of approaches were used to measure fidelity, with data collection measures ranging from researcher coding of observational data (using checklists or scales) to participant self-report measures to simple counting of sessions attended. A mixture of provider self-report and audio observation were most common for delivery and participant self-report was most common for receipt and enactment. However, there was an overall lack of methodological rigour in the approaches used for data collection (e.g. lack of attention to psychometrics and use of untrained, potentially biased raters) when appraised against a priori quality criteria for fidelity assessment.

2.6.2 Relation to other literature/interpretations

The lack of attention, consistency and rigour in the conceptualisation and measurement of fidelity in physical activity interventions found in this review confirms previous findings. For example, a recent scoping review found that only 5% of published articles addressed the issue of fidelity in motivational physical activity interventions (Quested et al., 2017). This also resembles findings in other behavioural domains (Gearing et al., 2011; Schinckus et al., 2014; Schoenwald & Garland, 2013). For instance, in a review of fidelity in diabetes self-management interventions, only fifteen studies were identified that

assessed intervention fidelity, with delivery adherence again being the most frequent concept assessed (Schinckus et al., 2014). In contrast, a review of fidelity in after-school programmes to promote behavioural and academic outcomes identified 55 studies (Maynard, Peters, Vaughn, & Sarteschi, 2013). However, the review of after-school programmes included strategies used to maintain fidelity (e.g. use of an intervention manual) and under further examination, only 29% (n = 16) of the included studies actually measured fidelity outcomes. Possible reasons for the lack of attention to fidelity assessment could be a lack of journal space, or a lack of definitive guidance requiring the reporting of fidelity data. The recent development of checklists such as the Template for Intervention Description and Replication (TIDieR) (Hoffmann et al., 2014) and the Medical Research Council (MRC) guidance on process evaluations (Moore et al., 2014) may help to improve this situation in the future

Another key finding from this review was the lack of attention to quality of measures used to assess fidelity in physical activity interventions. Where checklists or rating scales were applied to session recordings or live session observation by researchers, there was a lack of clarity regarding the use of skilled and unbiased raters. Many studies appeared to assume that the use of researchers (who were not necessarily involved in intervention development) was sufficient to evidence rater competence. However, this would not distinguish between junior or experienced researchers and so may introduce a high risk of error. This could also have implications for the validity and reliability of the findings, as it has been shown that (using the MITI coding tool), scoring is more reliable for coders with higher levels of experience than for those with lower levels (Moyers, Martin, Manuel, Hendrickson, & Miller, 2005). There is a further methodological tension here, as those in the best position to rate competence and adherence are arguably the intervention developers themselves or providers (due to the training received in all of the treatment components). However, developers and providers directly involved in the project may have a vested interest in demonstrating high quality of delivery (Perepletchikova & Kazdin, 2005) and obtaining skilled independent raters may be more difficult to find for novel interventions. A solution to this dilemma might be to use experts with a wide range of expertise in intervention design or

delivery with clear definitions and instructions on the intervention components and their intended use (perhaps with examples of good practice provided by the developers). The use of multiple raters and checking of inter-rater reliability could also help to reduce the risk of bias further.

Only a few studies used objective data collection methods. This may be problematic as objective measures showed poor convergent validity with self-report measures of intervention fidelity in some studies (Hardeman et al., 2008; Quinn et al., 2016). Factors responsible for this could include social desirability or a lack of sophistication /accuracy /reliability of the measures used. For example, provider self-report measures were typically assessing broad concepts such as a global appreciation of delivery (Brawley et al., 2013), whereas researcher observations assessed more finely-detailed concepts such as the number of specific intervention components delivered (Bombardier et al., 2013). Finally, the lack of attention to the psychometric properties of measurement tools used to assess fidelity also increases the potential for bias due to unknown validity and reliability (Terwee et al., 2007). This lack of psychometric integrity could be due in part to resource constraints, as novel interventions often require new instruments to be developed. Hence, a balance must be found between scientific rigour and pragmatism.

The importance of assessing intervention fidelity for the interpretation of the findings of intervention effectiveness studies is increasingly recognised (Borrelli, 2011; Gearing et al., 2011; Moore, Raisanen, Moore, Din, & Murphy, 2013). However the current findings suggest that conceptualisation and measurement of intervention fidelity remains heterogeneous in the field of physical activity promotion research (Gearing et al., 2011; Schinckus et al., 2014). Methodological checklists (e.g. Cochrane) exist to evaluate the quality and rigour of reporting of randomised trials (Higgins et al., 2011). However, there is currently no such tool for intervention fidelity measurement. Despite this, as demonstrated by this review, the behaviour change consortium (Bellg et al., 2004; Borrelli, 2011; Resnick, 2005) have provided a useful basis for categorisation, planning and critical appraisal of intervention fidelity assessments. It is worth noting that studies that used motivational interviewing had access to validated tools with instructions regarding observation method and rater characteristics (e.g. MITI, BECCI). This provides a good example of

what might be possible for future development of fidelity assessment methods in the wider field of physical activity interventions. Further research could combine existing tools such as the Behaviour Change taxonomy (Abraham & Michie, 2008) and the BCC Framework (Borrelli, 2011) to construct and check the reliability and validity of intervention fidelity checklist items for each behaviour change technique in the intervention. A focus on delivery style as well as content is also important however (Hardcastle, Fortier, Blake, & Hagger, 2016).

2.6.3 Strengths and limitations

Although previous studies have looked at fidelity to theory (Keller et al., 2009) and use of fidelity-enhancing strategies (Breckon et al., 2008), to the best of our knowledge this is the first systematic review to specifically identify intervention fidelity assessment methods for physical activity interventions and critique them. Our systematic approach highlighted key conceptual and methodological gaps in current practice. There are however, several limitations of this review that should be acknowledged. First, effectiveness studies may not have reported intervention fidelity in their titles abstracts, or keywords, as implementation is rarely a key focus of intervention studies (Popay et al., 2006). This means that it would be possible to miss some relevant studies using the search strategies employed here. However, this review was concerned with understanding how studies typically assessed fidelity and the methodological implications of current practice, rather than aiming to provide a comprehensive overview of the field. It has been previously pointed out, that studies that do not mention fidelity in their titles, abstracts or keywords most likely do not consider it a significant focus (Quested et al., 2017). As such, we were confident that the search strategy employed yielded a representative sample of studies in which the issue of fidelity was given significant consideration. Second, although the BCC Framework (Borrelli, 2011) was used for structuring the analysis, it is worth noting that other conceptual frameworks of intervention fidelity exist, which may have highlighted slightly different issues. For instance, Carrol et al's (2007) Conceptual Framework for Implementation Fidelity (Carroll et al., 2007) includes content (active ingredients), coverage (reach of the intervention), frequency (number of sessions), duration (time taken), complexity (difficulty), quality of delivery (competence), facilitation strategies (strategies to enhance

delivery) and participant responsiveness (participant receipt). Although there is much overlap with the BCC Framework, there are some minor differences. The BCC Framework was used here as it conceptualised intervention fidelity across key stages from design to implementation that are not all covered by Carroll et al's., (2007) framework. Thirdly, due to the lack of a consensus of reporting standards for fidelity assessment, the level of description of the methods and measures used was generally poor, so ascertaining the provenance and reliability of relevant information was challenging (Popay et al., 2006). However, to attempt to mitigate this, a second coder was used to double check the extracted data and companion papers were sourced and included. Finally, the appraisal criteria used were developed for the purposes of this study based on a combination of existing approaches (Table 2), as definitive criteria do not appear to exist in the literature. As such, there may be other important appraisal criteria that were not considered here. However, we hope this will at least provide a building block for further development.

2.6.4 Implications/Recommendations

Based on this review some key recommendations are proposed. Firstly, clearer conceptualisation of fidelity is needed when researchers plan and conduct fidelity analyses. This could be achieved by applying structures such as the BCC Framework. Secondly, researchers should clearly report all aspects of fidelity assessment measures (e.g. observational methods, rater attributes, and sampling procedures) as these can have implications for the likely risk of bias. Thirdly, clearer guidelines are needed on fidelity measurement, including consideration of data collection, sampling, measurement validity and reliability, minimizing the effects of rater bias and other methodological issues. This could then act as an adjunct to existing checklists such as TIDieR. Fourthly, a possible approach for critically appraising fidelity assessment methods in behavioural interventions has been proposed in this review and may provide a useful template for future studies. Finally, researchers should acknowledge the inherent strengths and weaknesses of their assessment methods when reporting and interpreting their intervention fidelity outcomes.

2.6.5 Conclusion

This review highlights new directions for research to improve the rigour and replicability of behavioural interventions for promoting physical activity by enhancing the assessment of intervention fidelity. The conceptualisation and measurement of fidelity in behavioural interventions for physical activity are wide ranging and of variable quality. Further work is needed to generate a more definitive understanding of the key concepts and best practice methods for conducting fidelity assessments of physical activity (and other behavioural) interventions.

Chapter 3 Development of a web-based intervention based on behavioural activation to promote physical activity for people with depression

3.1 Chapter Outline

As stated in chapter 1, one of the primary objectives of this thesis is to develop and pilot a behavioural intervention promoting physical activity for the treatment of depression. Chapter 2 (systematic) revealed that behavioural interventions promoting physical activity often measured intervention delivery using provider self-report and observational methods. However, interventions which were delivered online were often measured using electronic web-based usage metrics (Lambert et al., 2017). The purpose of chapter 3, is to provide an account of the developmental process of a web-based intervention to promote free living physical activity in people with depression.

3.2 The MRC Framework

The MRC framework states that, before a substantial evaluation is undertaken, a complex intervention needs to be properly developed. This process involves (a) identifying the evidence base, (b) identifying and developing theory and (c) modelling process and outcomes (Craig et al., 2008). However, another important consideration during development is identifying the mode of delivery, as this can have implications for how fidelity is maintained and assessed throughout a trial.

3.3 Web-based delivery systems

Web-based interventions have shown promise in reducing depression (Nyström et al., 2017; Rebar et al., 2016; Rosenbaum, Newby, Steel, Andrews, & Ward, 2015) and promoting physical activity (Webb, Joseph, Yardley, & Michie, 2010; Foster et al., 2013). Web-based interventions also have the potential to be delivered directly to the community, overcoming barriers to intervention recruitment. Up to 50% of people with mild to moderate depression do not seek help in primary care due to negative beliefs about treatment, social stigma and identity conflict (i.e. the desire to protect one's identity from the threat of depressive symptoms) (Farmer, Farrand, & O'Mahen, 2012). Web-

based interventions could help to reduce this treatment gap by providing anonymity, ease of access to treatment and flexibility.

Ensuring adequate training of providers and delivery fidelity of behavioural interventions promoting physical activity can be challenging and resource intensive (Lambert et al., 2017). Chapter 1 identified that interventions which used web-based systems to deliver behavioural interventions were able to reduce the need for provider training and standardise intervention content. Furthermore, it was found that electronic usage metrics could be used to objectively measure how much of the intervention was being delivered (e.g. website log-ins, time spent on website, number of pages viewed). Web-based interventions can be used to increase provider adherence to treatment protocols and manuals, reducing provider drift from protocol (Andersson, 2010). However, entirely self-delivered web-based systems could remove the issue of delivery fidelity by providing standardised content (Titov et al., 2010). Furthermore, a recent study proposed that web-based systems may offer a novel way to understand the specific mechanisms responsible for changes in depression outcomes in behavioural interventions (Watkins et al., 2016). However, web-based delivery methods can pose both a strength and a threat to intervention fidelity. The absence of a human provider means that people may receive an inadequate dose, or may not even receive the intervention at all (e.g. if a friend of family member was using the website). There may also be issues with ensuring that people are adequately receiving and understanding the intervention as intended (Eaton, Doorenbos, Schmitz, Carpenter, & McGregor, 2011).

Despite the potential for web-based interventions to target depression and physical activity, the overall evidence base is lacking, with a recent systematic review only including two studies (described and critiqued in chapter 1) (Rosenbaum, Newby, Steel, Andrews, & Ward, 2015). The aims of the present chapter were as follows. First, to describe the development and theoretical framework for an existing behavioural intervention which specifically promoted physical activity for depression (BACPAc). Second, to describe the process of operationalising the theoretical framework into a web-based platform using the Centre for Research on eHealth and Disease Management (CeHReS) roadmap. (eMotion). Third, to provide a description of eMotion.

3.4 Development and theoretical framework for eMotion

3.4.1 Rationale for Behavioural Activation and Physical Activity

Behavioural activation (BA) emerged from a component analysis which found that the behavioural element of CBT was just as effective as the full package of CBT for reducing depression (Jacobson et al., 2001). Various models of BA exist, however all are based on a behavioural formulation of depression (Jacobson et al., 2001). One such model aims to reduce depressive symptoms by decreasing behavioural avoidance and increasing activities that provide positive reinforcement (Farrand et al., 2014; Richards, 2010). The basic conceptual foundation for BA, is that depressed mood is the result of a lack of exposure to response contingent reinforcement, or an increase in punishment for 'healthy' behaviours (e.g. physical activity) (Richards, 2010). People with depression often stop engaging in activities they previously enjoyed (e.g. meeting friends) as they are perceived as too difficult (Jacobson et al., 2001). Avoiding such activities therefore provides a sense of immediate relief which is then negatively reinforced. People with depression can also experience less pleasure or achievement that comes from engaging in positive activities (anhedonia), resulting in reduced positive reinforcement (Jacobson et al., 2001). Depression can therefore be conceptualised as the product of a cycle of reduced positive reinforcement and increased negative reinforcement (Richards, 2010). BA helps people break this cycle by increasing their exposure to sources of positive reinforcement (Lejuez et al., 2001) thus "acting their way out of depression". This is in contrast to the "thinking (and acting) your way out" approach represented by contemporary cognitive behavioural therapies (Jacobson et al., 2001).

The model of BA used in the BAcPac (Farrand et al., 2014) study, aimed to alleviate depression by promoting behaviours that are perceived by people to be routine (e.g. shopping for food, walking the dog), pleasurable (e.g. seeing friends, going to the cinema) or necessary (paying bills, taking children to school), to help people identify contextually relevant positive behaviours in their own life. This rationale was then extended in BAcPac by encouraging the consideration of physical activity as part of the persons selection of behavioural strategies (Farrand et al., 2014) on the grounds that physical activity may offer an added benefit for relieving depression. BAcPac adapted the existing BA

protocol currently delivered in the Improving Access to Psychological Therapies Service (Richards, 2010) using focus groups and intervention mapping methods (Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, 2011) to deconstruct BA and rebuild it with a focus on physical activity.

3.4.2 Self-determination theory and logic model of eMotion

Encouraging people to engage in, and maintain physical activity is challenging (Taylor & Faulkner, 2014). Interventions should be guided by theory and evidence (Foster et al., 2005; Richards et al., 2013) and by employing behaviour change techniques (BCTs) with known efficacy (Michie et al., 2013). Self-determination theory (SDT) (Deci & Ryan, 2000) posits that both behaviour and wellbeing are consequences of intrinsic motivation (the inherent pleasure in performing a behaviour) that comes from the satisfaction of core psychological needs. These psychological needs are: (a) autonomy, feeling like ones behaviour can be self-determined and can make a difference to key outcomes (e.g. sense of well-being); (b) competence, feeling a sense of mastery or skills development and (c) relatedness, feeling that the behaviour is accepted and approved of /supported by others. Fulfilment of these needs is considered essential for psychological growth and wellbeing, as well as for the initiation and maintenance of behaviour (Deci & Ryan, 2000). Intrinsic forms of motivation have been associated with adoption and maintenance of physical activity (Teixeira, Carraça, Markland, Silva, & Ryan, 2012) and a recent review proposed that interventions that focussed on patient preference could lead to more sustainable changes in physical activity (and mood) by enhancing autonomy, as well as by focusing on more sustainable, intrinsically motivated changes (Nyström et al., 2015). Although BA promotes behaviour change as part of its rationale (Farrand et al., 2014; Richards, 2010), it lacks a clear underlying theory of behaviour change. The dual focus of motivation and wellbeing therefore made SDT well placed to guide the process of adding a physical activity focus to BA (Deci & Ryan, 2000) (Figure 3.1)

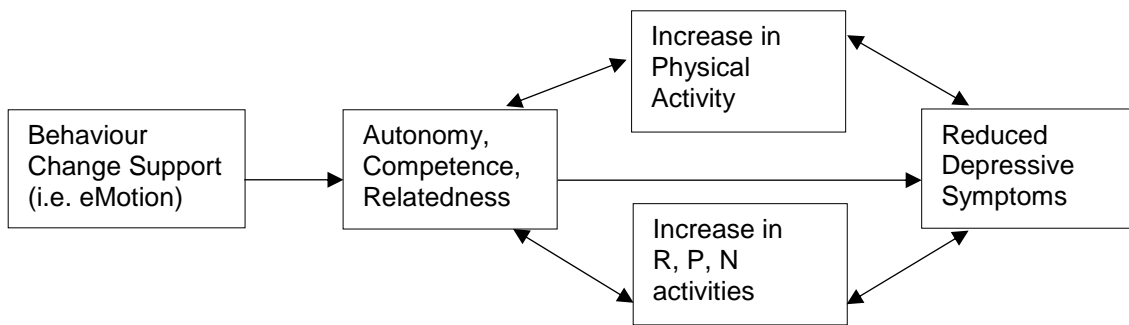


Figure 3.1: Logic model of eMotion

3.4.3 Using Intervention mapping to adapt BA

The process of deconstructing BA in BAcPac was first described in Farrand et al., (2014), and has been built on in the present study. The process involved first identifying the overall behavioural objective in the existing BA protocol (Richards, 2010) (i.e. engage in routine, pleasurable and necessary activities) followed by the learning objectives (e.g. participants understand the rationale for BA) (Farrand et al., 2014; Richards, 2010). The associated theoretical determinant outlined by SDT was then paired with each learning objective (e.g. increased understanding of the BA rationale supports autonomous/intrinsically generated motivation). Each learning objective identified in the BA protocol was then complemented with a learning objective related to physical activity (e.g. participants understand the rationale for physical activity) (Table 3.1). Once all the learning objectives had been identified for both categories of behaviour, they were matched with relevant BCTs (Michie et al., 2013) to facilitate transparency and replicability (appendix 5) (e.g. for the learning objective ‘participants understand the rationale for physical activity’ the BCT ‘provide information about emotional consequences’ was used).

Chapter 3

Table 3.1: Behavioural objectives and theoretical determinants for eMotion

Behavioural Objectives	Autonomy	Competence	Relatedness
Engage in Routine (R), Pleasurable (P), Necessary (N) activities	<p>Understand the aetiology of depression/low mood</p> <p>Understand the rationale for BA which includes reference to interaction of physiological, behavioural and cognitive emotional symptoms and the role of avoidance in maintaining low mood and the idea of routine, pleasurable and necessary activities</p> <p>Able to identify when depression occurs and what the accompanying behaviour was</p> <p>Able to identify routine, pleasurable and necessary (or physical) activities – things that they would like to do or try but have stopped doing or not tried since they became depressed</p> <p>Able to reflect on and take ownership their previous week of planned activities</p> <p>Feel that own perspective, feelings, and agenda are acknowledged</p>	<p>Understand how own current activity (lack of) contributes to low mood and vice versa and has accurate baseline to evaluate change</p> <p>Able to organise activities into a hierarchy of most difficult, medium difficulty, easiest. Should include some of each type of routine, pleasurable and necessary activity</p> <p>Able to schedule some activities into their week, using a blank diary to specify a mixture of the easiest routine, pleasurable and necessary activities. Activities should be detailed precisely: what, where, when, and who with.</p> <p>Small and regular activities are better in the early stages</p> <p>Able to feel sense of achievement at completing R,P,N activity</p> <p>Being able to reflect and build on successful completion of R,P,N activity</p> <p>Able to reflect constructively on failures of R,P,N activity goals without feeling demotivated</p> <p>Able to recognise symptoms of low mood, cueing the planning of routine, pleasurable and necessary activities</p>	<p>Feeling a genuine sense of empathy (encouraging ongoing engagement with the intervention)</p> <p>Feeling a sense of relatedness from endorsement of R,P,N activities by important others</p> <p>Feeling a sense of relatedness from participating in similar R,P,N activities to important others</p>
Engage in physical activity	<p>Understand link between physical (in)activity and low mood</p> <p>Understand how physical activity fits into the BA rationale (e.g. increasing physical activity promotes positive reinforcement)</p> <p>Understand the other health benefits of physical activity</p> <p>Able to identify physical activities that they would like to do or try but have stopped doing or not tried since they became depressed</p> <p>Able to reflect on and take ownership of engaging in physical activities</p> <p>Feel that own perspective, feelings, and agenda are acknowledged</p>	<p>Able to reflect on previous week and identify when depression occurs and whether was physically active or not</p> <p>Able to organise activities into a hierarchy of most difficult, medium difficulty, easiest. Should include some type of physical activity.</p> <p>Able to set achievable physical activity goals</p> <p>Able to reflect and build on successful completion of physical activity</p> <p>Able to reflect constructively on failures of physical activity goals without feeling demotivated</p> <p>Able to recognise symptoms of low mood, cueing the planning of physical activities</p>	<p>Feeling a genuine sense of empathy (encouraging ongoing engagement with the intervention)</p> <p>Feeling a sense of relatedness from endorsement of physical activities by important others</p> <p>Feeling a sense of relatedness from participating in similar physical activities to important others</p>

3.5 Framework for development of the online platform

3.5.1 Using the Centre for eHealth Research and Disease Management (CeHreS) Roadmap

BACPAc was designed to be delivered as a written self-help intervention, supported by a mental health workforce specifically trained to support low intensity CBT self-help interventions (Farrand et al., 2014). Web-based interventions are often developed without any consideration of the interaction between the user and technology, which may have implications for participant engagement and outcomes (van Gemert-Pijnen et al., 2011). The Centre for eHealth Research and Disease Management (CeHRes) roadmap provides a holistic process for developing intervention content in the system with which it will be delivered (e.g. online) with a focus on stakeholder engagement (e.g. patient public involvement (PPI)). Based on principles of persuasive technologies (i.e. the use of technology to change attitudes and behaviour) (Chatterjee & Price, 2009), and human-centred design (i.e. how the technology fits the needs of the end user) (Maguire, 2001), the CeHReS roadmap is intended to improve the uptake and impact of eHealth technologies. The CeHRes roadmap is a holistic approach and has five key iterative stages which are: (1) contextual enquiry, (2) value specification, (3) design, (4) operationalisation and (5) summative evaluation. This roadmap provided a useful guide to understand and address key issues when adapting BACPAc for use in a web-based setting (e.g. understanding features that might enhance effectiveness). For the purposes of this chapter, only the first three stages are relevant as they fit well within the 'development' phase outlined in the MRC framework (Craig et al., 2008). The contextual enquiry involved gathering information from intended users and literature to see how the proposed technology might fit into their daily routines. The value specification built on the contextual enquiry and involved key stakeholders making decisions about the key values and features that should be included in the intervention. The design stage involved constructing an initial prototype of the technology based on the previous two stages and gaining feedback on system design quality, intervention quality and service quality.

3.5.2 Contextual Enquiry: Method

The contextual enquiry involved further understanding of the context for delivering interventions (in this case, a web-based intervention for people with depression). As such, it was important to know about predictors of uptake, adherence and effectiveness of web-based interventions relating to physical activity promotion and depression research. To address these aims, we conducted a structured literature search (and narrative synthesis), which was then supplemented with patient public involvement (PPI) (i.e. people with depression) and consultations with experts in the field. The findings from these diverse sources were integrated using a triangulation protocol (O’Cathain, Murphy, & Nicholl, 2010). Triangulation can be adopted in the interpretation phase of research when different data sets have been collected and analysed separately helping to build a fuller picture, whilst giving weight to more robust findings.

3.5.2.1 *Structured Literature Search.*

A literature search of the databases PsycInfo, PsycArticles, MEDLINE, Embase and Google Scholar was undertaken for all studies published in English. Searches involved identifying systematic reviews and meta-analyses published in the last 10 years which reviewed trials evaluating web-based physical activity interventions for depression, web-based psychological interventions for depression or web-based behavioural interventions promoting physical activity. Search terms included variations of the terms ‘web delivered’ ‘depression’ ‘physical activity’ and ‘systematic review’ (full search in appendix 4). Citation searches were performed on key reviews and experts in the field were consulted about other relevant literature. Selected reviews were then included based on the following criteria: (1) they were systemic reviews or meta-analyses evaluating trials; (2) they reviewed web-delivered interventions promoting physical activity and/or reducing depression; (3) included adults aged 18 or over; (4) were published in the last ten years. Studies were excluded if they looked at any other mode of delivery (e.g. app based). All reviews were checked for relevant information that could inform development.

3.5.2.2 Patient, public involvement (PPI)

The contextual enquiry, value specification and design stage were all complemented with ongoing input from a PPI group of twelve people with lived experience of depression (The Lived Experience Group). The involvement of PPI is recommended for all stages of health research (including the intervention development stage) and has been adopted by previous researchers when developing interventions targeting physical activity promotion and/or depression (Farrand et al., 2014; Greaves et al., 2016; Haase, Taylor, Fox, Thorp, & Lewis, 2010; Kelders, Pots, Oskam, Bohlmeijer, & van Gemert-Pijnen, 2013). The Lived Experience Group is based at the University of Exeter and work closely with the Mood Disorders Centre to provide consultation on research studies and ensure end user needs are being met. Key questions put to the PPI group included: “general thoughts on web-based treatments for low mood”, “previous experiences of online treatments for low mood” and “expected needs”. Four separate individuals (recruited opportunistically through personal and professional networks) who have experienced depression were also consulted with to provide informal feedback on the first version of the intervention.

3.5.2.3 Consultation with experts in the field.

Collaborators with expertise in behaviour change (CG), physical activity and mental health (AT & AH), BA for depression (PF) were part of the supervisory team. In order to acquire expertise in web-based interventions for mental health a further collaborator (CW) was approached, who has expertise and years of experience in web-based cognitive behavioural interventions for depression. These collaborators also provided feedback on the first version of the intervention.

3.5.3 Contextual Enquiry: Results

3.5.3.1 Reviews identified

Our structured literature search identified a range of relevant systematic reviews which provided data on features that might enhance the effectiveness and engagement of web-based interventions targeting depression or promoting physical activity (Alkhalidi et al., 2016; Andersson & Cuijpers, 2009; Brouwer et al., 2011; Coull & Morris, 2011; Cowpertwait & Clarke, 2013; Davies, Morriss, & Glazebrook, 2014; Donkin et al., 2011; Farrand & Woodford, 2013; Foster et al.,

2013; Gellatly et al., 2007; Grist & Cavanagh, 2013; Maher et al., 2014; Musiat & Tarrier, 2014; Richards & Richardson, 2012; Waller & Gilbody, 2009; Webb, Joseph, Yardley, & Michie, 2010; Wildeboer, Kelders, & van Gemert-Pijnen, 2016).

3.5.3.2 *Need for Support in interventions for depression.*

Systematic reviews indicated a strong need for support. One review identified 34 RCT's evaluating the effect self-help interventions compared to waiting list (n = 23), usual care (n = 11) or attention placebo (n=5) control groups for the management of depressive symptoms (Gellatly et al., 2007). RCT's using a guided model (defined as inclusion of a therapist (professional or paraprofessional) delivered by either phone, face-to-face or email) reported a higher effect size for depression (0.80) than those which were 'pure' self-help (no support of any kind) (0.06). Another review examined 24 RCTs and 17 open trials evaluating the effect computer based treatments compared to control for the management of depression (Richards & Richardson, 2012). When compared with control, for interventions that provided no support (n = 9), the mean post treatment effect was 0.36, for interventions with administrative support (n = 5) the mean post treatment effect was 0.58 and for studies with therapist support (n = 7) the mean post treatment effect was 0.78. A similar pattern was also observed for dropout rates (74%, 38.4% and 28% respectively) (Richards & Richardson, 2012).

Another systematic review and meta-analysis (Farrand & Woodford, 2013) looked at the effectiveness of support of 38 RCTs of written self-help cognitive behavioural therapy (CBT). Findings from this review indicated that self-help CBT (for a range of mental health conditions) yielded a medium effect size, but did not significantly vary based on whether they were self-administered (no specific rationale, overview or support provided at any time with contact restricted to the research team regarding non-process issues) (0.42), had minimal; contact (provided with a rationale for the use of self-help or the materials overviewed which may also include regular check-ins regarding progress but without any focus upon process issues) (0.55), or were fully guided (initial support session in which a rationale and overview of the materials is provided, alongside regular scheduled support sessions during which progress is discussed alongside an additional discussion of process issues) (0.53).

Another review found a moderate mean post treatment effect for professionally supported treatments (0.61) and a small post treatment effect for unsupported treatments (0.25) (Andersson & Cuijpers, 2009). Finally another review found that web-based interventions with human support had larger effect sizes (0.48) than self-guided (0.32). However, only small differences were found between the type of human support, with human support involving full engagement in client treatments (0.57) and simple feedback on progress (0.47) yielding similar effects (Cowpertwait & Clarke, 2013). The theme of support was reinforced by PPI and expert consultation, with stakeholders mentioning that access to support either via telephone or over email would help to keep them motivated to engage with the intervention. Conversely, some members of the PPI group stated that human support could make them feel pressured, and if not handled appropriately would discourage them from staying with the study.

3.5.3.3 *Need for Support in interventions promoting physical activity.*

The need for support was also salient in interventions promoting physical activity, although effects appeared smaller. A systematic review of 85 web-based interventions for behaviour change (20 of which included physical activity) (Webb et al., 2010) found that access to an advisor via the telephone had small effects on behaviour change (0.29). In a systemic review of predictors of dropout and adherence to online interventions (Beatty & Binnion, 2016), 6 out of 9 of the included studies found that having in-person guidance or therapist support was associated with increased adherence. Other reviews also found that increased counsellor support (e.g. email, phone contact, or counsellor led chat sessions) (Brouwer et al., 2011; Kelders et al., 2012) or technology-based strategies (e.g. prompts) (Alkhalidi et al., 2016) were associated with increased engagement with web-based interventions promoting behaviour change

3.5.3.4 *Use of theoretical models in interventions for depression.*

The use of theoretical models to guide intervention development was a theme observed from the literature and expert consultation, but not PPI input. The review by Gellatly et al., (2007) found that interventions based on theoretical models resembling CBT yielded a higher effect size (.61) for depression than those that were purely psychoeducational in nature (.11) when compared to control (usual care, waiting list or attention placebo).

3.5.3.5 Use of theoretical models in interventions promoting physical activity.

For physical activity, the review by Webb et al. (2010) found that increased use of theory was positively associated with effect sizes for a range of health behaviours. More specifically, effective BCT's included stress management, communication skills training, coping planning, facilitating social comparisons, goal setting, action planning, and feedback on performance. Another review found that the inclusion of education components was a significant moderator of physical activity change yielding higher effects sizes (.20) than interventions without (.08) (Davies, Spence, Vandelanotte, Caperchione, & Mummery, 2012). Consultation with experts in the field of online physical activity and depression interventions also supported the idea of using theory and BCTs to guide intervention development and provide a more robust, conceptually integrated and replicable intervention.

3.5.3.6 Use of persuasive design features in interventions for depression.

One review found that the inclusion of persuasive design features (e.g. tunnelling, tailoring or reminders) was associated with effectiveness of web-based interventions for depression (Wildeboer et al., 2016). Reviews also found that interventions that included reminders had larger effect sizes (.49) than those without (.24) (Cowpertwait & Clarke, 2013) and that interventions that included reminders and prompts had higher engagement than interventions that did not (Alkhalidi et al., 2016).

3.5.3.7 Use of persuasive design features in interventions promoting physical activity.

Webb et al., (2010) found that automated feedback via emails had small effects on behaviour change (.18) with inclusion of text message support yielding the largest effects (.81).

3.5.3.8 User Friendliness.

A systematic review of barriers to adherence of online treatments found that factors such as usability and technological problems predicted lack of adherence to a web-based platform (Beatty & Binnion, 2016). Another review found that using the term 'therapy' and coming across patronizing led to people

dropping out of web-based depression treatments (Waller & Gilbody, 2009). Another systematic review of barriers to adherence of online treatments also found that factors such as usability and technological problems predicted lack of adherence to a web-based platform (Beatty & Binnion, 2016). This was also supported by PPI input. Being 'user friendly' was a theme that came from the literature and all stakeholders. PPI input also indicated that dense heavy to read texts were not desirable, and that navigation difficulties could provide barriers to engagement. A 'user friendly' approach would be beneficial as people with depression often have very low motivation and so there was a need to keep things simple.

3.5.3.9 *Graded progression*

PPI input and expert consultations revealed that web-based interventions should provide a graded approach to progression to ensure people are not overwhelmed. Furthermore, they should be flexible, so people can access them in their own time. Finally, a suggestion from the PPI group was made to allow access to existing diary keeping apps. Expert consultation also revealed that adding too much interactivity could over complicate things, and hinder navigation.

3.5.3.10 *Participant factors.*

One review found that participants' lack of time of working through online systems was a key reason for drop out (Waller & Gilbody, 2009). The PPI groups also mentioned that they felt that people with depression would be more inclined to access and use an online self-help system if they had come to it out of their own volition as opposed to being referred by a medical practitioner. Expert consultations also supported this statement, feeling that recruiting from a community rather than clinical setting would provide a larger pool of willing participants as they have not already been on long waiting lists for treatment and do not have an expectation of receiving 'face to face' therapy. These statements were also supported by systematic reviews which showed that RCT's comparing web-based depression treatments to control groups, tended to attract larger pools of willing participants and yield higher effect sizes for those recruited from non-clinical (1.02, 0.66 and 0.60) as opposed to clinical settings (0.31, 0.22 and 0.46) (Coull & Morris, 2011; Gellatly et al., 2007;

Richards & Richardson, 2012). A meta-analysis of individual patient data also found that people with a lower educational status had a higher dropout rate of online interventions, possibly due to the complexity associated with information technologies and CBT based treatments (Karyotaki et al., 2015).

3.5.4 Value specification: Method

The value specification involved establishing which values (based on findings from the contextual enquiry) stakeholders (PPI and experts) deemed important. These values were then translated into a specific list of features to enhance engagement which would be included in the design of the intervention.

3.5.5 Value specification: Results

Based on the contextual enquiry and consultation with PPI and experts, a list of 'features to enhance engagement' were identified (table 3.2). It was clear from the contextual enquiry that some form of human support was needed to help promote adherence to, and the effect of, a web-based interventions. However, the intensity of this support was not clear. After meeting with stakeholders and considering the resource requirements, it was decided that providing administrative support (guiding users to register and work through the intervention, but no clinical engagement or feedback) (Richards & Richardson, 2012) would be a good compromise that might enhance the potential effectiveness of the intervention without being too costly. To provide as much support as possible, a researcher contacted all participants who were randomised to either intervention or control group by phone to fully explain the study procedures. Participants randomised to receive the intervention group were also contacted by phone or email during the intervention to provide additional administrative support for using the web-based platform if needed. Administrative support could also potentially be achieved at a lower cost than therapist support in real life settings outside of the context of a trial. Weekly supportive emails were sent to encourage the user to log back in, and audio recordings were used to deliver intervention content in an attempt to enhance the sense of having a therapeutic relationship (simulating involvement of a real person, using natural language, as opposed to text-based instruction).

Furthermore, unlockable weekly modules were used to give users a sense of progression (or tunnelling) through the intervention. The contextual

enquiry also revealed that providing ‘theoretical underpinning’ was important to ensure that theory was being consistently used to guide development, but without making the user experience too complex. An inherent benefit of psychological therapeutic approaches based on BA, are their simplicity (potentially making them easier and more cost effective to deliver (Richards et al., 2016). In addition, established BCT’s (Michie et al., 2013) were employed to enable a transparent and replicable description of the intervention. To keep the intervention as ‘user friendly’ as possible, an existing platform (Living Life to the Full), already used to deliver a range of self-help treatments, was adopted (Williams et al., 2013). This helped to minimise the likelihood of technical problems which can occur in newly developed platforms, and also provide a more user-friendly environment due to the previous user-testing already provided to refine the platform. Finally, we chose to recruit from the community by placing adverts asking if people were experiencing ‘low mood’ (rather than “depression”) to ensure that a greater reach of people with depressive symptoms as possible was achieved. Once approached, participants completed the Patient Health Questionnaire depression scale (PHQ-8) (Kroenke et al., 2009) to ensure participants met study inclusion criteria (≥ 10 on the PHQ-8).

Table 3.2: Key themes identified from the contextual enquiry and user requirements

Theme from contextual enquiry	Features to enhance engagement
Support	All participants would be contacted by phone at the beginning of the study to help with registration and to give them an overview of the intervention An additional attempt to contact the user would be made via telephone or email to provide any technical, motivational support Weekly email supportive email messages would be sent to remind participants' to sign in and review goals Audio used to deliver intervention to mimic human support Unlockable weekly modules to tunnel participants through intervention
Theoretical Basis	Simple strategies based on BA approach used to guide development Behaviour change techniques are fully operationalised in intervention
User friendly	Existing tested platform used Access to technical support if participants experience problems Avoid use of patronizing language, do not use the term 'therapy'
Graded approach	Promote graded engagement with the intervention
Recruitment	Recruit people from the community rather than referred through primary care

3.5.6 Design: Method

3.5.6.1 Usability testing

The 'design' component of the CeHReS framework involved translating the user requirements of the intervention into a prototype that can be tested by stakeholders. Stakeholders can then feedback to the developers informing iterative intervention development. The design phase of development for eMotion involved usability testing a working prototype of eMotion that aligned with the values and user requirements. This was built and tested with four experts and four members of the PPI group. They were asked to work their way through the system making any comments on a structured feedback form as they went through. They were also asked to provide comments on the general look and feel of the website. Comments received were prioritised under the

following headings “Must do”, “Should do”, “Could do” and “Won’t do”. This ensured that changes were prioritised based on time and resources.

3.5.6.2 *Design Fidelity*

All theoretical content of the intervention was operationalised with BCTs using the BCT taxonomy v1 (Michie et al., 2013) (appendix 6). The BCT taxonomy is an extensive taxonomy of consensually agreed, distinct techniques used in behaviour change interventions which enabled systematic specification of the active ingredients of eMotion. BCTs were selected based on each learning objective (e.g. for the learning objective ‘understand link between physical (in)activity and low mood’ the BCT ‘Information about Emotional Consequences’ was chosen. The presence or absence of BCTs in eMotion was assessed by an independent researcher using a coding manual which contained BCTs from the v1 (Michie et al., 2013). Areas of discrepancy between the rater and the design specification were discussed and changes made to the intervention or the specification document, until consensus was agreed. A full description of this innovative design process is reported in chapter 4.

3.5.7 Design: Results

3.5.7.1 Usability testing

Table 3.3 gives an overview of the key changes made after the usability testing phase. Key changes included; aspects related to content, navigation and interactivity. Due to limited resources, only one iterative phase was possible.

Table 3.3: Key changes made after user feedback

Comments	Action Taken
¹ Acknowledge co-morbid anxiety as potential participants may be deterred thinking it is only relevant for those with depression	Text changed to acknowledge that people with co-morbid anxiety are still able to access system
¹ Use of the word 'worksheet' may be off putting/daunting as implies 'work'.	Unable to change name 'worksheet' as built in system, so reassured participant's that worksheet was not meant in a conventional sense.
^{1,2} Prompted to 'click on slide' which was not part of platform functionality	Changed to say, 'click to left of slide'
¹ Did not know where to click to get to next slide in module	Added text to ask participants to click on the arrow
^{1,2} Didn't expect audio voiceover on eMotion, make this clearer	Put bold text explaining that audio is a key feature, and will need speakers or headphones
¹ Would like an option for a text summary of the slides	Added a summary sheet for each module
^{1,2} Lack of interactivity with worksheets, only able to print off	Allowed ability to write on worksheets. Also encouraged printing and using ideas from worksheets in own way (e.g. using own diaries)
¹ Navigation issues on how to return to the main dashboard	Made navigation clearer and simpler
² Excessive use of 'OK' when recording voice over	Re-recorded voice over, greater consideration of non-lexical conversation sounds (e.g. ok, hmm)
² Clarity of some of the visuals was blurry	Loaded clearer visuals
² Repetative unlockable module	Two unlockable modules combined into one

¹User comment, ²Expert comment

3.5.7.2 *Design Fidelity*

Some areas of discrepancy were found between intended techniques and techniques identified by the coder. This process resulted in changing 12 (out of a possible 221) discrepancies for BCTs targeting just routine, pleasurable or necessary activities, and 16 (out of a possible 221) discrepancies for BCTs relating to physical activity. These discrepancies were resolved through discussion, and where appropriate, changes were made to the intervention or specification document. This process was fundamental for increasing the convergence between the intervention description and eMotion. A more thorough account of this is reported in chapter 4.

3.5.7.3 *Operationalisation and summative evaluation*

Operationalisation and summative evaluation involves launching the intervention to test out the various organisational and working procedures, evaluating how it is being used and the effects. eMotion is currently the subject of a pilot trial evaluation (trial identifier: NCT03084055), which will help to address further methodological uncertainties relating to the intervention, and trial procedures (e.g. recruitment, attrition, data collection).

3.6 Intervention description

The following description of eMotion conforms with guidelines (Hoffmann et al., 2014). Table 3.4 provides an overview of the eMotion website and a full detailed description can be found in appendix 5.

3.6.1 Content

eMotion includes 13 modules (1 introduction modules, 8 weekly modules, 1 generic problem-solving module and 3 unlockable modules) (table 3.4), consisting of visual content with an audio voice-over triggered when each slide opens. Printable, interactive worksheets and emails are also included, with links in the slides to allow downloading to a personal computer or other device (e.g. tablet or smartphone). Graded/gradual recovery is promoted, to balance the process of graded activity scheduling, with problem-solving of any set-backs from previous goals. Weekly modules are delivered over 8 weeks, with the introduction and problem-solving modules available upon registration. Each weekly module unlocks once the participant has completed the preceding

module. In addition, three 'unlockable modules' focussed on physical activity are made available once the participant has reached weeks 5, 6 and 7 of the programme. Core information relating to the BA rationale (figure 3.2) is front-loaded and delivered in the introduction module and weeks 1 and 2. This includes assisting people to identify (figure 3.3), grade (figure 3.4) and plan activities (figure 3.5) with the remaining weeks dedicated to promoting structured weekly reflection and goal review (figure 3.6). The rationale for eMotion is also emphasises and reinforces the added value of activities that include a physical activity. eMotion also promotes engagement with all aspects of the intervention in day to day settings (e.g. by using worksheets provided, or by using their own diaries) rather than just spending time on the website. This has been described as 'effective engagement' and has been suggested as a more comprehensive way of promoting and understanding adherence to web-based interventions (Perski, Blandford, West, & Michie, 2016; Ryan, Bergin, & Wells, 2017; Yardley et al., 2016). This is also intended to reinforce a sense of autonomy and participants will be internalising the skills learnt.

Table 3.4: eMotion intervention structure

	Session Title	Behavioural Activation Content	Physical Activity Content
Introduction	Introduction*	Introduce programme and give overview of depression	Explain how low mood and inactivity are linked
Core Modules	Week 1*	Explain the rationale for behavioural activation	Rationale altered to emphasise the added value of PA
	Week 2*	Prompt user to self-monitor existing activities over following week	
		Prompt user to identify routine, pleasurable, and necessary activities and rank it terms of ease	
		Prompt user to make hierarchy of routine, pleasurable, and necessary activities	
Unlockable Modules	Weeks 3 - 8	Prompt user to review progress with plan and amend accordingly	Reinforce the added value of PA
	Moving on with PA (unlocked at week 3)	Prompts user to problem solve any difficulties	Revisit and reinforce benefits of physical activity for mood
	Monitor physical activity (unlocked at week 4)	Prompts user to build on success	Prompt user to self-monitor physical activity
Problem Solving	Build up your physical activity (unlocked at week 5)		Provide user with extra tips on how to incorporate physical activity into their lifestyle
	Breaking down activities (available at any point)	Help user to break down activities	

*Minimum intervention dose



Figure 3.2: eMotion content (Rationale)



Identifying Activities

Under each type of activity, why not write down what you want to be able to achieve? Include all activities, whether or not you think you can do them at the moment. Even only a couple of activities will help.

Routine (e.g. walking the dog, food shopping)	Pleasurable (e.g. going out with friends, reading)	Necessary (e.g. paying bills, walking children to school)

BACPAC
Beating Anxiety & Depression

Can you identify any activities?

Figure 3.3: eMotion content (Identify Activities)

Can you Rank the activities?

Organising Activities

Why not take the activities you listed as and use the columns to rank them from least difficult to most difficult?

Least Difficult	Medium Difficult	Most Difficult

BACPAC
Actively Beating Depression

Figure 3.4: eMotion content (Rank Activities)

Now to plan the easiest activities

My Next Steps Diary

Why not use this diary to record the activities you ranked as 'least difficult' over the course of the week. If possible, try to spread the activities over different days over the week so you don't get overloaded!

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Morning	What Where Who						
Afternoon	What Where Who						
Evening	What Where Who						
Comments							

Tip: Try and be as specific as possible when describing your chosen activity. Try to include what you will be doing, who you will be doing it with and where you will be doing it (e.g. going shopping, with a friend, in town).

BACPAC
Actively Beating Depression

Figure 3.5: eMotion Content (Plan Activities)



Lets Review Your Diary

Review My Activities

ACTIVITY THERE/COMPLETED	WHAT WAS GOOD?	HOW CAN YOU BUILD ON THIS?	ACTIVITY NOT COMPLETED	WHAT WERE THE BARRIERS?	WHAT CAN YOU DO NEXT TIME?

Tip: If the activity went well, think about how you could slightly improve on it next time. If it did not go so well, then think about how you can break it down using the problem solving worksheet.

eMotion
Actively beating depression

Figure 3.6: eMotion Content (Review Activities)

3.6.2 Delivery style

eMotion is self-administered with minimal contact support (Farrand & Woodford, 2013). The participant is provided with a rationale for the use of self-help materials and administrative support to help with registration and technical issues at the beginning and 2 weeks into the intervention. The audio content and support was voiced and provided by the primary intervention developer (JL) who has previous experience of providing coaching support on a web-based weight loss intervention (Dennison et al., 2014). The delivery of eMotion is one-way (i.e. from therapist to client), so an attempt was made to mimic a style congruent with motivational interviewing (Miller & Rollnick, 2002) using audio delivery. Core techniques employed include using collaborative language (e.g. inviting the participant to try different strategies rather than ‘telling’ them the next steps), and evocation using open-ended questions (e.g. “if you didn’t achieve your goals, why do you think that was?”). Setbacks are also normalised (e.g. “don’t worry if you didn’t achieve your goals, this is perfectly normal”) and reframed so it suggests that failing to achieve a plan for behaviour change is not a failed week on the programme, but an opportunity to explore ambivalence or challenges about (reasons for and against) increasing the targeted routine, pleasurable and necessary activities and through experience and feedback develop greater understanding about what might or might not work for each person.

3.6.3 Delivery mode

eMotion is delivered on an individual basis using an existing online platform (Living Life to the Full) which delivers the content using a series of audio visual modules. Participants assigned to eMotion are provided with ‘minimal contact’ support (Farrand & Woodford, 2013). This support is provided at the beginning and at week 2. A dashboard documents the participant’s progress through eMotion (i.e. modules completed, time spent on website).

3.7 Discussion

eMotion is a web-based intervention designed to treat depression and simultaneously promote physical activity. The intervention builds on the BAcPac intervention (Farrand et al., 2014) and was iteratively developed using the CeHReS roadmap (Kelders et al., 2013; van Gemert-Pijnen et al., 2011). eMotion is self-delivered, with minimal facilitation and can be delivered with minimal resources compared with current face-to-face therapies for depression.

Systematic descriptions of psychological interventions are lacking, and this chapter provides a clear transparent account of the process of developing the eMotion intervention using theory, evidence and stakeholder engagement. Other development frameworks could have been used, such as intervention mapping (Bartholomew, Parcel, 1998; Bartholomew et al., 2011), and the MRC framework (Craig et al., 2008). However, intervention mapping can be highly technical and prescriptive, requiring considerable resources (Greaves et al., 2016), and the MRC framework is more focussed on evaluation as opposed to development (Wight, Wimbush, Jepson, & Doi, 2016). The CeHReS roadmap also has an explicit focus on the fit between the technology and content, which the other frameworks do not offer (Kelders et al., 2013).

The eMotion pilot trial with nested process evaluation will provide feedback on the usage of various intervention components and provide qualitative feedback from service users to inform further refinement of the intervention and trial procedures. Once clearly developed and articulated, it is then planned to evaluate eMotion in a fully powered phase 3 randomised controlled effectiveness and cost effectiveness trial (Craig et al., 2008).

One limitation of the developmental process, was the lack of further iterations during the developmental process. The CeHReS roadmap is intended to involve many iterations (van Gemert-Pijnen et al., 2011) and only one stage of user feedback was obtained during the 'design' stage. However, we felt that one stage of user feedback was sufficient to refine the intervention and test in a pilot trial (trial identifier: NCT03084055) in which further in depth qualitative feedback relating to the design has been obtained. Another limitation is that evidence from systematic reviews indicates that community recruitment may result in a greater number of willing participants who may be more educated

and wealthy than those recruited from clinical settings (Gellatly et al., 2007; Richards & Richardson, 2012). Although yielding larger effects, this could contribute to widening the gap. However, the inverse care law suggests that people who most need access to services often have less opportunity (Tudor Hart, 1971). Furthermore, there is also a significant treatment gap for people in the community not receiving treatment for depression (Kohn, Saxena, Levav, & Saraceno, 2004) possibly explained by a sense of identify conflict or stigma (Farmer et al., 2012). Therefore, at a time when a large proportion of the population have access to the internet, the opportunity to extend care via web-based support at community level is appealing and may help to close the treatment gap.

This development chapter will serve as a useful document to ground any future development work made. If the intervention improves outcomes and is deemed effective, this chapter can also be used by other researchers to replicate eMotion (along with actual slide and audio content, which is available on request /subject to permissions from the lead author), or to develop similar interventions.

eMotion aims to offer client-centred support through optimising engagement in web-based support, building on a previous similar face-to-face intervention (BACPAc) (Farrand et al., 2014). By trying to increase acceptability of eMotion, it is hoped that support to become more physically active may be offered to a wider range of people with low mood in the community, especially those who are least active with lower levels of motivation to engage with structured exercise programmes.

Chapter 4 Ensuring design fidelity in behavioural interventions: A novel method for assessing design fidelity and its application to the assessment and improvement of the design of a web-based intervention combining behavioural activation and physical activity

4.1 Chapter Outline

Chapter 3 (intervention development) described the development and theoretical framework of the eMotion intervention. The intervention description contains the key change objectives of eMotion, the behaviour change techniques (BCTs) used to target each change objective, and the strategy used to operationalise each BCT. Chapter 2 (systematic review) highlighted that although "design fidelity" is part of the The National Institute for Health Behaviour Change Consortium (NIH BCC) framework, there were no studies which assessed the extent to which intended BCTs, consistent with the underpinning theory or logic model, are clearly articulated in intervention materials (e.g. web-based systems, protocols, manuals) for behavioural interventions targeting physical activity (Lambert et al., 2017). Design fidelity is defined as the extent to which active ingredients of an intervention are operationalised as intended (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005). The purpose of chapter 4, is to propose a new way to assess design fidelity and test this approach on the eMotion intervention. The purpose of chapter 4 is to provide a rationale for assessing design fidelity in behavioural research. Provide a detailed description of the method used to assess design fidelity. Provide the results of assessing design fidelity for eMotion and discuss the implications of assessing/not assessing design fidelity in behavioural intervention research.

4.2 A recap on fidelity

Intervention fidelity can be defined as the reliability and validity of behavioural interventions (Bellg et al., 2004). NIH BCC highlight that interventions can fail to represent their intended content and mechanisms of action in terms of their design, provider training, delivery, receipt of the intended

treatment and enactment of the skills promoted (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005). Lack of consideration of intervention fidelity can lead to type 1 (where an intervention which is not faithful to its intended content or mechanisms is incorrectly judged to be effective), or type 2 (where potentially effective interventions are discarded because they did not faithfully deliver the intended content or mechanisms of change) errors (Bellg et al., 2004).

4.3 How is fidelity currently being assessed?

Chapter 2 reported on a systematic review of behavioural interventions promoting physical activity. The review identified a range of methods currently used by researchers to assess fidelity across the domains of training, delivery, receipt and enactment (Lambert et al., 2017). These methods included: using checklists to assess provider competence before delivering an intervention ('training') (Williams, Michie, Dale, Stallard, & French, 2015), observing the presence of intended intervention components during delivery (Hardeman et al., 2008), verifying participants understanding of intervention components ('receipt') (Bodde, Seo, Frey, Lohrmann, Van Puymbroeck, et al., 2012), and observing participant use of intervention components (e.g. goal setting) in participants' day-to-day lives ('enactment') (Brawley et al., 2013). However, there were no examples of studies reporting the assessment of design fidelity.

4.4 Design Fidelity

Assessing design fidelity involves measuring the extent to which behavioural interventions articulate their theoretical models. For design fidelity, the NIH BCC proposes that intervention designers: a) specify and incorporate the active ingredients (or BCTs) in the intervention, b) use a 'panel of experts' to assess intervention protocols to ensure they adequately incorporate the underlying theoretical and clinical guidelines, and c) ensure that the measures reflect the hypothesised theoretical constructs/mechanisms of action (Borrelli, 2011). Several programmes of work have sought to address the first recommendation (i.e., specification of active ingredients in interventions) using taxonomies of behaviour change techniques (BCTs) (Borek, Abraham, Smith, Greaves, & Tarrant, 2015; Hartmann-Boyce, Aveyard, Koshiaris, & Jebb, 2016; Michie et al., 2011; Michie et al., 2013). A BCT is an observable, replicable, component of an intervention, designed to alter or redirect a causal process that

regulates behaviour (Abraham & Michie, 2008). The core aim of taxonomies is to lay the foundation for the design of reliable/replicable behaviour change interventions by enabling precise specification of the active ingredients of existing interventions (Michie et al., 2013). However, design fidelity can be compromised if: a) the intervention designer(s) fail to operationalise intended BCTs in an unambiguous way into the actual intervention content (e.g. web-based interventions, manuals, protocols), or b) the intervention designers include additional BCTs which target different processes to those specified.

4.5 Current advice on assessing design fidelity

A previous study compared the presence of BCTs in 13 published intervention descriptions to their corresponding intervention manuals and found a correspondence rate of only 74% (Abraham & Michie, 2008). These findings indicate that the first potential gap in fidelity occurs at a much earlier stage than delivery. For example, if a BCT is not clearly operationalised in an intervention protocol, you would not expect a provider to deliver it in practice. By contrast, pharmacological interventions are able to use laboratory techniques to confirm the identity of the drug (is it the drug indicated on the label?), assay (how much drug is there and is it consistent with the labelled amount?), impurities (are there process impurities or degradation impurities?), and dissolution (does the active ingredient dissolve out of the dosage unit so that the drug is available for the body to absorb?). The NIH BCC guidance attempts to mimic this process in a behavioural context, by recommending the use of a 'protocol review group' to ensure BCTs are fully specified in intervention content. However, as identified in chapter 2 (systematic review), there is a lack of guidance as to, or examples of, who this 'protocol review group' should comprise of and how to effectively and reliably use them to determine whether the intervention protocol and materials accurately reflect the underlying BCTs in an unbiased way (design fidelity).

4.6 Aims

The main aims of this chapter were as follows. First, to propose a systematic method for assessing the extent to which underlying BCTs are operationalised in behavioural interventions. Second, to test this method using the eMotion intervention materials (as described in chapter 3, intervention development and

appendix 5). Third, to make alterations to eMotion as necessary to increase concordance with the intended intervention design

4.7 Method

4.7.1 Developing a systematic method for assessing the extent to which BCTs are operationalised

Before assessing design fidelity, the intervention developers must first ensure they have a precise specification of the intended content of the intervention. For example, this might consist of an intervention map (Bartholomew et al., 2011), or set of tables derived from the Behaviour Change Wheel (Michie et al., 2011). This specification can be as detailed as resources permit (e.g. specifying BCTs at the level of the intervention, module or text). As no explicit guidance for assessing 'design fidelity' exists, recommendations for assessing other domains of fidelity (Borrelli, 2011) as identified in our systematic review (Lambert et al., 2017) were used to devise a method for assessing the extent to which BCTs are operationalised in intervention content (table 4.1). The resulting method involves an independent coder assessing the presence and location of intended (or non-intended) BCTs in the intervention content (e.g. web-pages, written information, worksheets, and behaviour-tracking devices), session delivery plans, and other delivery materials (e.g. presentation slides, interactive game materials). The coder should be independent of the study design team with experience in using the relevant BCTs and intervention development. The coding criteria (or coding manual) should be developed a priori /before the beginning of the assessment. The intervention content can then be compared against the intervention description to identify areas of concordance or discordance, and researchers can resolve any discrepancies in coding through discussion. Discordant aspects of the intervention (areas where the intervention diverges from the intended design) can then be addressed by refining the intervention materials or intervention description.

Table 4.1: Criteria for assessing the extent to which BCTs are operationalised in intervention content

Domains	Criteria for assessing design fidelity
What should be assessed?	<p>Presence and location of intended BCTs in intervention content (e.g. manuals, protocols, web-based delivery platforms).</p> <p>Presence and location of non-intended BCTs in intervention content (e.g. manuals, protocols, web-based delivery platforms).</p>
How should data be collected?	Audit of intervention content coded according to criteria developed a priori.
Who should assess?	<p>Coders should be versed in use of and coding of BCTs</p> <p>Coders should be independent of the intervention study /its design.</p> <p>Coders should not be aware of where BCTs are located in the content.</p>
How should it be assessed?	<p>Inter-rater reliability (e.g. by using statistical technical techniques) between coders and intervention description (as specified by the intervention developers).</p> <p>Resolved through discussion</p>

4.7.2 Test method on the eMotion intervention

4.7.2.1 Brief summary of eMotion

As a test of the assessment method described above, we assessed the design fidelity of the eMotion web-based intervention, which uses behavioural activation (BA) techniques to simultaneously promote physical activity and reduce symptoms of depression (eMotion). eMotion is based on Self-Determination Theory (SDT) (Deci & Ryan., 1985) and BA principles (Farrand et al., 2014; Hopko et al., 2003; Lejuez et al., 2001; Richards, 2010). The development of eMotion is described in detail in chapter 3. In brief, eMotion was hosted on an online platform for delivery of web-based mental health interventions called Living Life to the Full (Williams et al., 2013). It comprised of

audio-visual modules including an introduction, eight “weekly” modules, three unlockable modules and a problem-solving module. The main aim of eMotion was to help people identify, plan, and review activities which were routine, pleasurable, or necessary, especially activities which include a physical activity component.

4.7.2.2 *Specification of intended content of eMotion*

Intervention mapping (Bartholomew et al., 2011) was used to specify the intervention content (e.g. .BCTs, materials, delivery format) in eMotion and the behaviour change taxonomy v1 (Michie et al., 2013) was used to label the intended BCTs wherever possible (chapter 3, table 3.1, and appendix 5). eMotion contained 17 BCTs based on key processes relating to Self Determination Theory, self-regulation theory (Bandura, 1991), and the principles of BA (Jacobson et al., 2001). Each BCT was intended to specifically target either a general behaviour which can provide a sense of positive reinforcement (i.e. routine, pleasurable or necessary activities), or a behaviour which includes a physical activity component (any bodily movement produced by skeletal muscles that requires energy expenditure (WHO, 2017)). BCTs were inserted into each specific module of eMotion and there were a total of 65 occurrences (at a module level) of BCTs relating to BA, and 53 relating to physical activity across eMotion (figure 4.1). The most frequently used techniques (six or more occurrences) were ‘Demonstration of behaviour’, ‘self-monitoring of behaviour’, ‘graded tasks’, ‘action planning’, ‘goal-setting behaviour’, ‘problem-solving’, ‘review behavioural goal’, and ‘social reward’.

4.7.2.3 *Coding Manual*

The full eMotion intervention description (appendix 5) was used to derive a set of checklist items as a basis for coding (appendix 6). The key aim of the coding manual was to facilitate the reliable identification of the BCTs in the audio-visual (patient-facing) content of eMotion. This coding manual was piloted (with another researcher) by applying the coding framework to a sample of eMotion content to ensure clarity of definitions and examples, and to refine the coding manual where appropriate. Borelli et al. (2011) recommend that an a priori list of proscribed BCTs is also used to ensure non intended techniques are not included in the intervention content. The final coding manual contained

definitions for 17 distinct BCTs, specifically targeting either a general behaviour which can provide a sense of positive reinforcement (i.e. routine, pleasurable or necessary activities) or a behaviour which included a physical activity component (appendix 6).

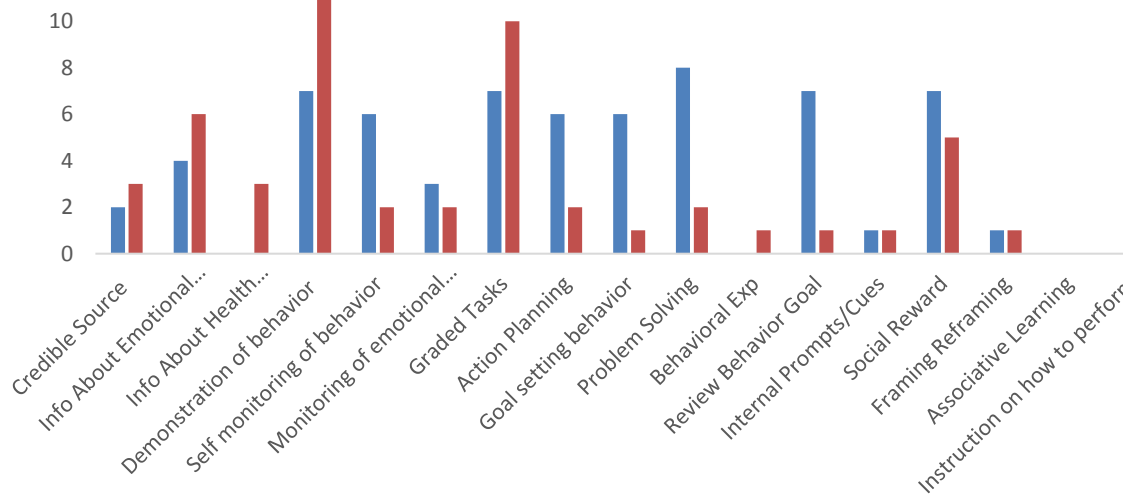


Figure 4.1: Number of modules containing intended techniques for behavioural activation (blue) and physical activity (red)

Table 4.2: Intended BCTs in each eMotion module

Module Name	Intended Module Content (BCTs)^{a,b,c}
Introduction	1a, 2a, 2b
Week 1	1a, 1b, 2a, 2b, 3b, 4b, 5a, 6a, 15a
Week 2	1b, 2a, 2b, 4a, 4b, 6a, 7a, 7b, 8a, 9a, 10a, 12a, 12b
Week 3	4a, 4b, 7a, 8a, 9a, 10a, 12a, 14a
Week 4	4a, 4b, 5a, 7a, 7b, 8a, 9a, 10a, 12a, 14a, 14b
Week 5	4a, 4b, 5a, 7a, 7b, 8a, 9a, 10a, 12a, 14a, 14b
Week 6	4a, 4b, 5a, 7a, 7b, 8a, 9a, 10a, 12a, 14a, 14b
Week 7	4a, 4b, 5a, 7a, 7b, 8a, 9a, 10a, 12a, 14a, 14b
Week 8	2a, 2b, 3b, 5a, 5b, 6a, 6b, 7b, 10a, 12a, 13a, 13b, 14a, 14b
Moving on with physical activity	1b, 2b, 3b, 4b, 7b, 8b, 9b, 10b, 15b, 17b
Monitoring your physical activity	2b, 4b, 5b, 6b, 7b, 8b, 11b
Increasing your physical activity	4b, 7b, 17b
Problem-Solving	4a, 4b, 7a, 7b, 10a, 10b, 14a

^aIntended techniques were not necessarily what were found in the final intervention ^bNumbers and letters correspond with techniques on coding manual (appendix 6) ^croutine, pleasurable or necessary behaviours (a) Physical activity (b)

4.7.2.4 Coding procedures

An independent coder (with no knowledge of the intended location or prevalence of the BCTs and no involvement in the eMotion study) was asked to work through the eMotion platform and rate the presence or absence of the specified BCTs, using the coding manual. The coder had expertise and experience in coding of behaviour change and physical activity interventions. They were provided with the coding manual and instructed to first go through each module, in turn, to familiarise themselves with the content. They were also instructed to read through the manual and ensure they understood all categories, especially the nuances between similar categories. After the first work-through, the coder was asked to work through the intervention again and rate the presence or absence of each BCT (specified in the coding manual) for each module of eMotion. Analysis of the coding responses was conducted for all content including the introductory, core, unlockable, and problem-solving modules. The coder was not instructed to identify the number of instances of a BCT, only whether it appeared at least once, in a module.

4.7.2.5 Analysis

The extent to which BCTs were operationalised as intended was expressed by calculating the inter-rater reliability between the independent coder and the original intervention description. As the prevalence of some of the intended BCTs in the intervention description was very small, the AC1 statistic (Wongpakaran et al., 2013) was used (rather than Kappa statistics) to estimate inter-rater reliability. Inter-rater reliability was calculated for each BCT in eMotion, and clustered by behavioural target (i.e. routine, pleasurable and necessary or physical activities). Discussions were then held between the lead author of the intervention (JL) and the independent coder to resolve any discrepancies. Any unresolved discrepancies were then discussed with another member of the design team and were resolved through further discussion. Design fidelity was defined in terms of the AC1 scores using the following thresholds of agreement: < 0.2 = poor, $0.2 \leq 0.4$ = fairly poor, $> 0.4 \leq 0.6$ = moderate, $> 0.6 \leq 0.8$ good, and $> 0.8 \leq 1$ = very good (Landis & Koch, 2008).

4.7.2.6 *Increasing concordance with the intended design*

After discussion, a contingency table (Table 4.3) was applied to all techniques with less than ‘very good’ reliability scores to guide remedial action to refine the intervention. This procedure was formative and intended to help refine and develop eMotion. However, it was also intended to provide a summative indication of design fidelity that could be used to evidence the extent to which BCTs had been operationalised as intended. The contingency table provided a systematic way of making decisions around BCTs specified in the intervention map which did not align with the intervention content.

Table 4.3: Contingency table for design fidelity

		Independent coder	
		Present	Absent
Intervention Specification	Present	Good design fidelity in terms of intended techniques (no action required)	Designer needs to add technique to content or amend intervention description to reflect its absence
	Absent	Designer removes technique from materials or amends intervention description to reflect its presence	Good design fidelity in terms of non-intended techniques (no action required)

4.8 Results

4.8.1 Development of a method to assess design fidelity

The design fidelity of eMotion intervention was tested using a coding manual comprising of 34 BCTs (17 targeting BA and 17 targeting physical activity). Reliability of identification of BCTs in each eMotion module was tested. Disagreements occurred when the independent coder judged the BCT to be present and the intervention designer judged the technique to be absent (or vice versa). Agreements occurred when both the independent coder and intervention designer judged the BCTs to be present or absent.

4.8.2 Agreement of intended techniques

4.8.2.1 *BCTs targeting behavioural activation (the promotion of routine, pleasurable and necessary activities)*

There was good overall agreement with BCTs identified by the independent coder in eMotion and the intervention description for R, P, and N activities ($AC1 = 0.72$) with a total of 37 (out of a possible 221) discrepancies (figure 4.2). Good to perfect levels of agreement (>0.6) were found for the following BCTs: credible source, information about health consequences, problem-solving, behavioural experiments, review behavioural goal, internal prompts/cues, social reward, framing/reframing, associative learning, instruction on how to perform a behaviour, and graded tasks. Information about emotional consequences, goal setting, and self-monitoring of behaviour had a moderate agreement ($0.4 - 0.6$). Those with the poorest agreement (≤ 0.4) were demonstration of behaviour, monitoring of emotional consequences, and action planning. Discussion between the independent coder and one of the intervention designers raised overall agreement considerably ($AC1 = 0.91$) yielding a total of 12 remaining discrepancies (figure 4.3). Demonstration of behaviour and monitoring of emotional consequences still had poor design fidelity ($AC1 < 0.4$) with monitoring of emotional consequences being present when not intended, and demonstration of behaviour not being present when intended (according to the opinion of the independent coder). The remaining discrepancies were then subjected to the contingency table (table 4.3).

4.8.2.2 BCTs targeting physical activity

There was good overall agreement with BCTs identified by the independent coder in eMotion for BCTs relating to physical activity ($AC1 = 0.67$) with a total of 44 (out of a possible 221) discrepancies (figure 4.2). Good to perfect levels of agreement (> 0.6) were found for the following BCTs: credible source, information about emotional consequences, information about health consequences, graded tasks, action planning, goal setting behaviour, problem-solving, behavioural experiments, internal prompts/cues, social reward, framing/reframing, associative learning, and instruction on how to perform a behaviour. Demonstration of behaviour, self-monitoring of behaviour, monitoring of emotional consequences, and review behavioural goal had the poorest agreement (≤ 0.4). Discussion between the independent coder and one of the intervention designers raised agreement, ($AC1 = 0.88$) with a residual total of 16 discrepancies (figure 4.3). The BCTs demonstration of behaviour and monitoring of emotional consequences still had the poorest agreement with monitoring of emotional consequences being present when not intended, and demonstration of behaviour not being present when intended (according to the opinion of the independent coder). The remaining discrepancies were then subjected to the contingency table (table 4.3).

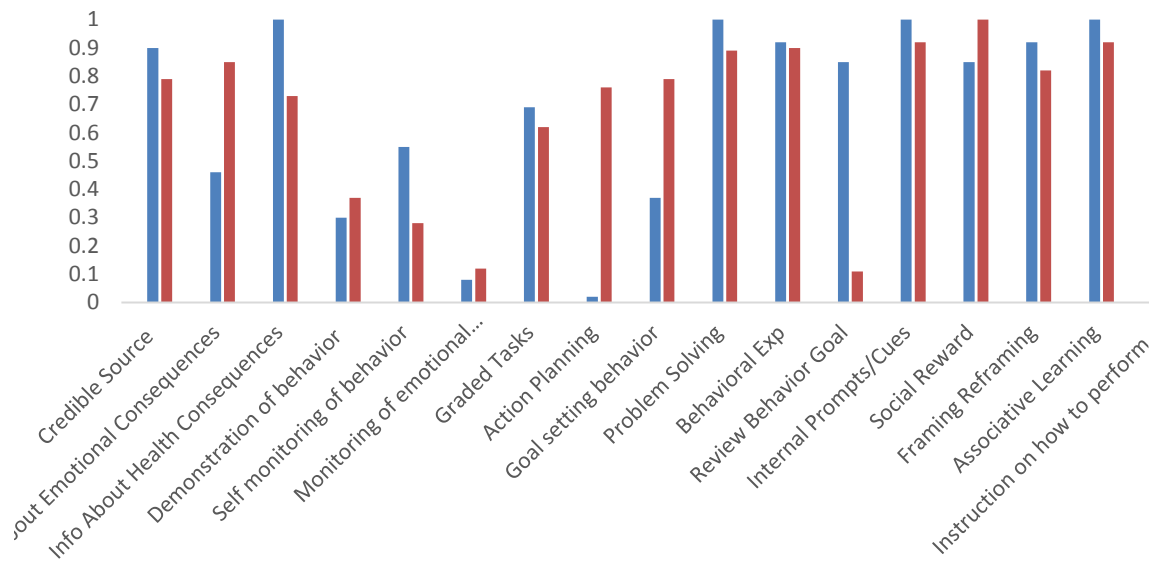


Figure 4.2: Agreement (AC1) of intended techniques for behavioural activation components (blue) and physical activity components (red) before discussion.

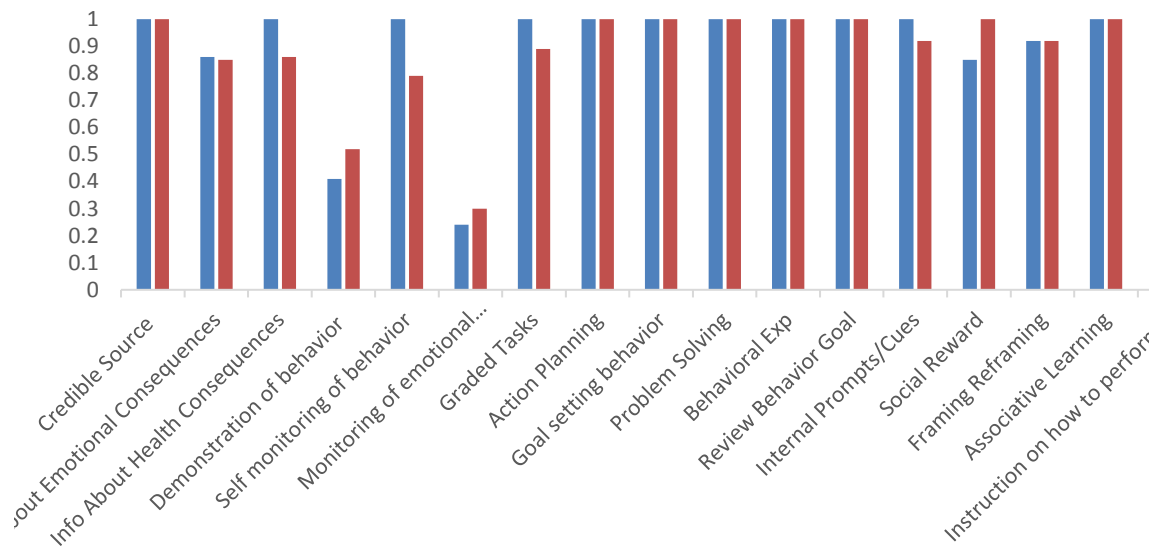


Figure 4.3: Agreement (AC1) of intended techniques for behavioural activation components (blue) and physical activity components (red) after discussion.

4.8.3 Applying the contingency table

After application of the contingency table (table 4.3), for BCTs targeting routine, pleasurable or necessary activities, one instance of 'social reward', one instance of 'framing/reframing' and four instances of 'demonstration of behaviour' were removed from the intervention description as they were not adequately reflected in the content as intended. One instance of 'information about emotional consequences' and five instances of 'monitoring of emotional consequences' were added to the intervention description. These changes resulted in perfect agreement between the intervention specification and the independent coder (AC1 =1.0). For BCTs targeting physical activity, one instance of 'self-monitoring', one instance of 'internal prompts/cues', one instance of 'framing/reframing' and three instances of 'demonstration of behaviour' were removed from the intervention description as they were not adequately reflected in the content as intended. One instance of 'information about emotional consequences', one instance of 'information about health consequences', one instance of 'demonstration of behaviour', one instance of 'graded tasks', one instance of 'self-monitoring of behaviour' and five instances of 'monitoring of emotional consequences' were added to the intervention description as they were present in the intervention content, although not originally in the intervention description. These changes resulted in perfect agreement between the intervention specification and the independent coder for all BCTs targeting physical activity (AC1 =1.0) (table 4.4). Due to perfect agreement, further consultations with the design team were not necessary.

Table 4.4: Amended module content in eMotion after applying contingency table

Module Name	Removed techniques	New techniques	Updated BCTs in eMotion description *
Introduction		4b	1a, 2a, 2b, 4b
Week 1	15a		1a, 1b, 2a, 2b, 3b, 4b, 5a, 6a
Week 2			1b, 2a, 2b, 4a, 4b, 6a, 7a, 7b, 8a, 9a, 10a, 12a, 12b
Week 3	4a, 4b	2a, 2b, 6a, 7b,	2a, 2b, 6a, 7a, 7b, 8a, 9a, 10a, 12a, 14a
Week 4	4a	6a, 6b	4b, 5a, 6a, 6b, 7a, 7b, 8a, 9a, 10a, 12a, 14a, 14b
Week 5	4a	6a, 6b	4b, 5a, 6a, 6b, 7a, 7b, 8a, 9a, 10a, 12a, 14a, 14b
Week 6	4b	6a, 6b	4a, 5a, 6a, 6b, 7a, 7b, 8a, 9a, 10a, 12a, 14a, 14b
Week 7	4a	6a, 6b	4b, 5a, 6a, 6b, 7a, 7b, 8a, 9a, 10a, 12a, 14a, 14b
Week 8	5b, 13b		2a, 2b, 3b, 5a, 6a, 6b, 7b, 10a, 12a, 13a, 14a, 14b
Moving on with physical activity	15b	6b,	1b, 2b, 3b, 4b, 6b, 7b, 8b, 9b, 10b, 17b
Monitoring your physical activity			2b, 4b, 5b, 6b, 7b, 8b, 11b
Increasing your physical activity		3b, 5b	3b, 4b, 5b, 7b, 17b
Problem-Solving	4b, 14a		4a, 7a, 7b, 10a, 10b
Total			130

*Numbers and letters correspond with behaviour change techniques on coding manual (appendix 6).

4.9 Discussion

4.9.1 Summary of findings

This chapter aimed to develop and pilot a methodology to assess the extent to which intended BCTs were present in the content of the eMotion intervention, and provide recommendations for refining the intervention. The study presents a novel methodology for checking intervention design fidelity, using independent coding to systematically check the presence or absence of intended and non-intended theoretical components. An application of the method to the development of eMotion identified (post-discussion) discrepancies relating to 12 out of 221 (AC1 =0.91) and 14 out of 221 (AC1 = 0.88) BCTs for BA and physical activity respectively. The intervention or its description were then amended to remove all discrepancies.

The method proposed can be applied to checking that intervention content fully represents its component BCTs or to checking theoretical integrity (the degree of fit between specified BCTs and proposed processes of change as specified in a logic model or specification of the underpinning intervention theory). Intervention designers could use this method in a summative way and provide the inter-rater reliability score as an indicator of design fidelity in their own interventions (e.g. for the purposes of systematic reviewing), or in a more iterative formative manner, to help improve design fidelity at the development stage (as exemplified here).

Much work has already been conducted to specify a process for mapping BCTs to theoretical determinants (Cane, O'Connor, & Michie, 2012), and articulate BCTs using a common language (Abraham & Michie, 2008; Michie et al., 2013). Also, guidelines have been developed for intervention reporting (Bellg et al., 2004; Borek et al., 2015; Borrelli, 2011; Borrelli et al., 2005; Hoffmann et al., 2014). The present study seeks to complement these existing approaches by presenting a method for assessing the extent to which BCTs are sufficiently operationalised (i.e. present as intended) in behaviour change interventions. The basic method could be extended to other complex behavioural interventions which combine multiple behavioural targets (e.g. (Taylor et al., 2014; Ussher et al., 2015)

4.9.2 Relation to other literature

Overall, the results suggest that the BCTs of eMotion were operationalised as intended. However, there was a low agreement for specific BCTs ('demonstration of behaviour' and 'monitoring of emotional consequences') indicating a slight lack of concordance between the intervention description and its corresponding content. Our process enabled us to address these discrepancies by removing or adding techniques to the intervention description where appropriate. The low agreement for 'demonstration of behaviour' could have been due to ambiguity around the definition. In a recent study, coders found it hard to distinguish between 'demonstration of behaviour' and 'instruction on how to perform a behaviour', despite achieving modest reliability results (Abraham et al., 2015).

The minimal overall content that needed changing was encouraging, and indicates that many of the BCTs were indeed 'operationalised as intended'. Having clear, checked, operationalisations of BCTs in the intervention content, as well as the training materials (e.g. delivery protocol) can ensure that correct training, delivery, receipt, and enactment takes place. In a previous study investigating the delivery of a behavioural intervention for physical activity (Proactive), it was found that only 44% of pre-specified BCTs were delivered by facilitators (Hardeman et al., 2008). Poor delivery may have been due to the facilitators own biases or insufficient training. However, it may also have been a result of inadequate operationalisation of techniques in the manuals and protocol that informed the training and delivery. This highlights the many stages at which intervention fidelity can fail (design, training, delivery, receipt, enactment) (Borrelli, 2011). It is essential, therefore, to have robust methods for assessing fidelity at each step, so that process evaluations can determine what factors may have caused an intervention to fail (or succeed) and what aspects could be improved for future implementation or research.

The NIH BCC recommends a list of strategies to enhance (e.g. by providing precise information about intervention dose) and assess fidelity which they then applied in a review of ten years of health behaviour research (Borrelli et al., 2005). In this study, 80%, 22%, 35%, 49%, and 57% of the 342 included articles showed evidence of adhering to strategies relating to design, training, delivery, receipt, and enactment, respectively (Borrelli et al., 2005). Although

80% was reported for design (which appears high), only strategies to enhance (rather than assess) design fidelity were recommended (e.g. provide a manual), with assessment only proposed in later work (Borrelli, 2011). This study progresses this field of research by clearly articulating a method for assessing design fidelity.

Ideally, this process would be most beneficial by ensuring an intervention reflects its proposed specification (after a careful process of intervention mapping). In the present study, this was not possible due to resource constraints. However, this process served the purpose of identifying discrepancies between the intervention content and the description, increasing convergence. This ensured a more accurate reflection of what the actual eMotion intervention description reported, as opposed to just what the design team intended. This could provide further scientific confidence to other intervention designers, reviewers, and adopters.

4.9.3 Strengths and Limitations

The main strength of this study is that we have developed and tested a novel methodology for enhancing the scientific confidence of BCTs present in behavioural interventions. We used an independent coder (who had no part in the development of eMotion) who was experienced in using behaviour change taxonomies (Elliott, White, Taylor, & Abraham, 2016) to code the intervention. This reduces the possible bias of finding BCTs due to previous knowledge of the intervention development process. We also used a robust statistical approach to check inter-rater reliability. However, several limitations should be acknowledged. Each researcher interprets the data according to their subjective experience which could lead to disagreements regarding either the presence or absence of BCTs or regarding the BCT definitions themselves (inter-rater reliability for coding of BCTs is far from being perfectly reliable for most BCTs) (Abraham & Michie, 2008). Hence, a more substantial 'panel of experts' might have been used to further enhance: a) assessment reliability, and b) the design fidelity of the eMotion intervention. Another limitation is a potential priming effect which could come as the coder works their way through the intervention. eMotion is developed in a modular format, with some modules looking very similar. An awareness of whether specific BCTs are supposed to occur could make the coder more likely to highlight them as present, even if they are not.

Finally, coding was done on a modular level, however, the 'dose' of BCT's could have been mapped at smaller units of analysis (e.g. slide by slide). However, this would be far more resource intensive and a compromise between rigour and pragmatism was adopted in the present study.

4.9.4 Future research

Future work could apply this same method using all techniques in an established BCT taxonomy (Michie et al., 2013), instead of an intervention-specific list; providing systematic coverage of all options helps to identify a fuller range of unintended techniques. The method can also be applied at the level of the whole intervention, module by module, or at a more granular level, as was the case in a recent line-by-line content analysis of brochures to promote walking (Elliott et al., 2016). The latter approach would undoubtedly be more resource intensive but could shed more light on the 'dose' rather than simply the presence or absence of intervention content. A more pragmatic approach could be to use a scaled down check in which BCTs are weighted by importance of likely effect (based on evidence) and when they are expected to be delivered, so only the 'core' BCTs are actually searched for by an independent coder.

The present intervention was informed by intervention mapping (Kok, Schaalma, Ruiter, Van Empelen, & Brug, 2004) which could explain the fact that there were so few discrepancies after discussion. Further research could test this empirically by assessing and comparing design fidelity for interventions which did or did not use intervention mapping or other intervention design frameworks (Bartholomew et al., 2011; Michie et al., 2011). Finally, this approach could be used in future interventions to confirm differentiation of intervention and comparator arms (i.e. the extent to which an intervention differs from a comparator or control group along critical domains). A similar approach has been proposed in a recent protocol by Lorencatto et al., (2016).

4.9.5 Conclusion

When developing behavioural interventions, it is important to assess fidelity across all five domains of the NIH BCC framework, as a lack of fidelity in any one domain could affect study outcomes, as well as generating errors in interpretation of evidence from evaluations of the intervention. This chapter has developed and tested a new method for assessing the domain of design fidelity,

which researchers have previously overlooked. This method can also be used to systematically improve design fidelity at the intervention development stage, as illustrated by its application to the eMotion intervention in the current study.

Chapter 5 The eMotion Pilot Trial: Design and Methods

5.1 Chapter Outline

The effect of physical activity on depression is well studied (Cooney et al., 2013; Mead et al., 2009; Nyström et al., 2015; Rebar et al., 2015). The possible mechanisms (Craft & Perna, 2004; Fox, 1999) and optimal dose (Nyström et al., 2015) of physical activity as a treatment for depression have also received attention. However, researchers need to translate these findings into feasible and practical interventions that help people initiate and maintain physical activity and are also acceptable to patients and providers (Taylor & Faulkner, 2014). Chapter 1 reviewed the key studies which have evaluated interventions promoting physical activity for depression and identified that there is a lack of good quality evidence. Chapter 1 also identified important methodological issues around measuring physical activity and fidelity, as well as a need to understand the mechanisms influencing behaviour and mood. Chapter 3 (eMotion development) described the development of a web-based intervention promoting physical activity for the treatment of depression. Chapter 5 describes the design and methods of a pilot randomised controlled trial (RCT) of the eMotion intervention.

5.2 Chapter aims

The purpose of the present chapter is to report on the methods of a pilot RCT and parallel process evaluation designed to inform the planning of a future RCT of the eMotion intervention. The key aims of the pilot RCT (results reported in Chapter 6) were to:

- Explore participant recruitment and attrition rates throughout the study.
- Explore the feasibility and acceptability of data collection and study procedures.
- Examine baseline data, including levels of physical activity and baseline differences between groups.

- To explore the fidelity of delivery of the intervention (usage) and its acceptability to participants.
- To estimate and explore the variance in key outcomes (depression scores and physical activity).

5.3 Trial Design

The eMotion trial was a two-arm, individually randomised, parallel group pilot RCT with a nested process evaluation (ClinicalTrials.gov Identifier: NCT03084055). The study is reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) recommendations for reporting of pilot RCTs (Boutron, Moher, Altman, Schulz, & Ravaud, 2008) and the Template for Intervention Description and Replication (TIDieR) recommendations on reporting of behaviour change interventions (Hoffmann et al., 2014). Following identification and recruitment, participants were randomised to receive either an eight-week, web-based, self-delivered intervention (eMotion) with 'minimal contact' facilitation (Farrand & Woodford, 2013) or to join a waiting list control group. A mixed-methods parallel process evaluation using quantitative and qualitative methods was conducted alongside the eMotion pilot RCT. The process evaluation was guided by the Medical Research Council (MRC) guidelines on the conduct of process evaluations (Moore et al., 2015) and the framework for understanding physical activity and mental health relationships (Taylor & Faulkner, 2014). The detailed methods and results of the process evaluation are reported in chapter 7.

5.4 Participant Flow

5.4.1 Eligibility criteria

Participants were eligible for the study if they: were over 18 years old, were living in the UK, had at least moderately severe depressive symptoms (defined as scoring at least 10 on the Patient Health Questionnaire 8 (PHQ-8)), had access to the internet, were able to walk continuously and unaided for a minimum of five minutes and provided informed consent to participate. No threshold was placed on baseline physical activity levels as we wished to assess the baseline physical activity levels of those recruited using a

recruitment approach that was non-explicit regarding the physical activity component of the intervention.

5.4.2 Recruitment

Adults with depressive symptoms in the community were recruited via advertisements in weekly newspapers, online advertising (e.g. Google, Facebook) and through banners on websites relating to mental health problems. All adverts contained the primary investigator's contact details. Potential participants did not need to be referred by a general practitioner or mental health care practitioner. Figure 5.1 shows the participant flowchart.

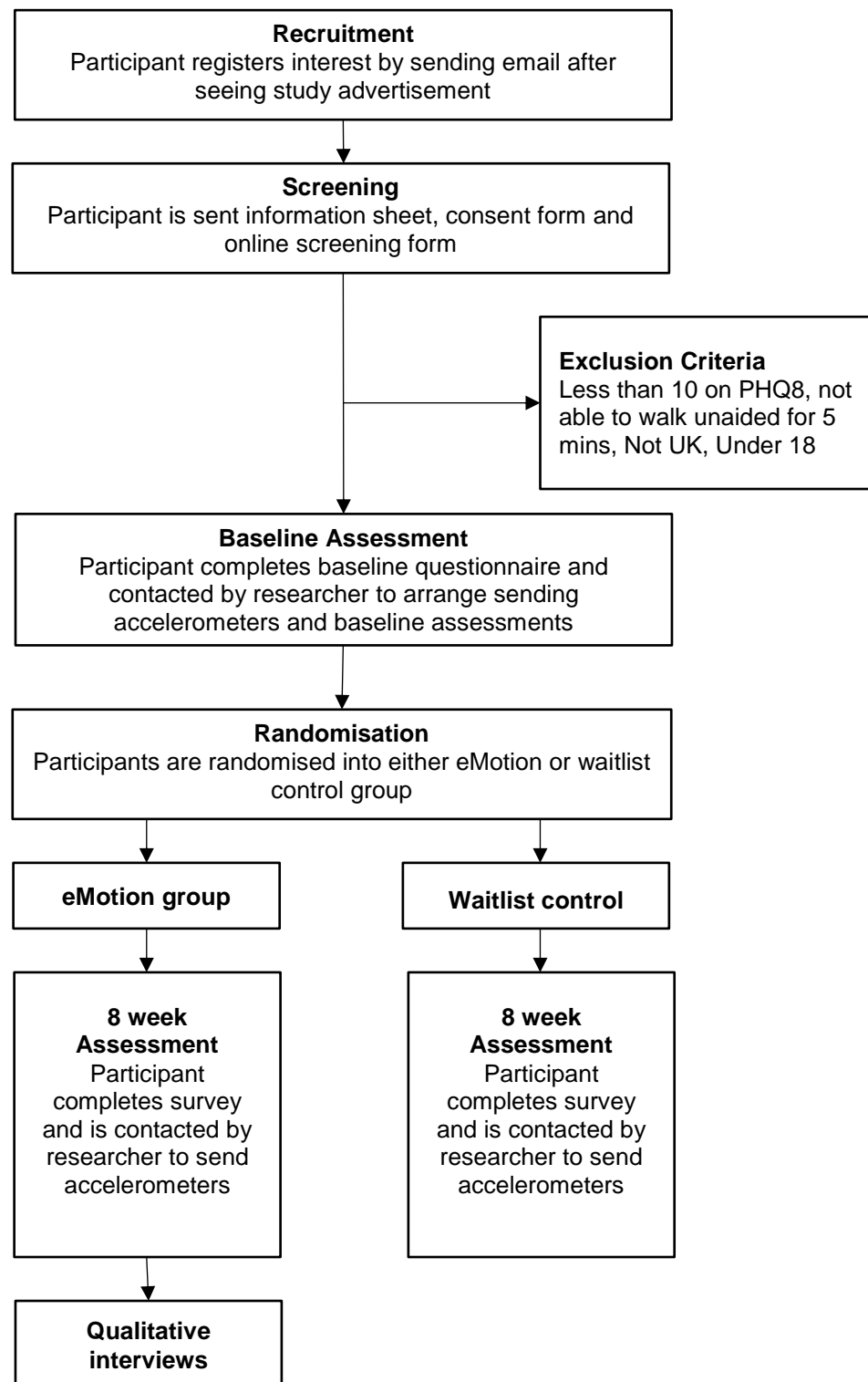


Figure 5.1: Intended participant flow through eMotion

5.4.3 Sample size

Due to the pilot nature of the study, no formal sample size calculations were conducted. However, to ensure a suitably reliable estimate of the standard deviations to power a future trial with 90% power, at least 15 people per arm are recommended if the expected effect size lies between 0.3 and 0.7 (Whitehead, Julious, Cooper, & Campbell, 2015). A previous meta-analysis of computer-based psychological treatments for depression reported a moderate effect size (0.56) and a drop-out rate of 57% (Richards & Richardson, 2012). As such, we opted for a target sample size of 62 (accounting for a possible attrition rate of 50%) to ensure we had at least 15 people per arm at follow up.

5.4.4 Screening

After contacting the researcher by phone or email, potential participants were sent the participant information sheet (PIS) (appendix 7), consent form (appendix 8), and a link to the screening questionnaire, all via email. At this point, they were informed that they could withdraw from the study at any time without consequence. Participants were also informed that they were under no obligation to provide a reason for withdrawing from the trial, but it would be helpful to have this information to inform the planning of our future research and were asked to consent if they were willing to be contacted under these circumstances. Once participants read the PIS, they were asked to complete the online consent form. The consent form was followed immediately by a screening questionnaire, which the principal investigator (PI) used to assess the eligibility of each participant.

5.4.5 Baseline measurement

After the screening was complete, baseline measures were administered via a separate online questionnaire, and a wrist-worn accelerometer was sent through the post. The participant was instructed to wear for the accelerometer for seven days and return it in a pre-stamped and addressed envelope. However, participant agreement to wear an accelerometer did not preclude randomisation.

5.4.6 Randomisation and allocation concealment

Once participants completed the baseline assessment, they were randomly allocated to either the intervention or waitlist control using simple randomisation at the individual level on a 1:1 ratio using an online randomisation service (Sealed Envelope Ltd. 2016). Non-identifiable participant numbers were entered into the website by the principal investigator in a consecutive manner (in the order of completed baseline assessment), and the randomisation service allocated them to either group A (eMotion) or group B (waiting list). A copy of the randomisation list can be seen in appendix 9. Participants randomised to the intervention arm were contacted by the PI by email and provided with a link to the intervention. They were then followed up by phone (by the eMotion supporter) to ensure they had registered for the website and knew what the first steps were.

5.4.7 Blinding

Due to limited resources for the study, following randomisation the PI was not blinded to which condition each participant was allocated. Due to the nature of the intervention, it was also impossible to blind participants to group allocation. However, as outcome measures were taken electronically, there was a reduced chance of observer bias as there was a reduced chance for PI to influence the participant's responses, or for the PI to misinterpret responses or introduce subjective bias into recorded observations.

5.4.8 Two months post-randomisation

Two months after randomisation, participants were sent an email with the link to an online survey (the questionnaire measures) and asked if they would be prepared to wear the accelerometer again. They were also called to confirm if they were happy to wear the accelerometer again if they did not respond to the email. Participants were contacted again if they did not respond after one week. If after this, there was still no response, participants were considered to have dropped out of the trial. Participants were not sent an accelerometer unless either an email or verbal confirmation was received. Within one month of the final intervention session, all participants who received eMotion were also invited to participate in a semi-structured interview over the phone. The purpose

of this was to further examine the acceptability of the intervention and to elicit suggestions for its improvement.

5.5 Intervention

5.5.1 eMotion

eMotion is a minimal contact (Farrand & Woodford, 2013) adapted self-help program based on the Behavioural Activation (BA) and Physical Activity (BAcPac) intervention (Farrand et al., 2014; Pentecost et al., 2015), administered online, and consisting of weekly text and audio modules with additional interactive worksheets. BA and physical activity promotion form the core of eMotion. The intervention is informed by previous BAcPac treatment manuals used in face-to-face settings with people with depression (Ekers, Richards, McMillan, Bland, & Gilbody, 2011; Farrand et al., 2014; Lejuez et al., 2001; Rhodes et al., 2014). The overall premise of BA is to (re)-engage participants in activities which provide positive reinforcement for non-depressed behaviour (e.g. seeing friends is positively reinforced with pleasurable feelings, resulting in repeated behaviour) as opposed to negative reinforcement which encourages avoidance and depressed type behaviours (see Chapter 3, section 3.6 and table 3.4 for a full description).

5.5.2 Support/Facilitation

Participants assigned to eMotion were provided with 'minimal contact' administrative support (Farrand & Woodford, 2013). This support provided the participant with a rationale for the use of self-help materials and check-ins related to progress (but with no focus on any clinical or behaviour change issues). This support was provided in week two of the intervention. The eMotion supporter was given access to a dashboard which documents the participant's progress through eMotion and their level of engagement. The role of the supporter was mainly to offer encouragement and feedback on progress through the intervention (not on clinical issues) and to provide a sense of accountability (Andersson, 2010). Support materials for the eMotion supporter included an introduction to the website, a fidelity worksheet to document required issues to cover whilst on the phone to participants, instructions on what to do in the case of an adverse event (e.g. suicidal ideation) and advice that their primary role was to facilitate use of the website and not offer any clinical

support (e.g. if participant is having issues thinking of activities, try and provide examples). The support materials and instructions were designed for use by undergraduate or postgraduate volunteers in psychology or related disciplines. However, for pragmatic reasons, in this study, the support was delivered by the PI.

5.6 Control (Waiting list)

Participants in the waiting list control group received no treatment. After data collection at the two-month time point, they were given access to eMotion to use at their leisure.

5.7 Data Collection

All participants were assessed at baseline and two months post-randomisation after baseline measures were collected (table 5.1). All data collection forms can be found in Appendix 10. The primary quantitative measures of interest for the pilot RCT related to feasibility (i.e. recruitment, retention, and data collection) and acceptability of trial methods and intervention engagement. Outcome measures to be used in the main trial were also collected. Results from the pilot RCT are reported in chapter 6.

Table 5.1: Schedule of outcome and process measures in the eMotion pilot study

Assessment	Screening	Baseline	2 months post randomisation
Demographics	x		
PHQ-8	x		x
GAD		x	x
IPAQ		x	x
PA measured using an accelerometer		x	x
Fidelity (Delivery) ^a			x
Fidelity (Receipt) ^b			x
Fidelity (Enactment) ^b			x
CSQ - SF ^{a,b}			x
Interviews ^{a,b}			x

^aeMotion group only, ^bProcess evaluation measures

5.7.1.1 Recruitment and attrition

Participant recruitment rates were measured by calculating the absolute number of people randomised into the trial relative to those who expressed an initial interest in the study. Given the advert-placing nature of the recruitment process, it was not possible to collect data on the number of people “invited” to the study. Participant attrition was defined as the percentage of randomised participants who did not provide primary outcome data (PHQ-8) at the two-month data collection point.

5.7.1.2 Feasibility of Data collection

Follow-up data collection was scheduled to take place two months post-randomisation, using a similar web-based questionnaire to the one administered as part of the baseline assessment. Feasibility of data collection was explored by assessing the extent to which the online questionnaires were completed as intended. The number of completed screening, baseline and two-month post randomisation questionnaires was assessed. For accelerometers, the number of devices which were sent out and returned at baseline and two months follow up was assessed as well as the amount of valid wear time. Reasons for any missing data were tabulated.

5.7.2 Primary outcome measures for the main study

All primary outcome measures administered are in appendix 10.

5.7.2.1 Depression

The Patient Health Questionnaire (PHQ-8) is the intended primary outcome measure for a future trial of eMotion, and it is recommended for use in clinical trials where questionnaires are self-delivered (Kroenke & Spitzer, 2002). The PHQ-8 was delivered at screening and two months post-randomisation using an online version of the questionnaire which the participant self-completes. The PHQ-8 is a freely available eight item self-report measure based on symptoms of depression described in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV). It measures the frequency of depressive symptoms over the preceding two week periods. A score of at least ten on the PHQ-8 has a positive likelihood ratio of 28 for detecting major depression (i.e. a patient with any depressive disorder is 28 times more likely to have a PHQ-8

score between that range of 10 to 24 than someone without a depressive disorder (Kroenke et al., 2009). Each item is rated on a scale of 0 to 3, producing a range of scores from 0 to 24 (0 – 4 (no depression), 5-9 (mild depression), 10 -14 (moderate depression), 15 – 19 (moderately severe depression) 20 -24 (severe depression). The PHQ-8 has been shown to have good validity, reliability, sensitivity and specificity. It has also been shown to discriminate between levels of major and major severe depression, with cut-off scores of 10-19 and 20-23 respectively (Kroenke et al., 2009). This criterion has been used in previous web-based intervention studies of low mood and depression (Baumeister et al., 2014).

5.7.3 Secondary outcome measures for the main study

5.7.3.1 Objective Physical Activity

GENEActiv Accelerometers were used to record physical activity at baseline and two months post randomisation. The GENEActiv is a small wrist-worn device that measures and records acceleration. Data were summarised into “ epochs” of one minute (as recommended in previous studies (Helgadóttir, Forsell, & Ekblom, 2015; Mailey et al., 2010)) to provide a measure of movement, with higher counts per minute reflecting higher levels of physical activity. A recording window of seven days (to initiate three days after being posted), recording at 100Hz, was pre-set to account for transits in the post while optimising the battery life of the device. Participants were mailed the device before randomisation and instructed to put the device on and wear it all day and night for seven days from the following morning, without changing their routine physical activity. Participants were given a record sheet to indicate when they started and stopped wearing it and any times during which the device was removed. The raw acceleration data from accelerometers was uploaded to a personal computer using GENEActiv software (version 3.1; ActivInsights, Kimbolton, UK) and converted to a signal vector magnitude using R (version 3.1.1). To be considered valid for analysis, data was needed for at least four days with a minimum of 10 hours, including at least one weekend day. Total physical activity was summed as average counts per minute. Light (LPA), moderate (MPA), vigorous (VPA), and moderate and vigorous (MVPA) physical activity were derived using established cut-offs points (Esliger et al., 2011).

Active “bouts” were defined as being periods of ≥ 10 minutes of sustained MVPA.

5.7.3.2 Self-reported physical activity

Minutes per week of MVPA were estimated using the International Physical Activity Questionnaire-Short Form (IPAQ-SF) at baseline and two months post-randomisation using an online questionnaire. The IPAQ-SF is a valid measure of self-reported physical activity (Craig et al., 2003) and has been used in previous behavioural trials promoting physical activity for depression (Nyström et al., 2017; Ström et al., 2013) as well as being the most frequently used measure in web-based studies for physical activity (Joseph, Durant, Benitez, & Pekmezi, 2014). The IPAQ-SF asks questions about time spent in the last seven days being active at different levels of intensity and time spent sitting still. The data were converted into daily time of MVPA and also into Metabolic Equivalent Task (MET)-minutes, (Craig et al., 2003) which is a measure of total energy expenditure. MET-minutes are calculated by multiplying the time doing an activity by the metabolic energy expenditure level for that activity (e.g. walking = 3.3 METs, moderate activity = 4.0 METs, vigorous = 8.0 METs). If data were missing, or if the response was ‘refused’ or ‘don’t know’, then that case was removed from any analysis requiring that value. Data were also truncated to avoid over-reporting errors by applying a cap of 180 minutes per day for vigorous activity, moderate activity or walking.

5.7.3.3 Anxiety

The General Anxiety Disorder scale (GAD-7) is a seven-item four-point scale (0-3) and was used to assess anxiety at baseline and two months post-randomisation using an online questionnaire. The GAD-7 measures the severity of anxiety symptoms over the past two weeks based on the DSM-IV criteria and is included in the minimum Improving Access to Psychological Therapies (IAPT) data set. The GAD-7 has good reliability, as well as criterion, construct, factorial, and procedural validity. At the cut point of, the GAD-7 has a sensitivity of 89% and specificity of 82% (Spitzer, Kroenke, Williams, & Lowe, 2006).

5.7.4 Demographic data

All demographic measures administered are in appendix 10. Age, gender, level of education (GCSE, A-levels, degree, postgraduate, or doctoral), employment status (full time, part time, homemaker, student, retired or unemployed) current receipt of psychotherapy (yes or no), current receipt of anti-depressants (yes or no), method of recruitment (social media, newspaper, word of mouth or other), ethnicity and location of residence (using postcode) were all collected at baseline using an online questionnaire.

5.7.4.1 Fidelity of intervention delivery

Fidelity of intervention delivery was assessed using website usage statistics that were available from the online intervention database. The database provided individual level data about whether or not the participant registered for eMotion, which modules they accessed and the total time spent on each module.

5.7.4.2 Acceptability

The Client Satisfaction Questionnaire – Short Form (CSQ-SF) is a 4 item measure which was used to assess participant satisfaction with their use of eMotion two months post-randomisation (given to intervention participants only). This measure was administered using an online questionnaire and has been used to assess treatment satisfaction in web-based studies of other interventions for depression (Williams et al., 2013).

5.7.5 Data collection for process evaluation

Additional quantitative and qualitative data were collected for the process evaluation relating to qualitative acceptability data and receipt and enactment of the intervention, and mechanisms of impact on behaviour and mood. Data were collected using survey items, open-ended questions, and semi-structured interviews and these are reported in detail in chapter 7.

5.8 Analysis

Quantitative methods were used to explore: the recruitment and attrition rates of trial participants, the feasibility of data collection and study procedures, baseline data (including levels of physical activity and baseline differences between groups and between dropouts), and fidelity of delivery (usage of

eMotion). Descriptive statistics were produced for all outcomes by trial arm at baseline and two-month follow-up. All quantitative analyses were conducted using Stata SE statistical software release 14 (StataCorp. 2015; College Station, TX). No formal hypothesis-testing relating to primary outcomes was planned as this was a pilot study. However, descriptive statistics were used to assess recruitment and retention rates, and baseline physical activity levels. Baseline demographic and clinical characteristics were presented descriptively as proportions or as means with standard deviations. Two types of exploratory analysis of the primary outcome for the main trial (PHQ-8) were conducted: 1) linear regression models to report changes in depression with 95% confidence intervals around the between-group mean difference and 2) logistic regression models by dichotomising the primary outcome to reflect clinically meaningful change where a reduction to below ten on the PHQ-8 indicates that the person may no longer qualify for major depression (Kroenke et al., 2009). The analyses included those who began treatment and provided follow-up data regardless of treatment compliance. Missing data were not imputed, so only data from participants who provided data at both time points were analysed. Similar analyses were conducted for anxiety, and objective and self-reported physical activity.

5.9 Data collection and management

Standard operating procedures were developed for each stage of data collection to standardise recruitment/retention processes in eMotion and maximise data quality. A number of checks (e.g. weekly double checking data entry with colleagues) were routinely performed to ensure any data inconsistencies arising from either screening, baseline assessment or 2 months post randomisation were identified and resolved at the earliest opportunity. Trial data were entered into a Microsoft Excel 2013 spreadsheet. All data collected via online surveys or accelerometers were downloaded on a weekly basis and kept securely on the university encrypted hard drives.

5.10 Ethics

This study was approved by the University of Exeter Sports and Health Sciences Research Ethics Committee (AM160316-21 151021/B/03). One possible ethical issue in this study was suicide risk in people experiencing

depression. As this was a research study on a non-clinical sample, all participants were advised on the PIS that the study was not a clinical or NHS treatment and that the University and researchers could not take clinical responsibility for the treatment of any conditions they might have including depression (Appendix 7). They were also signposted to other appropriate resources in case they wished to seek formal treatment. If, at any point in the study (e.g. during screening or after inclusion), participants indicated suicidal intent, the University of Exeter Mood Disorders Suicide Risk Protocol (Appendix 11) was invoked.

5.11 Summary of main findings in relation to the thesis

The present chapter presented a detailed description of the methodology employed to collect and analyse the data for the eMotion pilot trial and parallel process evaluation. Chapters 3 and 4 have reported on the development and design fidelity of the eMotion intervention. Chapter 6 will present the quantitative findings relating to the feasibility, acceptability and exploratory outcomes for the eMotion trial.

Chapter 6 The eMotion Pilot Trial Results

6.1 Chapter Outline

The chapter 6 describes the results of the pilot trial concerning feasibility, acceptability and exploratory analysis of the eMotion trial and presents a structured discussion of the findings.

6.2 Recruitment and attrition rates

A total of 183 people responded to the adverts of which 100 completed screening for eligibility (Figure 6.1). Of the 183 individuals who inquired about the study 100 were screened for eligibility and 62 (34% (95% CI: 27 to 41%)) were eligible for inclusion and randomised into the trial. The average monthly recruitment rate was 7 per month (Figure 6.2). In total, 62 people met the inclusion criteria, provided baseline primary outcome data (PHQ-8 and demographics) and were randomised between May 2016 and February 2017 (32 eMotion, 30 Waiting list). Overall attrition for the planned main trial primary outcome (PHQ-8) at two months post-randomisation was 12 people (19% (95% CI: 11 to 31%)). Of those randomised, 58 (94%) participants provided complete secondary outcome baseline measurements (e.g. GAD7, IPAQ-SF) and 52 (84%) provided usable accelerometer data at baseline. At two-month follow-up, 50 (81% of those randomised (95% CI: 71 to 91 %)) provided PHQ-8 (and other survey data) and 24 (39% of those randomised (95% CI: 27 to 52%)) provided usable accelerometer data (with data for at least 3 weekdays and one weekend day >10 hours per day). Mean weekend days of wear time for the accelerometers was 2.0 (SD = 0.2) at baseline and 1.9 (SD = 0.3) at two-month post-randomisation. Mean weekday days of wear time for the accelerometers was 4.8 (SD = 0.3) at baseline and 4.6 (SD = 0.9) at two months post randomisation. Only 47 (76%) and 33 (53%) participants provided valid IPAQ-SF data at baseline, and two months post-randomisation respectively. This lack of usable IPAQ-SF data was due to people providing invalid responses to the IPAQ-SF meaning we excluded the case as per IPAQ-SF scoring guidelines (Lee, Macfarlane, Lam, & Stewart, 2011).

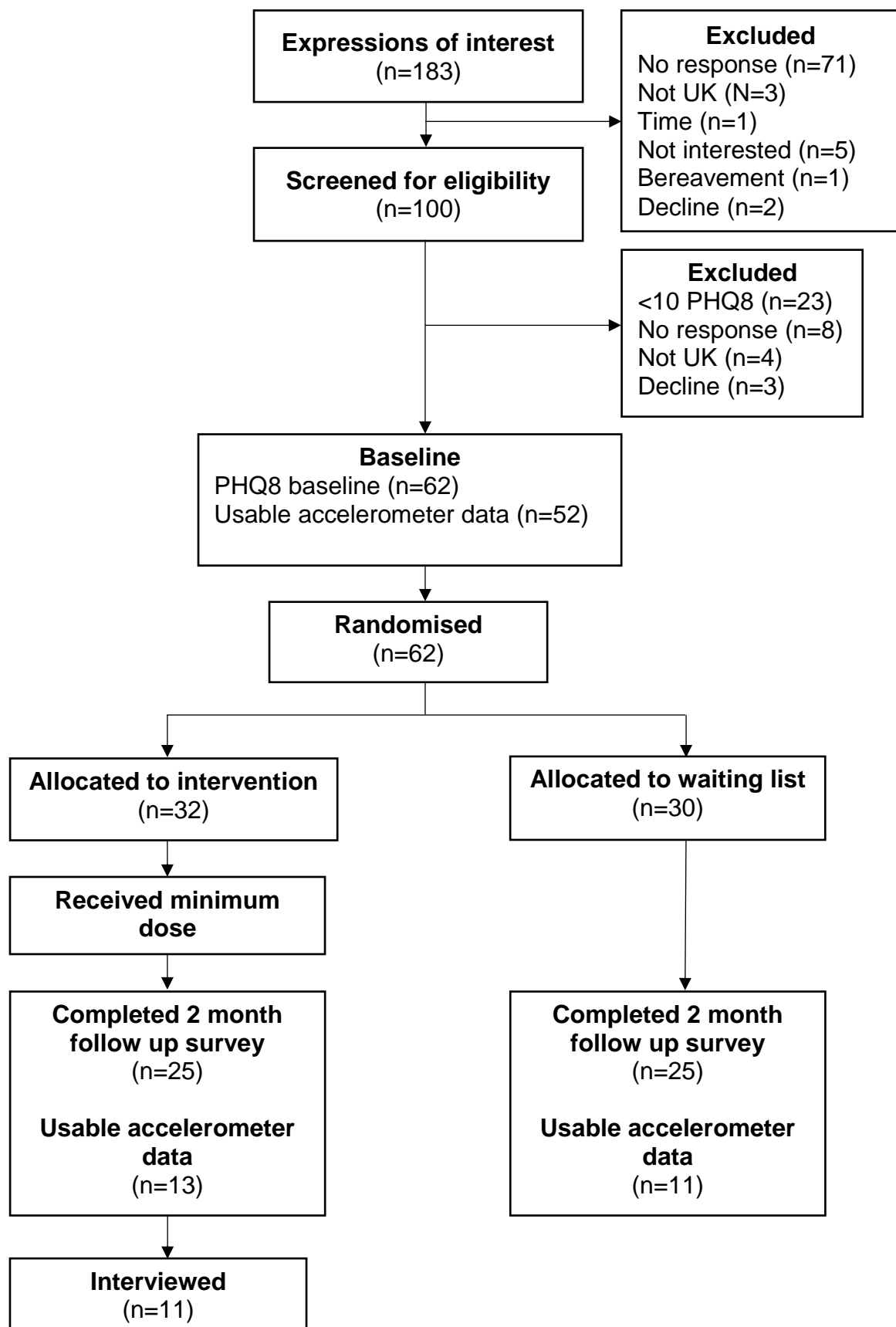


Figure 6.1: Flow of participants through the trial

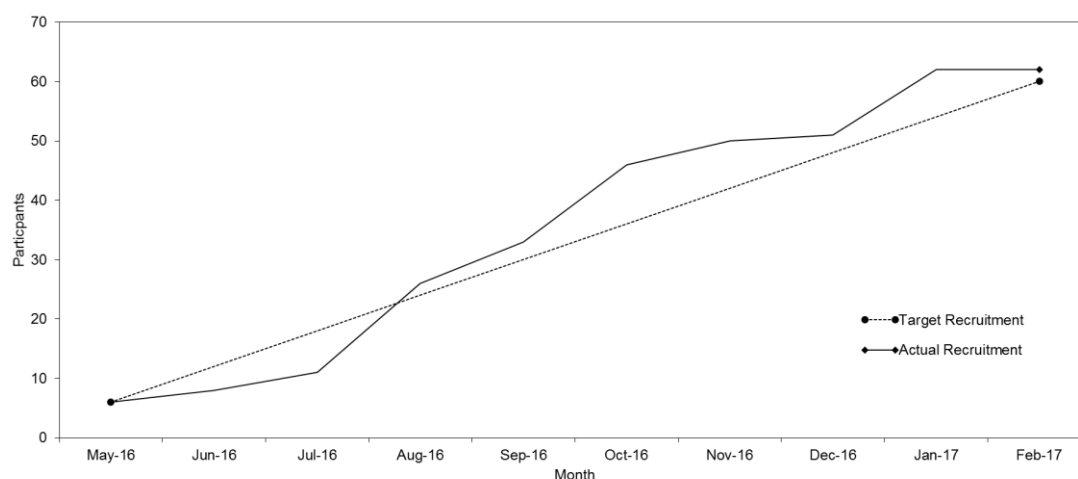


Figure 6.2: Participant target and actual recruitment rates

6.3 Feasibility of accelerometer data collection

At baseline, six accelerometers were not sent out due to participants not responding to the request to wear, or not being allowed to wear it for work, and three accelerometers had data processing problems (technical failure). At follow-up, missing accelerometer data was primarily due to participants not responding to the request to wear the device again (despite still completing the online questionnaire) ($n=13$) or participants being lost to follow-up (not responding in any way) ($n=9$). See table 6.1 for a full list of reasons for missing data.

Table 6.1: Reasons for missing GENEActiv data

Reasons for missing GENE Active	Baseline	Post
Loss to follow-up*		9
Forgetting to wear		1
Not returned		1
Refused as device uncomfortable*		3
Refused to wear the device for work reasons*	2	2
No response to request to wear*	4	13
Invalid data/Unable to extract due to device malfunction	3	1
Under four-day threshold	1	3

*Device not sent out

6.4 Baseline demographic and clinical characteristics

Baseline characteristics are shown in Table 6.2. The mean age was 38 years with 84% being female and 97% classified as white British. Nearly half the sample was recruited through social media (Facebook or Twitter) with the second most popular method being 'word of mouth' (i.e. hearing about the study from friend's family). Participants had a range of educational levels, and most of the sample were employed either part or full-time. The mean score on the PHQ-8 was 14.6 (SD = 3.2), and the average score on the GAD-7 was 11.8 (4.5).

All physical activity data was positively skewed (see example histogram in appendix 12), so medians and interquartile ranges were reported. The median daily total minutes of accelerometer-measured physical activity was 174.3 (IQR = 136.8 to 212.5) for light physical activity (LPA), 53.5 (IQR = 39.8 to 80.7) for moderate physical activity (MPA), 2.9 (IQR = 1.0 to 6.2) for vigorous physical activity (VPA) and 55.2 (IQR = 40.9 to 90.7) for moderate and vigorous physical activity (MVPA). The median weekly total minutes of accelerometer-measured MVPA in at least ten-minute bouts was 35.8 (IQR = 0.0 to 98.6), and only seven people (13%) were achieving at least 150 minutes of MVPA in at least ten-minute bouts per week.

The median level of daily self-reported MVPA was 12.9 minutes (IQR = 0.0 to 25.7). Over half (58%) of the sample were receiving anti-depressants, and 13% were receiving some form of psychotherapy, with a higher proportion receiving therapy in the waiting list control group (n = 7; 23%) than the intervention group (n=1; 3%). The intervention group also had a higher median of 71 minutes of total MVPA per day (IQR = 46.7 to 85.9) compared to only 53 minutes (IQR = 40.2 to 95.5) in the waiting list control group. Finally, the intervention group appeared to be older by two years with a mean of 39.3 (12.0) compared to 36.9 (12.6) in the waiting list control group.

Table 6.2: Participant demographic and clinical characteristics at baseline

	eMotion		Waiting List		Whole Sample	
	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n
Female	26 (81%)	32	26 (87%)	30	51 (83.61%)	62
Age in years	39.3 (12.0)	32	36.9 (12.6)	30	38.1 (12.3)	62
Depression (PHQ-8)	14.4 (3.4)	32	14.8 (2.9)	30	14.6 (3.2)	62
Anxiety (GAD-7)	11.5 (4.7)	31	12.3 (4.2)	27	11.8 (4.5)	58
Physical Activity (Accelerometer)						
Mins per week MVPA in 10 min bouts ^a	29.5 (0.0 to 98.8)	27	42.1 (8.1 to 93.7)	25	35.8 (0.0 to 98.6)	52
Mins per day LPA ^a	176.0 (136.7 to 208.9)	27	172.6 (136.9 to 216.8)	25	174.3 (136.8 to 212.5)	52
Mins per day MPA ^a	67.9 (42.9 to 79.0)	27	51.2 (38.6 to 85.8)	25	53.5 (39.8 to 80.7)	52
Mins per day VPA ^a	3.4 (1.3 to 10.1)	27	1.6 (0.8 to 4.8)	25	2.9 (1.0 to 6.2)	52
Mins per day of MVPA ^a	71.0 (46.7 to 85.9)	27	52.8 (40.2 to 95.5)	25	55.2 (40.9 to 90.7)	52
Physical Activity (IPAQ-SF)						
Minutes per day of MVPA in 10 minute bouts ^a	12.9 (0.0 to 25.7)	27	10.7 (3.6 to 17.9)	20	12.9 (0.0 to 25.7)	47
Weekly METS ^{a,b}	2215.0 (626.0 to 3857.0)	27	2253.0 (1085.0 to 4801.0)	20	2215.0 (993.0 to 4364.0)	47
Sitting (mins per day) ^a	380.0 (270.0 to 540.0)	26	485.0 (340.0 to 620.0)	20	405.0 (300.0 to 570.0)	46
	%	n	%	n	%	n
Receiving Therapy	3	32	23	30	13	62
Anti-depressants	56	32	60	30	58	62
>150m per week of MVPA (10 min bouts)	11	27	16	25	13	52
Currently employed, studying or training	88	32	90	30	89	62
Educated to A level of beyond	81	32	77	30	77	62

^aData were positively skewed, so figures reported are median (IQR). ^bIncludes walking, moderate and vigorous activity.

6.4.1 Factors influencing trial retention

T-tests were conducted to see if there was a significant difference in baseline variables in participants that dropped out of the trial and those that did not (table 6.3). No significant differences were found.

Table 6.3: Baseline factors influencing trial retention

	Followed up	N	Loss to follow-up	N	Between-group difference ^a
Female	42 (84.0%)	50	10 (83.3%)	12	0.955
Age in years	37.8 (13.1)	50	39.5 (8.3)	12	1.7 (-6.2 to 9.6)
Depression (PHQ-8)	14.4 (3.1)	50	15.5 (3.8)	12	1.1 (-1.0 to 3.2)
Anxiety (GAD-7)	11.6 (4.5)	47	13.0 (4.5)	11	1.4 (-1.5 to 4.4)
Therapy	8 (16.0%)	50	0 (0%)	12	0.138
Anti-depressants	30 (60%)	50	6 (50%)	12	0.528

^aConfidence intervals or p values reported. *p<0.05. **p<0.01

6.5 Intervention fidelity (delivery)

Table 6.4 summarises engagement with the eMotion website by participants in the intervention arm of the trial. In total, 28 (90%) of the 32 intervention participants registered for eMotion and clicked on the introduction module. The mean number of logins, modules accessed and total minutes spent on eMotion was 5.4 (SD=5.7), 3.8 (SD=3.42) and 76.3 (SD = 121.1) respectively. 53% percent of participants completed at least the introduction, week 1 and week 2 (the minimum dose) and 25% of participants completed up to at least week 4. Only one participant used every module.

Table 6.4: Module usage by eMotion intervention participants

	Usage data ^a
Number registered (%)	28 (88)
Mean number of logins (SD)	5.4 (5.7)
Mean total minutes (SD)	76.3 (121.1)
Introduction (%)	28 (88)
Week 1 (%)	25 (78)
Week 2 (%)	17 (53)
Week 3 (%)	10 (31)
Week 4 (%)	8 (25)
Week 5 (%)	6 (19)
Week 6 (%)	5 (16)
Week 7 (%)	5 (16)
Week 8 (%)	5 (16)
Moving on with PA (%)	6 (19)
Monitor PA (%)	3 (9)
Build up PA (%)	2 (6)
Problem-Solving (%)	1 (3)
Accessed first three modules (%)	17 (53)

6.6 Acceptability

Of the 32 participants randomised to eMotion who provided follow-up data (n = 25), 1(4%) felt almost all their needs had been met, 8 (32%) felt most of their needs had been met, 13 (52%) felt only a few of their needs had been met, and 3 (12%) felt none of their needs had been met, 6 (24%) said they would definitely use the programme again, 8 (32%) said 'Yes I think so', 10 (40%) said 'No, I don't think so' and 1 (4%) said 'Definitely not'. Finally, 4 (16%) said they were 'Very Satisfied', 10 (40%) said they were 'Mostly Satisfied', 10 (40%) said they were 'Indifferent, or Mildly Satisfied', and 1 (4%) said they were 'Quite Dissatisfied'. Interviews and feedback forms indicated a number of ways the intervention could be improved and are reported in chapter 7.

6.7 Exploratory analysis

6.7.1 Changes in primary outcome

Due to the pilot nature of the trial, only exploratory analyses were conducted (i.e. no formal hypothesis testing). The exploratory analyses for the primary outcome are summarised in Table 6.5. At two months post randomisation, the intervention group had a larger reduction in depressive symptoms than waiting list controls (Adjusted Mean Diff -3.6, 95% CI: -6.1 to -1.1). A criterion for clinically relevant change was to assess whether participants went below a score of 10 on the PHQ-8 (inclusion criteria for the trial). In the intervention group, 56% (14/25) of depression scores went below the threshold of 10 on the PHQ-8, compared to 28% (7/25) in the waiting list control group ($X^2(1) = 4.023$, $p = 0.045$). For those that completed the minimum dose of intervention and provided data at two months post-randomisation ($n=15$), there was a slightly larger reduction in depressive symptoms compared with controls (Mean Diff -3.8 95% CI: -6.79 to -0.86).

Table 6.5: Between-group changes in depression

	eMotion (SD)	N	Waiting List (SD)	N	Adj mean difference ^a
Depression (PHQ-8)					
2 month post	8.7 (4.8)	25	12.9 (4.2)	25	-3.6 (-6.1 to -1.1)**

^aMultiple regression adjusted for baseline value and confidence intervals reported * $p < 0.05$.

** $p < 0.01$

6.9.2. Changes in secondary outcomes

Table 6.6 provides data for all secondary outcomes. There was a larger reduction in symptoms of anxiety when compared to control (Adjusted Mean Diff -3.3 95% CI: -5.4 to -1.2). Data were available for 24 trial participants at two months post-randomisation who had at least four days of usable accelerometer data (with at least one weekend day and three weekdays of over 10 hours). Table 6.6 provides details of the mean daily minutes of LPA, MPA, VPA, MVPA and MVPA in at least 10 minutes bouts. Linear regression analysis controlling for baseline physical activity revealed no between-group differences in physical

activity. Data were available for 33 trial participants at two months post-randomisation who provided valid IPAQ SF data. Table 6.6 provides details of the mean daily minutes of MVPA, weekly MET-minutes, and mean daily minutes of sitting. Linear regression analysis controlling for baseline physical activity revealed no between-group differences in physical activity.

Table 6.6: Between-group changes in secondary outcomes

	eMotion (SD)	N	Waiting List (SD)	N	Ad mean difference ^b
Anxiety (GAD-7)					
Baseline	10.1(5.42)	31	12.0 (4.7)	27	
2 month post	7.1 (3.8)	25	10.9 (3.7)	25	-3.3 (-5.4 to -1.2)**
Mins per day of objective LPA^a					
Baseline	176.0 (136.7 to 208.9)	27	172.6 (136.9 to 216.8)	25	
2 month post	202.5 (137.0 to 222.6)	13	169.3 (101.9 to 187.2)	11	6.3 (-28.0 to 40.7) ^b
Mins per day of objective MPA^a					
Baseline	67.9 (42.9 to 79.0)	27	51.2 (38.6 to 85.8)	25	
2 months post	57.0 (49.0 to 80.0)	13	50.0 (33.8 to 67.0)	11	-1.6 (-14.9 to 11.7) ^b
Mins per day objective VPA^a					
Baseline	3.4 (1.3 to 10.1)	27	1.6 (0.8 to 4.8)	25	
2 months post	11.1 (3.4 to 10.7)	13	1.8 (0.6 to 4.9)	11	2.6 (-3.2 – 8.4) ^b
Mins per day of objective MVPA^a					
Baseline	71.0 (46.7 to 85.9)	27	52.8 (40.2 to 95.5)	25	
2 months post	63.9 (58.4 to 90.4)	13	51.8 (34.5 to 76.0)	11	2.9 (-11.1 – 16.9) ^b
Mins per week of objective MVPA in 10 min bouts^a					
Baseline	29.5 (0.0 to 98.8)	27	42.1 (8.1 to 93.7)	25	
2 month post	97.6 (49.7 to 166.3)	13	13.0 (0.0 to 131.4)	11	16.4 (-43.7 to 76.5) ^b
IPAQ-SF Daily Minutes of MVPA^a					
Baseline	12.9 (0.0 to 25.7)	27	10.7; (3.6 to 17.9)	20	
2 month post	11.4 (4.3 to 25.7)	19	15.7 (0.0 to 22.9)	14	0.2 (-8.7 to 9.2) ^b
IPAQ-SF Weekly METS^a					
Baseline	2205.0 (626.0 to 3857.0)	27	2253.0 (1085.0 to 4801.0)	20	
2 month post	2001.5 (1531.0 to 5621.0)	19	1986.0 (1236.0 to 4737.0)	14	453.1 (-1512.9 to 2419.2)
IPAQ-SF Sitting (mins per day)^a					
Baseline	380.0 (270.0 to 540.0)	26	485.0 (340.0 to 620.0)	20	
2 month post	390.0 (300.0 to 480.0)	19	305.0 (210.0 to 570.0)	14	63.3 (-41.2 to 167.8) ^b

^aAs physical activity data were skewed, medians and interquartile ranges (IQR) are presented, and analysis was repeated using bootstrapping. ^bMultiple regression adjusted for baseline value and confidence intervals reported. *p<0.05. **p<0.

6.7.2 Sensitivity analysis

The results may have been influenced by other co-interventions that were taking place during the trial. More participants in the control group (n=7) reported receiving some form of psychological therapy at baseline than in the intervention group (n=1). When this variable was entered into the regression analysis as a covariate, the impact of co-treatment was not significant, and the intervention group still had a higher reduction in depressive symptoms than controls (Mean Diff -3.3, 95% CI: -5.9 to -0.7). Other baseline covariates (age, gender, employment, education level, anti-depressant usage) that may have influenced depression scores were also entered in the regression model together. Findings indicated that none of these variables had a significant covariate effect on depression scores and the residual difference between groups was still significant (Mean Diff -3.1, 95% CI: -5.7 to -0.5). Within the intervention group, linear regression analyses revealed no significant relationships between numbers of modules accessed, number of logins or total minutes spent on the website with depression outcomes.

6.8 Discussion

6.8.1 Summary of findings

The present study examined the feasibility of conducting an RCT of the eMotion intervention. We successfully recruited a less active population (only 13% engaging in over 150 minutes of MVPA in ten-minute bouts per week) with elevated depressive symptoms (≥ 10 on the PHQ-8). The trial also had acceptable attrition rates concerning the primary outcome at two months (19% (95% CI: 11 to 30%). Concerning the feasibility of data collection, 85% of people provided (usable) accelerometer data at baseline but only 39% at two-month post-randomisation suggesting that using accelerometers may be feasible in a population with depressive symptoms, subject to refinements of the study procedures. Of those randomised to the intervention group, 90% registered for eMotion, and 53% completed the 'minimum dose' (introduction, week 1 and week 2). Exploratory analyses revealed larger changes in depressive symptoms and anxiety in the eMotion group compared to wait list control at 2 months post randomisation. Therefore, eMotion may have the potential to reduce symptoms of depression and anxiety and warrants further

investigation in larger trials. Descriptive physical activity data revealed a higher weekly median of 97.6 minutes of MVPA in ten-minute bouts per week (IQR = 49.7 to 166.3) than the control group (Median = 13.0, IQR = 0.0 to 131.4). However, we were unable to collect adequate usable physical activity data for both measures to run any meaningful exploratory analysis. Methods for collecting follow-up data need improving in future research (e.g. via face-to-face contact, or incentives) to conclude whether the intervention would have increased physical activity.

6.8.2 Relationship to other literature

The recruitment rates achieved, resemble other web-based interventions promoting physical activity for depression. Other studies have found rates between 26% and 46% of people being approached to being subsequently randomised (Mailey et al., 2010; Nyström et al., 2017; Rosenbaum et al., 2015; Soucy, Provencher, Fortier, & McFadden, 2017; Ström et al., 2013). Mailey et al., (2010) recruited students registered with mental health counselling services but did not have an inclusion criterion for the level of depressive symptoms, possibly contributing to their higher recruitment rate (46%). In eMotion, we excluded 23 people for scoring under ten on the PHQ-8. If we had adopted the same strategy as Mailey et al., (2010), our rates would have been the same (46%).

In comparison to other web-based trials of psychological and physical activity interventions for depression, our retention rate (those who provided data at two-month post randomisation) of 81% was acceptable. A recent three-arm RCT comparing administratively supported web-based BA, physical activity and a waitlist control group had a similar retention rate to ours (82%) (Soucy et al., 2017). Conversely, a systematic review of online psychological treatments for depression reported drop-out rates of 74% for unsupported, 38.4% for administratively supported and 28% for therapist supported treatments (Richards & Richardson, 2012). As such, the eMotion trial may have been better at retaining participants than previous web-based interventions. Some individual trials of web-based physical activity interventions for depression have reported lower attrition rates than ours (8% to 12%) (Mailey et al., 2010; Nyström et al., 2017). However, both of these trials provided therapist support, whereas our study only provided administrative support. Our data, combined with previous

research, suggest that some low level of administrative support may be adequate to retain an acceptable level of participants at follow-up.

As highlighted in chapter 1, many studies investigating the effect of physical activity on depression conceptualise physical activity as a prescribed structured intervention and do not measure baseline levels or change in physical activity (Cooney et al., 2013; Rebar et al., 2015). Also, change in physical activity has typically not been measured or reported in recent trials of psychological treatments for depression (Cuijpers, De Wit, & Taylor, 2014). 52 out of the 62 randomised in eMotion provided useable accelerometer data at baseline, as such this is one of the few evaluation studies to successfully report baseline physical activity using accelerometers in people living in the community with elevated depressive symptoms. eMotion also builds on a previous trial which used accelerometers to determine the extent to which participation in light, moderate, and vigorous-intensity exercise intervention influenced habitual physical activity and sedentary behaviour patterns in depressed adults (Helgadottir et al., 2017; Helgadóttir et al., 2015). A recent review of 23 psychometric studies showed that the IPAQ-SF has weak correlations when compared to objective measures (such as accelerometers), with correlation coefficients ranging from 0.09 to 0.39 for total physical activity (Lee, Macfarlane, Lam, & Stewart, 2011). Given the unreliability of self-report measures of physical activity, it is important to use objective measures when measuring physical activity in people with depression. It is hoped that this study will provide reassurance to researchers that objectively measuring physical activity in this hard to reach population is feasible.

The mean age and ethnic mix of participants are similar to previous UK-based studies (Chalder et al., 2012; Pentecost et al., 2015). However, the present study had a larger proportion of females (84%) than the BAcPac study (48%) and a lower mean baseline score of 14.6 on the PHQ-8 (SD = 3.2). For example, the baseline PHQ-9 score in BAcPac was 16.1(SD =3.8) (in the control arm) and 16.8 (SD = 3.8) (in the intervention arm) (Pentecost et al., 2015). However, participants in BAcPac had clinically confirmed depression and were recruited directly from the IAPT service. In the present study, it is possible that only those participants with relatively positive views of physical

activity or higher levels of motivation to use an online intervention would have agreed to take part.

In the present study, the baseline median level of objective daily MVPA (in ten-minute bouts) was 5.1 (IQR: 0.0 to 14.1), and only seven people in the sample were achieving the UK government guidelines of 150 minutes of MVPA per week. A recent cross-sectional study ($n = 165$) of adults with depression (≥ 10 on the PHQ-9) reported a baseline mean of 18.2 (SD = 17.4) minutes of MVPA (in ten minutes bouts) per day (Helgadóttir et al., 2015) suggesting that the sample in the present study was less active. One possible explanation for the lower activity level in the eMotion study was due to the recruitment method. The sample in Helgadóttir, Forsell and Ekblom, (2015), were taken from an RCT evaluating the effects of exercise (light, moderate or vigorous) on depression. Although scoring ≥ 10 on the PHQ-9, it is plausible that the clear indication of 'exercise' in the participant information sheet created a selection bias which resulted in a more physically active sample (i.e., the study attracted a subset of people with depression who were already active). In eMotion, however, the intervention itself was not the exercise itself, but rather a behavioural intervention to promote routine, pleasurable and necessary activities (which could include physical activity). As such, this may have led to us recruiting a less active sample than other trials that adopt a more explicit exercise focus. The current UK government guidelines for increasing physical activity in the UK is that adults should be active daily, accumulating up to 150 minutes per week of at least moderate intensity in bouts of at least ten minutes (Department of Health, 2011). As such, it also appears that we recruited a sample that was not achieving these guidelines (either based on self-report or on objective measures).

Interestingly, the median baseline level of total daily MVPA in eMotion (when measured using accelerometers) was 55.2 (IQR = 40.9 to 90.0), and Helgadóttir, Forsell and Ekblom, (2015) reported a mean daily MVPA level of 41.6 (SD = 23.9) minutes per day. This high level of MVPA reported in both studies suggest that the participants were achieving more than the recommended daily levels of physical activity. However, the UK government guidelines (Department of Health, 2011) specifically recommended that the physical activity is conducted within 10-minute bouts, to have any beneficial

effect, making the 10-minute bout measure (in both studies) more informative. Furthermore, a recent study demonstrated that feedback from accelerometers might also be incompatible with current physical activity recommendations more generally, as they are based on self-reported data from cohort studies (Thompson et al., 2016). Thompson et al., (2016) state that a more accurate median for average total MVPA levels in the UK (when measured with wearable devices and not restricted to ten-minute bouts) is 735 minutes per week or 105 minutes per day. The daily accelerometer measured baseline total MVPA in the present study fell far below this level giving further weight to our conclusion we recruited a sample that is less active than the general population.

Another consideration is the fact that the current guidelines (150 minutes of MVPA per week) are based on improving and maintaining physical health, rather than mental health (Department of Health, 2011a). As such, researchers still do not know what an appropriate number of minutes of physical activity per week would be for maintaining mental health. It is possible that the number of minutes of MVPA per week needed to maintain mental health may be lower than 150. For example, a recent longitudinal cohort study ($n = 33,908$) found that 12% of future cases of depression could be prevented with just 60 minutes of any intensity physical activity per week (Harvey et al., 2017). These findings could mean that the psychological benefits of physical activity (e.g. autonomy and competence), are more important, than the dose (e.g. time, intensity, frequency) (Nyström et al., 2015).

Exploratory analysis revealed a decrease in symptoms of depression and anxiety in favour of the intervention group at two months post randomisation, a similar reduction to that found in previous studies promoting physical activity for depression (Nyström et al., 2017; Pentecost et al., 2015; Rosenbaum et al., 2015; Soucy et al., 2017; Ström et al., 2013). However, other studies did not find such an effect (Chalder et al., 2012; Mailey et al., 2010; Vickers et al., 2009), possibly due to low power and the use of active control conditions (Ekkekakis, 2015). Our findings also support the utility of using BA as a treatment for depression more generally and are consistent with findings from a large-scale RCT that found BA to be no less effective than CBT for treating depression (Richards et al., 2016).

6.8.3 Strengths and Limitations

eMotion is the first study to deliver BA in combination with the explicit promotion of physical activity, in an online format. The main strength of this study was the use of rigorous methods to assess the feasibility of conducting a full-scale randomised controlled trial and the conduct of exploratory analyses of the potential efficacy of eMotion. We used objective methods where possible to assess physical activity and validated self-report measures of depression symptoms. However, several limitations of this study need to be acknowledged. Although we randomised participants, due to a lack of resources for increased staffing there was no blinding. This could have introduced bias, and potentially inflated the observed effects (Suresh, 2011). However, the potential for the researcher to bias the self-reported measure of depression symptoms was limited due to an absence of any face-to-face contact. Randomisation resulted in reasonably balanced groups (according to key demographic and clinical variables). However, there appeared to be more people receiving some form of psychotherapy in the control arm. A future trial could remedy this by either adding therapy as a minimisation variable, or as exclusion criteria.

A limitation of this study is that the PHQ-8 was used rather than a clinical interview. A score of at least ten on the PHQ-8 also has a positive likelihood ratio of 28 for detecting major depression (i.e. a patient with any depressive disorder is 28 times more likely to have a PHQ-8 score between that range of 10 to 24 than someone without a depressive disorder (Kroenke et al., 2009). As such, it was felt that the PHQ-8 would provide a good proxy for depression in the absence of a clinical interview.

Another limitation is that the PHQ-8 was used rather than the more conventional PHQ-9. However, the self-report PHQ-8 rather than the PHQ-9 was chosen due to the lack of any directly available clinical surveillance or support for participants, as it would not have been feasible to follow up any (online) survey responses expressing suicidal ideation in response to PHQ item 9 with an immediate telephone interview. The PHQ-8 is specifically recommended for use in such circumstances (Kroenke et al., 2009) and potential participants entering the trial were signposted to relevant support (appendix 7) and advised not to take part in the trial if they were experiencing suicidal ideation. Furthermore, the PHQ-8 is very similar to the PHQ-9 except

for the fact that item 9 is dropped, and they have both shown good convergent validity ($r=0.997$), indicating they are comparable across studies (Razykov, Ziegelstein, Whooley, & Thombs, 2012).

Only 56% of the participants in the intervention arm accessed at least the introduction, week 1 and week 2 (minimum dose) possibly indicating poor adherence to the intervention. However, regression analysis revealed that usage had no association with change in depression. eMotion actively encouraged participants to engage with the process of BA in their day to day lives (e.g. planning and reviewing goals using their diaries) or too 'effectively engage' with the intervention sufficiently enough to achieve the intended outcomes (reduction in depression) (Yardley et al., 2016). Recent studies have suggested that usage metrics reveal little about offline engagement with intervention processes and that usage cessation could either indicate disengagement from the intervention, or the development of sufficient mastery (Yardley et al., 2016).

We observed a higher success rate in collecting accelerometer data at baseline than at follow-up (44%) due to problems in contacting participants to arrange delivery of accelerometers. Some people also raised concerns about the inconvenience of wearing the GENEActiv accelerometers at baseline which may have contributed to the poorer follow-up. A larger trial could remedy the low levels of follow-up accelerometer data by a) incentivising people to wear the accelerometers at follow-up b) by providing some face-to-face contact to encourage a sense of accountability to the researcher and c) by taking a less cautious approach about the need to avoid loss of accelerometers (i.e. sending them out without the necessity for any prior /confirmatory contact). A recent study which reported on the feasibility of wearing smaller and cheaper wrist-worn devices may be promising (Doherty et al., 2017).

The baseline characteristics appeared to reflect no important differences in baseline characteristics between the two trial arms suggesting successful randomisation. However, due to lack of power it is possible that there may have been differences between participants in the arms which could have influenced the findings.

Finally, despite finding promising effects regarding the primary outcome, the trial was not powered to detect changes in depression. As such the findings presented here must be interpreted with caution and may not be generalisable to the wider population of the UK or internationally. Recruiting from the community may have also created a selection bias attracting only those are motivated to take part in online trials. Furthermore, although there was no explicit focus on physical activity, we may still have recruited a more active sample than the typical depressed population due to the fact we provided accelerometers at baseline. However, the purpose of the eMotion trial was to examine the feasibility of conducting a trial, rather than to make clinical judgements about effectiveness. As eMotion was a pilot trial, we recommend that other researchers exercise caution when interpreting these results, and a larger scale trial is needed to estimate the effectiveness of the eMotion intervention.

6.8.4 Implications for future research

Future studies should refine procedures (as indicated above) and further develop the intervention based on the feedback to optimise user engagement and experiences. Despite achieving modest reductions in depression, acceptability data showed that only 56% of the participants in eMotion were mostly or very satisfied with their experience of eMotion. Qualitative interviews performed on a sample of participants (n=11) have helped to identify barriers and facilitators to engaging with the intervention and with the trial, as well as identified how to address the high attrition rate for physical activity and minimise attrition generally (reported in chapter 7).

Based on the limited data presented, eMotion has the potential to reduce depressive symptoms for people with high levels of symptoms in the community and to ease the burden on NHS resources caused by depression. There may also be further potential to increase physical activity in this population. In line with the MRC framework (Craig et al., 2008), large, well-controlled randomised controlled trials that build on the findings from this pilot trial could help to more definitively test whether such an intervention is effective in reducing depression and increasing physical activity in community-dwelling populations with depression in the UK and elsewhere.

6.8.5 Conclusion

The eMotion intervention is novel in attempting to offer an integrated solution to the two critical public health priorities of depression and increased physical activity. The evaluation methods piloted here are suitable (with some adaptation) for use in delivering a full-scale trial and the recruitment and retention data show that such a trial would be feasible. Exploratory analyses of outcomes data also suggest that the intervention may be effective in reducing symptoms of depression and anxiety. Subject to further refinements, the eMotion intervention warrants further research possibly within the context of another pilot or full-scale RCT.

Chapter 7 Process Evaluation of the eMotion intervention

7.1 Chapter Outline

This chapter presents the results of the parallel process evaluation conducted alongside the pilot randomised controlled trial (RCT) of the eMotion intervention (chapters 5 and 6). Measures of receipt and enactment were used to capture the extent to which some of the intended behaviour change techniques (BCTs) (stated in chapters 3 and 4) were received and enacted. The present chapter explores this data, including the relationship between intervention fidelity and changes in outcome measures in the eMotion study.

7.2 Background

The theoretical mechanisms by which interventions improve physical activity and impact on mood are still poorly understood. Furthermore, interventions promoting physical activity have only modest (and usually short-term) effects (Foster et al., 2005; Greaves et al., 2011) and very few have attempted to promote physical activity for depression. As such, it is vital that researchers explore how interventions are used and experienced by participants and seek to identify potential facilitators and barriers to their wider implementation in practice.

Process evaluations are a vital strategy for exploring intervention mechanisms and aim to explore implementation (feasibility, acceptability and fidelity of delivery, receipt and enactment), mechanisms of impact (theoretical and practical mediators of effectiveness) and context (moderators). Process evaluations, therefore, lead to further insight into why a complex intervention either was or was not effective (Moore et al., 2015). As established in chapter 1, there is a lack of evaluations (including process evaluations) of behavioural interventions promoting physical activity for depression highlighting the need for more research.

eMotion was a complex, web-based intervention, that aimed to reduce depression in adults by encouraging the engagement in routine, pleasurable, necessary and physical activities using established BCTs (Michie et al., 2013) (see chapters 3 & 4). A process evaluation would provide further insight into the

acceptability and fidelity as well as the theoretical mechanisms of eMotion, enabling further refinement and inform future research and practice.

At the evaluation stage, Moore et al., (2015) recommend the collection of quantitative process measures to allow testing of hypothesised causal pathways and contextual factors. However, at the feasibility or pilot stage, a more appropriate approach may be to use basic quantitative methods (e.g. mean changes in process and outcome measures) combined with qualitative data to provide further insight into the intervention processes (Moore et al., 2015). Understanding the association between processes (i.e. mediators and moderators) and outcomes provides further insight into both behavioural and psychological change (Sniehotta, 2009). Informed by the Medical Research Council (MRC) guidelines on the conduct of process evaluations (Moore et al., 2015) and the framework for understanding physical activity and mental health (Faulkner & Taylor, 2014), we built a comprehensive process evaluation into the design of the eMotion pilot RCT resulting in a testable logic model that included mechanisms relating to behaviour change, and improvement in mood (Figure 7.1). Key elements explored in this process model included implementation (intervention fidelity and acceptability), mechanisms relating to improvement in physical activity (e.g. self-determination theory (Deci & Ryan, 2000; Deci & Ryan, 1985)) and mechanisms relating to reductions in depressive symptoms (e.g. behavioural activation, distraction).

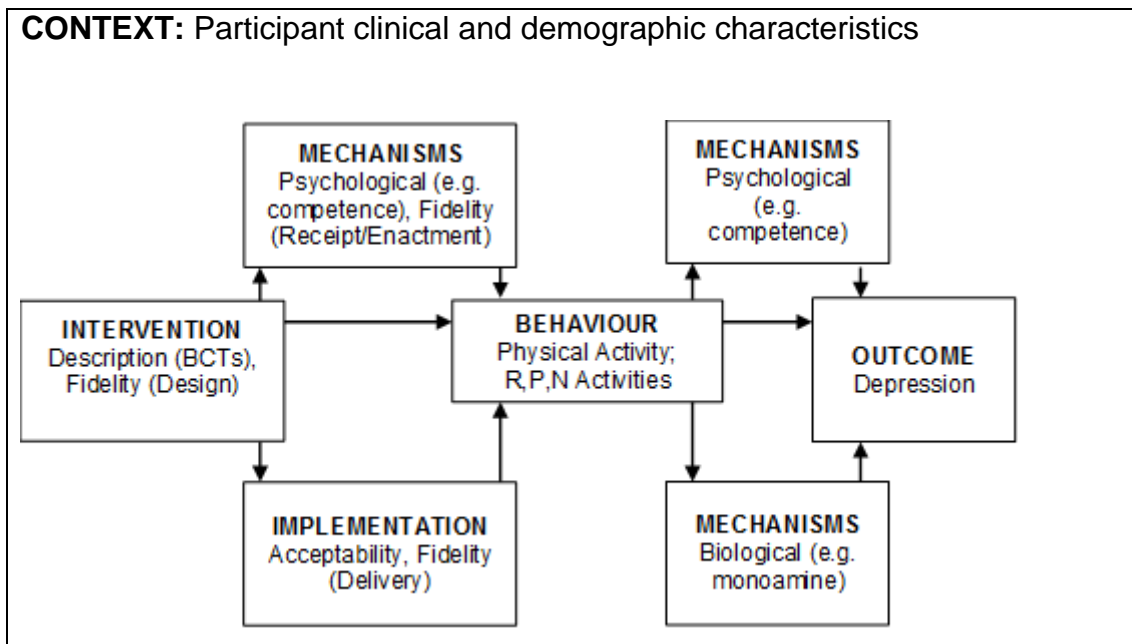


Figure 7.1: Process model for eMotion

7.3 Aims

The first stage of a process evaluation is to develop an intervention and provide a clear description of its causal assumptions (Moore et al., 2015). Chapter 3 provided a clear description of eMotion with further detail regarding the development, change objectives/mechanisms of change and BCTs. The present chapter aimed to report on a process evaluation of eMotion to understand more about the factors that may contribute to the outcomes of the eMotion pilot trial and inform refinements to the intervention and study procedures, thereby informing the design of a full-scale trial of the intervention.

The current chapter presents a) a quantitative process evaluation of the understanding, ability and use of the main BCTs used in eMotion, and b) a qualitative process evaluation of participant's perceptions of the acceptability, fidelity, and mechanisms of eMotion. Specific research questions for the quantitative evaluation were as follows:

1. To what extent did participants understand the BCTs delivered by eMotion?
2. To what extent did participants feel confident (or able) to use BCTs in eMotion?

3. To what extent did participants report using the BCTs delivered in eMotion?
4. To what extent did eMotion change participants' beliefs about physical activity as a treatment for depression?

Specific research questions for our qualitative evaluation were as follows:

1. What participant factors affected engagement with eMotion?
2. How acceptable were the eMotion intervention and study processes to participants?
3. How did participants describe their understanding, ability to use, and usage of BCTs included in eMotion?
4. What were the fundamental aspects of the intervention that helped to change behaviour or impact on mood from the participants' point of view or feel?

7.4 Methods

7.4.1 Data Collection

We used a mixed methods approach with multiple quantitative and qualitative process measures and data collection methods integrated into the design of eMotion (Table 7.1). A composite approach to analysing the data was taken (Yardley & Bishop, 2007) which involved analysing the quantitative and qualitative components separately and integrating them for discussion. This approach was taken to increase the clarity of the methods and results while enabling deeper and more detailed qualitative insight into how participants experienced eMotion.

Table 7.1: Domains, research questions and methods for evaluating each process

Source (N)	Context	Implementation		Mechanisms	
	Participant factors	Fidelity	Acceptability	Behaviour change	Depression
Outcome measures (25)	X	X	X	X	
Open ended questions (21)	X	X	X	X	X
Semi-structured interviews (11)	X	X	X	X	X

7.4.2 Quantitative approach

7.4.2.1 *Participants*

Questionnaires were given to all participants in eMotion. A detailed description of the baseline sample is reported in chapter 6.

7.4.2.2 *Data collection*

Participants were assessed at baseline and two months later using an online questionnaire (chapter 5, Table 5.1) (All assessment items can be found in Appendix 10). The primary quantitative measures of interest for the process evaluation related to fidelity (i.e. understanding and ability (receipt) and use of BCTs (enactment)) and mechanisms (outcome expectancies).

Fidelity of receipt (understanding how the intervention is supposed to work)

Participant understanding of how emotions, behaviours, thoughts and physical feelings affect each other to maintain depression over time was assessed using an online questionnaire. A bespoke measure of understanding was designed by the intervention developers based on a previous study (Brawley et al., 2013) which was identified in the systematic review of fidelity measures (chapter 2, section 2.5). This measure was a one item five-point Likert scale (Strongly Agree to Strongly Disagree) assessing participant agreement with the following statement:

“I understand how emotions, behaviours, thoughts and physical feelings affect each other to maintain depression over time.”

Fidelity of receipt (ability)

Participants’ perceived ability to enact behavioural strategies (i.e. use BCTs) was assessed using an online questionnaire. Perceived ability was measured by asking participants in both the intervention and control group to rate their confidence in using specific BCTs (i.e. identification of activities, grading activities for ease of use, planning and dealing with setbacks) in the last two months on a scale from 1 (not at all confident) to 10 (very confident). This measure was adapted from similar measures of confidence in the ProActive trial (Hardeman et al., 2008) which was identified in the systematic review of fidelity measures (chapter 2, section 2.5).

Fidelity of enactment

Participants’ self-reported use of behavioural strategies was assessed using an online questionnaire. Participants in the intervention and control group were asked if they had used specific BCTs relating to behavioural activation (BA) in last two months using a binary scale (yes/no). This measure was adapted from similar measures of BCT usage that showed that BCT use was significantly associated with weight loss, providing initial evidence of the validity of this type of measure (Hankonen et al., 2014). A similar measure has also been used in the proactive trial (Hardeman et al., 2008) which was identified in the systematic review (chapter 2, section 2.5).

Outcome expectations of physical activity

Participants’ expectations of engaging in physical activity for depression was assessed using a bespoke measure of attitude designed by the intervention developers. This measure was one item, five-point Likert scale measuring participant agreement with the following statement:

“I believe that doing 30 minutes of moderate physical activity (e.g. brisk walk) can make a big difference on my mood.”

7.4.2.3 *Statistical analysis*

Analyses were conducted using Stata 14 for those who provided data two months post-randomisation. Mean changes in quantitative process variables and standard deviations were reported for continuous process outcomes in both trial arms (understanding confidence to use BCTs, and outcome expectations towards physical activity) and percentages were reported for binary process outcomes (use of BCTs in the last two months) at baseline and two months post-randomisation. Linear regression models were used to compare 0-2 month changes in continuous process outcomes between the intervention and control group with 95% confidence intervals). Logistic regression was used to compare 0-2 month changes in binary process outcomes between the intervention and control groups with odds ratios (OR) and 95% confidence intervals. Any continuous process variables that changed as a result of the intervention were assessed as potential mediators of the primary outcome (depression scores).

Mediation was explored through calculating bootstrap confidence intervals of indirect effects for hypothesised mediated relationships based on 5000 iterations (Baron & Kenny, 1986), including all participants and controlling for group allocation. Following the procedure outlined by Baron and Kenny (1986), this was performed in a step-by-step process (Figure 7.2). The first step involved testing path *c* to see if the independent variable (eMotion) had a direct effect on the outcome variable (depression change). The second step involved testing path *a*, to see if the independent variable affected any of the process variables. Path *a* was tested by running a regression analysis to see if the independent variable affected any of the potential process variables. The third step involved testing path *b* by checking to see if the process variable (mediator) predicted the outcome variable. Finally, step four involved testing the indirect effect of path *c* (path *c'*) by running a multiple regression on the independent variable (eMotion) with the dependent variable (depression change) and controlling for baseline depression and the process variable. Mediation was demonstrated if adding the mediating variable to the model removed significant explanatory variance from the regression model.

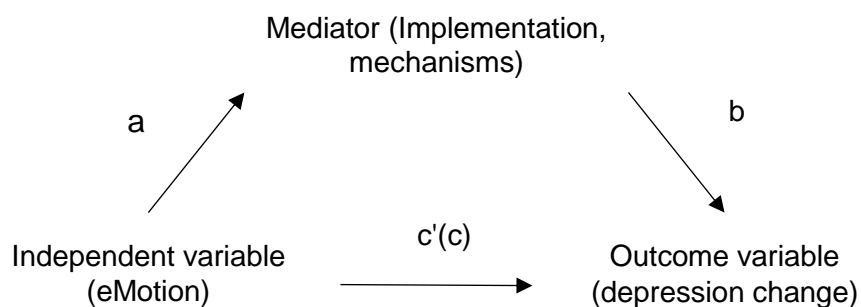


Figure 7.2: Mediation of eMotion process variables

7.4.3 Qualitative Approach

Qualitative data was collected on acceptability, fidelity and mechanisms of change for both behaviour and mood and aspects of the process evaluation (highlighted in Table 7.1). Data were collected using an open-ended survey questions delivered via an online questionnaire at two months post-randomisation and semi-structured interviews within two months after the study had ended.

7.4.3.1 Open-ended survey questions

As part of the main online survey, all participants in the intervention arm were asked to provide their general opinion/thoughts about eMotion using an open-ended question format provided in the Client Satisfaction Questionnaire-Short Form (CSQ-SF). The CSQ-SF asked participants to provide general comments about any aspect relating to the intervention or trial procedures by responding to the following question:

“Finally, what are your thoughts about the programme you received so far within the study (for example, what was good or bad about it?) and do you have any ideas about how the programme might be improved?”

7.4.3.2 Participants

A purposive sample of participants in the intervention arm of the eMotion pilot study was selected for interview to ensure diversity regarding demographics, depression score, the experience of eMotion, and whether they

completed the minimum intervention dose. Participants were purposively sampled to ensure a mix of people that completed and did not complete eMotion and those who had positive experiences vs those that had less positive. We also sampled people who did or did not experience reductions in their depression (to under ten on the PHQ-8) at 2-months follow-up. The target sample size (n=10) was predetermined based on resources.

7.4.3.3 Procedures

As part of the consent process, all eMotion trial participants were asked whether they would be willing to be contacted at a later date to discuss their experiences of the eMotion study. eMotion participants were invited to take part in an interview via email. If willing to take part, a date and time were arranged for a researcher to call. Interviews were conducted within one month after the intervention had finished. The main pilot RCT and nested qualitative study received Ethics Committee approval from Sports and Health Sciences. Interviews were conducted over the telephone by JL and AF. JL had a postgraduate degree in Health Psychology and training and experience in conducting qualitative interviews for other trials. AF was an undergraduate student in medical sciences and received training from JL and CG. In addition, AF was provided with formal qualitative training and was given feedback by JL after her first interview was conducted. Both AF and JL received formal training in managing suicide risk provided at the Mood Disorders Centre at the University of Exeter. Four interviews were conducted by JL and seven were conducted by AF.

Participants had no prior encounter with AF but had previously spoken to JL over the phone at screening and post-intervention. A semi-structured topic guide was developed by JL and CG to address the key research questions outlined above. The topic guide is in Appendix 14 and included questions relating to the implementation (study acceptability, intervention acceptability and fidelity) and mechanisms (in relation to change in behaviour and change in mood) of the eMotion intervention. Participants were prompted to elaborate on their experiences through additional probe questions. The topic guide was pilot tested with two research colleagues, and no amendments were needed. Interviews were audio-recorded with participants' prior consent and transcribed

verbatim by AF and a transcription service. The transcripts were then double checked against audio recordings by JL for accuracy.

7.4.3.4 Qualitative data analysis

Data were analysed by JL and AF using a deductive thematic approach guided by predefined research themes about the data. These included, participant factors, acceptability, mechanisms of eMotion on behaviour, and mechanisms of behaviour on mood (figure 7.1). Each sentence was coded for semantic content using NVivo 11 software (QSR International). Thematic analysis (Braun & Clarke, 2006) was chosen to allow identification of patterns in the data about the process-related research questions. Thematic analysis has been used in previous process evaluation studies (Ly et al., 2015; Moore, Raisanen, Moore, Din, & Murphy, 2013; Searle et al., 2014; Trigwell et al., 2015) to explore issues relating to fidelity and mechanisms, and was deemed appropriate given limited resources. The first step (familiarisation with the data) was achieved by rereading the transcripts from interviews and generating initial codes. A 'code' is described as a feature of the semantic content that refers to "the most basic segment, or element, of the raw data or information that can be assessed in a meaningful way regarding the phenomenon" (Braun & Clarke, 2006, p. 18). The next phase involved combining conceptually similar codes into overarching themes based on the relevant research questions, which were then reviewed and defined. An iterative process using two coders (JL and AF) was employed to minimise subjective bias and increase the reliability of the codes generated. AF independently read through and coded half the interview transcripts, and JL independently coded all the transcripts. Discussions were then held around possible codes and themes generated. Further depth to the analysis was achieved by cross-tabulating hypothesised relationships and exploring negative cases (that could contradict the emerging coding frame) to ensure sufficient triangulation of generated themes.

7.5 Results

7.5.1 Quantitative findings

7.5.1.1 *Participant characteristics*

Of the 62 randomised, at baseline 57 participants provided measurements for understanding, ability, enactment and affective attitude. At the two-month follow-up, 50 (81% of those randomised) provided follow-up data. Within the intervention group, 21 (66%) completed the open-ended survey items. Demographics of the baseline sample are reported in chapter 6, Table 6.2.

7.5.1.2 *Changes in process variables*

The quantitative results are summarised in Table 7.2. At two months post-randomisation, participants randomised to the eMotion group reported a significant difference, compared with controls, in levels of understanding about how thoughts, feelings and behaviours affect mood (Adjusted Mean Diff 0.5, 95% CI: 0.0 to 1.0). Significant differences were also found for confidence to identify (Adjusted Mean Diff 1.4, 95% CI: 0.0 to 2.8) and plan (Mean Diff 1.8, 95% CI: 0.5 to 3.1) achievable activities to improve mood as well as confidence to deal with setbacks (Mean Diff 1.5, 95% CI: 0.2 to 2.7). Table 7.2 shows that, for the whole sample, those who were randomised to the eMotion group were significantly more likely to select (OR 5.7, 95% CI: 1.2 to 27.5) and plan (OR 6.3, 95% CI: 1.5 to 26.8) activities to improve their mood over the past two months. A ceiling effect was observed for outcome expectancies towards physical activity which may have led to the non-significant change as a result of engaging with eMotion (Adjusted Mean Diff 0.37, 95% CI: -.3.0 to 1.0).

Table 7.2: Summary of changes in process variables

	eMotion (SD)	N	Waiting List (SD)	N	Adjusted mean difference between groups/Odd Ratios (95% CI)
Understanding of intervention					
Baseline	4 (0.2)	29	4.2 (0.7)	27	
2 month post	4.2 (0.9)	25	4 (0.9)	25	0.5 (0.0 to 1.0)*
Believe that PA can improve mood					
Baseline	3.70 (0.8)	29	3.9 (0.8)	27	
2 month post	4.0 (1.1)	25	3.8 (1.1)	25	0.4 (-0.3 to 1.0)
Confidence to identify activities that improve mood					
Baseline	5.0 (2.6)	29	5.2 (2.4)	27	
2 month post	7.0 (2.5)	25	5.7 (2.7)	25	1.4 (0.0 to 2.8)*
Identified Activities that improved mood					
Baseline	14 (48%)	29	15 (55%)	27	
2 month post	21 (84%)	25	16 (64%)	25	3.4 (0.7 to 17.0)
Confidence to select activities that improve mood					
Baseline	4.1 (2.3)	29	4.3 (2.5)	27	
2 month post	6.2 (2.6)	25	5.0 (2.6)	25	1.3 (-.02 to 2.6)
Selected Activities that improve mood					
Baseline	11 (38%)	29	14 (52%)	27	
2 month post	21 (84%)	25	14 (56%)	25	5.7 (1.2 to 27.5)
Confidence to plan activities that improve mood					
Baseline	3.7 (2.3)	29	3.7 (2.3)	27	
2 month post	6.0 (2.5)	25	4.3 (2.6)	25	1.8 (0.5 to 3.1)**
Planned Activities that improve mood					
Baseline	4 (14%)	29	11 (41%)	27	
2 month post	19 (76%)	25	10 (40%)	25	6.3 (1.5 to 26.8)
Confidence to deal with setbacks					
Baseline	3.2 (2.2)	29	3.2 (2.0)	27	
2 month post	5.1 (2.7)	25	3.6 (2.2)	25	1.5 (0.2 to 2.7)*
Dealt with Setbacks					
Baseline	5 (17%)	29	5 (19%)	27	
2 month post	14 (64%)	22	6 (35%)	17	4.5 (0.7 to 27.7)

7.5.1.3 Mediation of process variables

Step one: As reported in chapter 6, the exploratory analysis revealed that those randomised to eMotion experienced a significantly larger reduction in depressive symptoms than controls ($B = -3.6$, 95% CI: -6.1 to -1.1, $p = 0.005$).

Step two: This step tested path 'a' in the mediation model (Fig. 7.2) to identify which potential mediators had a statistically significant association with treatment allocation. The potential mediators which were significant ($p < 0.05$) within the regression models (Table 7.2) was 'change in understanding of the intervention', 'change in confidence to identify activities that improve mood', 'change in confidence to plan activities that improve mood' and 'change in confidence to deal with setbacks'.

Step three: This step tested path 'b' in the mediation model (Fig. 7.2) to identify which of the potential mediators, shown to be predicted by the intervention (in step two), also predicted change in depression. The only mediator that significantly predicted change in depression was 'change in confidence to deal with setbacks' (Fig. 7.3).

Step four: Change in confidence to deal with setbacks had a significant indirect effect (unadjusted) between the intervention and change in depression. The indirect, direct and total effects of each of the models are given in Figure 7.3. A bootstrap test of the indirect effect of eMotion on depression, with 'change in confidence to deal with setbacks' as the potential mediator, was -2.4 (95% CI: -5.2 to 0.4) which was not significant ($p = 0.09$), suggesting a mediational effect (Figure 7.3).

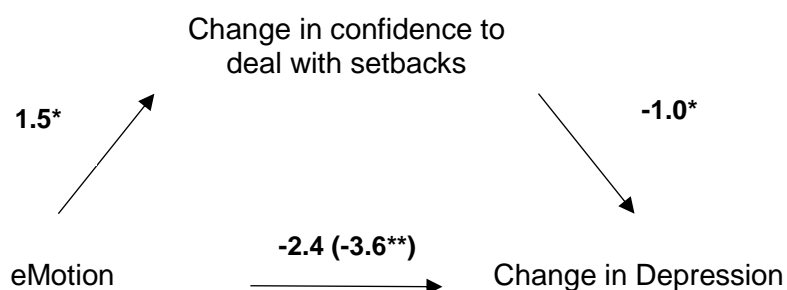


Figure 7.3: Results of mediation of eMotion process variables

* $p < 0.05$ ** $p < 0.01$ *** $p < 0.001$

7.5.2 Qualitative findings

Of the 21 participants invited for a telephone interview, eleven completed interviews. All interviews took place between November 2016 and February 2017. Interviews lasted between 10 and 55 minutes and took place between one and two months after the intervention had ended. Participant characteristics are provided in Table 7.3. Results are presented under five main headings: participant factors, the acceptability of eMotion, fidelity, mechanisms of change on behaviour and mechanisms of change on depression reflecting the research questions stated earlier. Table 7.4 provides details of the codes elicited and how these were organised into themes. Quotes are presented to support analysis and are labelled by participant ID number, gender, age, and pre- and post-depression level (if reported).

Table 7.3: Participant characteristics (interviews)

Participant	Gender	Age	PHQ-8 Baseline	PHQ-8 2-month follow up
106	Female	29	23	10
123	Female	54	21	21
120	Female	19	14	5
129	Female	38	11	1
110	Female	45	16	NR
144	Male	50	11	6
146	Male	33	12	7
152	Female	54	14	5
154	Female	27	12	2
158	Female	49	10	14
159	Female	22	12	6

Table 7.4: Codes, themes and subthemes

Main themes and subthemes	Initial codes	Example interview extract
Participant factors		
Work commitments	<ul style="list-style-type: none"> - Lack of time due to work - Lack of cognitive resources after work 	“I started doing it, and I thought it was a bit sort of too much for me to kind of deal with it because I was, you know with work at the same time as well”
Initial expectations of treatment	<ul style="list-style-type: none"> - Curious/excited to try it out - Novelty aspect - Different to previous experiences of CBT - Anonymity aspect - Unrealistic expectations 	“I was really; I was interested in it. It was actually a friend of mine that saw the study and then sent me a link to it and said why don't you try this. So I can see the premise behind it, yeah I was quite excited about being involved with it really”
Acceptability		
Content and structure	<ul style="list-style-type: none"> - Too much information - Information confusing - Repetitiveness boring - Nothing new - Repetition good for habit formation 	“But the wording and the things like that I felt a bit sort of too much information and I couldn't take it in”
Provision of support	<ul style="list-style-type: none"> - Hard to self-motivate - Need to feel supported - Support may have discouraged 	“it's really hard to motivate yourself, but feeling that there's someone or a program or someone you know backing you really”
Platform and technical issues	<ul style="list-style-type: none"> - Difficulties logging in - Navigation easy 	“It was quite hard to login into it all and things like that, on the internet. That was a bit confusing I thought
Audio delivery	<ul style="list-style-type: none"> - Audio helped to reinforce learning - Made it feel more personal - Felt it was not patronising 	“I sort of responded to that as well because it's got... Obviously, I am an auditory and a visual learner so to have them both together it really reinforced it, that did help”
Email reminders and worksheets	<ul style="list-style-type: none"> - Emails got lost in busy inboxes - Emails mainly used for work - Like to have some 'physical' to write on 	“rather than going through emails, because you get 30-40 emails a day, and you just go through them, and it might just get lost, and a text message might just be better with a link to it I think”
Improvements	<ul style="list-style-type: none"> - Would be better as an app - More visual - More interactive - Progress charts - Provision of printed materials - Discussion forums - Link to outlook calendars 	“I found that, because I tried to do it on my iPhone to load things up, but I didn't find it works on there. It kept, maybe if there is something more like an app based for your phone so that it is easier to log in and get in and that. It just you have a phone on you all the time, so you always kind off, or something like an app to help you keep track on your 8 weeks on the module”

Table 7.4: Codes, themes and subthemes (Cont'd)

Main themes and subthemes	Initial codes	Example interview extract
Fidelity		
Engagement with techniques	<ul style="list-style-type: none"> - Identified activities - Found examples/suggestions helpful - Used personal diaries to set plans - Used commercial activity monitors - Moved from writing activities down to mentally rehearsing - Hard to list activities 	<p>“That actually was really, that was really good. That really worked well for me. I found that really easy and I think it was because I’ve got it in front of me that the suggestions at the top of each column were very useful. Like ‘routine’, ‘walking the dog’, ‘food shopping’, ‘pleasurable’, ‘going out with friends’, ‘reading’ it was just I don’t know whether I would have been able to work that out on my own. I’m not stupid, but I might not have been able to work out what each thing ranked as”</p>
Theoretical mechanisms for behaviour		
Link between activity and mood	<ul style="list-style-type: none"> - Conscious awareness of link between (lack of) PA and mood - Scepticism that PA would help ‘their’ mood - Increased awareness of how lack of PA 	<p>“And I mean I think sort of the logical brain it knows that and I probably know that because everyone tells you that exercise it is good for helping with low mood but until I think until you’ve actually experienced it yourself there’s always a sort of an element of doubt about that, and I’ve always been quite sceptical about it really”</p>
Increased sense of competence	<ul style="list-style-type: none"> - Prioritising made it easier to be active - Able to problem solve barriers 	<p>“Yeah I did, and it was again it gave it some kind of, ‘cos I think sometimes you just it all moulds into one, and then it all becomes really difficult. So if you can plan it and put it in order of priority, I think it makes it easier”</p>

Table 7.4: Codes, themes and subthemes (Cont'd)

Main themes and subthemes	Initial codes	Example interview extract
Theoretical mechanisms for depression		
Increased sense of achievement form PA	<ul style="list-style-type: none"> - Doing what you're supposed to be doing - Able to achieve other things 	<p>"I think it was probably more of a psychological thing. I don't know; you hear if you do more activity, more exercise and it improves your mood, so it's a psychological thing. But actually I'm doing an activity, I'm doing what I should be doing, so therefore I should be happy with myself doing that. Rather than having it to do with your hormone levels and your serotonin or whatever. Is it to do with that or it is because I'm proud of myself because I've managed to do some activity rather than staying in the house or not seeing anybody. So yeah, it's sort of that really"</p>
PA as a distraction from negative thoughts	<ul style="list-style-type: none"> - Focus taken away from how you are thinking - Switch off brain - Mentally resting 	<p>"I think sort of just taking your mind off things sometimes. So yeah just sort of there's one, there's one activity where I think I just completely switch off my brain and think about playing because I'm concentrating on myself and not thinking about work, so I think mentally yes, it's mentally sort of giving your mind a rest. Yeah that's where some of the stress buster comes in I guess"</p>
Meaningful activities rather than 'active'	<ul style="list-style-type: none"> - Trouble enjoying exercise - Lack of meaning 	<p>"As someone who does exercise, but has trouble enjoying it and doing things that are meaningful and when it got to halfway through the modules, and it started talking about things that were necessary and the things that were meaningful that when I really started to engage and I feel that [I] understand this now and it's more addressed to me"</p>
Taking control	<ul style="list-style-type: none"> - Increased knowledge of what to focus on - Understand about PA benefits - Able to plan 	<p>"I think what also it sort of helped me focus on is that if things are very, very bad, I needed to concentrate on the necessary because the necessary could you know if you don't do the necessary, then obviously things could get really you know could get really bad. It was also, and that really helped because I had started I had never had that as I say never had that distinction I think before in that way. So it was very good, very useful"</p>

7.5.2.1 **How did participant factors shape engagement with eMotion?**

Work and family commitments

Participants' work or family commitments was a prominent theme that emerged from the interviews, with many people perceiving it hard to find the time to sit down and work through the eMotion. Others found eMotion mentally challenging after a day at work:

"I started doing it, and I thought it was a bit sort of too much for me to kind of deal with it because I was, you know with work at the same time as well" (106, Female)

"But then I realised that getting further than that when you are actually doing 12 hour days, and then you're getting home, and you are just like argh I can't do it" (129, Female)

Initial expectations of eMotion

Expectations about eMotion appeared to shape participant's experiences. Many people had high initial expectations about working through eMotion and felt that it would be something different to what they had already tried. They liked a novelty aspect of the self-delivered programme. Some people also felt that it would offer benefits as opposed to traditional face-to-face treatments. For example, some felt that continuously talking to someone made them feel worse, and an online medium would allow them to work through their issues more proactively in their own time as opposed to talking to a therapist:

"I was really; I was interested in it. It was actually a friend of mine that saw the study and then sent me a link to it and said why don't you try this. So I can see the premise behind it, yeah I was quite excited about being involved with it really" (129, Female)

"I thought that was helpful because I find it very, I find it quite tricky to speak to people, and also I have also had CBT, cognitive behavioural therapy before, and I have been to see various other people and for some reason talking things over and continuously talking made everything feel worse for me, so I was relieved that it was online, I didn't have to, I didn't have to worry about what I was saying or what my face looked like or what my body looked when I was seeing them and I could

just deal with it in my own time and I could pick it up as and when if I didn't feel, if I thought a little low" (159, Female)

However, despite positive expectations, some of these participants felt let down as they could not see an immediate solution to their depression from engaging with the programme:

"I couldn't , I thought it was trying to help me work out what I could do to lift my mood, but I wasn't seeing an immediate answer to that, so I didn't make me feel like I need to move on" (123, Female)

7.5.2.2 How acceptable was eMotion?

The acceptability of eMotion could be assessed across several sub-themes relating to content and structure, provision of support, platform and technical issues, style of delivery, emails and worksheets. An additional theme of improvements was used to draw together ideas for improvement across this category.

Content and structure

The results showed that some people regarded the audiovisual content provided by eMotion as overwhelming and sometimes confusing. Some people also felt the linear weekly structure and length of eMotion was off-putting by being repetitive and giving the impression they had to 'keep up' with each week's prescribed activity.

"But the wording and the things like that I felt a bit sort of too much information and I couldn't take it in" (106, Female)

"And then I felt like I was getting way behind and thought I had to keep up to date, so I just thought I've knocked it on the head" (110, Female)

Compared to their experiences of other online courses, some people also felt that the programme did not show them anything different compared to their previous experiences with other online courses to help with mood. They felt that the repetitive content was boring rather than engaging:

“I think it’s probably just me, I do a lot of online courses for work, and on those, it’s just puts me off a bit.” (146, Male)

“It’s also trying to keep your interest isn’t it, trying to keep you there really, keep it yeah, cause I kind of I’ve got a bit, you know I get a bit bored of the same thing sometimes” (106, Female)

Conversely, others felt the audio-visual information provided by eMotion was clear and useful and liked the weekly structure and organisation. Some also felt that the repetitive nature of the subsequent modules was necessary to ensure continuity and helped to reinforce habit formation. Some participants also felt the programme was somewhat interactive and accessible.

“I felt like the explanations of how you use all the parts of the different modules was really good” (120, Female)

“It seemed very well organised and the messages I was getting and how I was put to me and the information I was given” (129, Female)

“I think to begin with I did and then I suddenly realised that actually, it was important to repeat the sort of things that you were doing because you know in the end it was very what’s the word, you know there is continuity there” (152, Female)

“I felt that there was obviously going to be a reason for that and that must be part of you know evaluating yourself if you like. So that didn’t really, it was about reviewing what you’d done and that felt ok and also it, I am wondering if the repetition is about sort of almost sort of lodging it in your brain more for things to become habitual rather than introducing brand new concepts every week. I don’t know if that’s right or not but that’s that felt ok; it felt comfortable” (158, Female)

Provision of support

Many considered the lack of support offered to be a barrier to engagement. Although eMotion provided some brief administrative support, many felt that more regular and accessible support was needed to help with any queries and to provide motivation to work through the website:

“No, probably not. But I know it’s just a trial, and you know maybe just someone even when you start to speak to you and any hiccups that you might be having” (110, Female)

“it’s really hard to motivate yourself, but feeling that there’s someone or a program or someone you know backing you really” (110, Female)

Conversely, others thought that support provided within the eMotion content was adequate and additional assistance was not needed. They felt it could have potentially added too much pressure, which would have discouraged them from continuing with eMotion:

“in terms of the facilitator yes I did enjoy not having to you know sit down, or I think the guidance was enough because it’s a straightforward intervention” (154, Female)

“I think the support from the modules was fine actually. I don’t think you needed [additional support]” (152, Female)

“No, I don’t think [additional support] is necessary for me. No, not at all. I think that would have probably put much, much more pressure on me” (158, Female)

Platform and technical issues

In terms of the physical platform used to deliver eMotion, most people found navigation to be straightforward, but some had difficulty in getting started:

*“I found it easy to navigate and didn’t have any issues with that at all”
(120, Female)*

*“It was quite hard to login into it all and things like that, on the internet.
That was a bit confusing I thought” (146, Male)*

Audio delivery

Many liked the audio delivery of eMotion, stating that it was more useful than written information, and it fitted with their learning styles. Some participants felt the audio delivery aspect helped to make eMotion feel more personal and helped them to normalise any setbacks that occurred. Furthermore, people responded well to the tone of delivery, and many explicitly stated that they perceived it as not patronising:

“I quite liked that is was spoken and not written, because often when the things are written down, you don’t read them” (120, Female)

“I sort of responded to that as well because it’s got... Obviously, I am an auditory and a visual learner so to have them both together it really reinforced it, that did help” (129, Female)

“Personal nature of it I suppose” (152, Female)

“[The audio delivery] made it, it brought it to life, and I think what I felt very important, most importantly for me personally was I didn’t feel it was patronising” (158, Female)

Email reminders and worksheets

Many felt that emails used in eMotion were not the best way to send reminders, as often they got lost in already busy inboxes, mainly used for work purposes. The worksheets were also well received with people liking the 'physical nature' of writing things down. However, some would have preferred to have had them sent to them rather than being asked to print them off:

“rather than going through emails, because you get 30-40 emails a day, and you just go through them, and it might just get lost, and a text message might just be better with a link to it I think” (129, Female)

“No it was really the additional benefits were the worksheets because I’ve never seen them like so before and so that was I thought that was good because the fact that it gave you something physical that you could focus on” (152, Female)

Improvements

Key improvements suggested by participants included: offering an app version, adding more visuals, increasing interactivity with the learning sessions, a “frequently asked questions” page, progress chart, increased flexibility, provision of booklets, online discussion forums to compare progress and share different ideas for activities, linking to existing outlook calendars, and “in the moment” support by having reminders or motivational messages sent to participants' smartphones.

“I found that, because I tried to do it on my iPhone to load things up, but I didn't find it works on there. It kept, maybe if there is something more like an app based for your phone so that it is easier to log in and get in and that. It just you have a phone on you all the time, so you always kind off, or something like an app to help you keep track on your 8 weeks on the module” (146, Male)

The participants also felt that people with depression often might have different needs and co-morbidities, such as chronic pain and insomnia. eMotion could, therefore, be improved by being more tailored or personalised to those needs.

“So whether it was just for depression or whether it was for people who had manic depression or stuff like that, people who had difficulty sleeping perhaps and then people who have chronic pain. So like tailor it a bit more” (106, Female)

7.5.2.3 What was the fidelity of eMotion, and how did this impact on behaviour and mood?

Engagement with techniques

Qualitative data supported the questionnaire data indicating that, as a result of using eMotion, participants identified different activities that could improve their mood and planned them for the subsequent week.

“That actually was really, that was really good. That really worked well for me. I found that really easy and I think it was because I’ve got it in front of me that the suggestions at the top of each column were very useful. Like ‘routine’, ‘walking the dog’, ‘food shopping’, ‘pleasurable’, ‘going out with friends’, ‘reading’ it was just I don’t know whether I would have been able to work that out on my own. I’m not stupid, but I might not have been able to work out what each thing ranked as” (158, Female)

Participants also reported using techniques they learned from eMotion in their everyday lives and adapting them to their own lives or environment. For example, people spoke of self-monitoring using commercial activity monitors, using their personal diaries to set plans. Others mentally rehearsed their plans to ensure they engaged in routine, pleasurable, necessary or physical activities:

“So I started, I think one of them was how you characterise the different activities, and I started to do that with when I was planning for my next week. And that was really useful in understanding what I was doing for myself and what I was doing because I felt that I had to do it. So those were really useful, definitely” (120, Female)

“I don’t write things down anymore, but I do think about categorising the things that I do in a day. And I try to make sure that I have something that physical or something that for me isn’t physical in my day. So I do, that kind of mentality in the language is still with me, and I think about that” (120, Female)

Others found it hard to engage with some of the techniques, especially the self-monitoring:

“The only thing I seem to remember being frustrating is when you have to list your activities, how many minutes or how many hours or whatever. That was, I was getting a bit confused on that side of things” (110, Female)

7.5.2.4 What were the theoretical mechanisms that increased behaviour in eMotion?

Participants reported a variety of possible mechanisms that may have resulted in behaviour change (i.e. increase in routine, pleasurable or necessary activities or physical activities) or a reduction in depression. These included an increased awareness of the links between behaviours and mood, and a greater sense of competence to overcome the challenges to engaging in actions that impact on mood.

Link between activity and mood

Many participants considered the link between physical activity and depression as quite logical, and that this was often endorsed by their peers. However, some also felt sceptical about the affective benefits of physical activity when applied to them.

“Yeah I mean I’ve always known about the sort of link with activity, and you know sort of your mental health side. I think I was just quite on board with it so to me it just sounded quite normal and natural” (152, Female)

“And I mean I think sort of the logical brain it knows that and I probably know that because everyone tells you that exercise it is good for helping with low mood but until I think until you’ve actually experienced it yourself there’s always a sort of an element of doubt about that, and I’ve always been quite sceptical about it really” (158, Female)

Participants also reported feeling an increased sense of conscious awareness of the link between the types of activities they were doing (or not) and their current mood state. This increased awareness prompted engagement in routine, pleasurable or necessary activities.

“So it did make me consider more. Obviously, I knew the link, but it made me consider more that actually I need to up my activity level because when I was rating things I was like hang on I haven’t done much today, I’ve sat on the sofa, perhaps wandered to the shop, I haven’t done anything else. So it prompted me to think I need to raise my activity levels rather than being told you need to do this, that and the other, so yeah it did make me think a little bit more” (129, Female)

“I think the best thing was that it’s, it does make you conscious, you are being consciously aware of you are doing something, and I think that kind of forces you to think and evaluate what you are doing” (154, Female)

Others reported noticing a more explicit link between their levels of physical activity and their current mood states:

“I did because I noticed that on three out of the seven days I didn’t exercise, I didn’t do anything, I was completely inert the whole, for one, two, three days and I put well this is my ‘I felt like shit, depressed’ in brackets ‘no exercise, no exercise, very depressed’ and then on another day I’ve got ‘felt ok because I’ve been out and about’ you know walking or just being active doing something” (158, Female)

“I’ve been better as well I would exercise, well when I first started this programme I also started exercising the same time, so I joined a gym and done a few extra bits, but actually I’ve realised that the exercise has affected my mood and that was because I was conscious of it because of the experiment” (159, Female)

Increased sense of competence

Participants indicated that eMotion was helpful in prioritising and planning, which in turn helped them to build their sense of competence in engaging in activities that might improve their mood:

“Yeah I did, and it was again it gave it some kind of, ‘cos I think sometimes you just it all moulds into one, and then it all becomes really difficult. So if you can plan it and put it in order of priority, I think it makes it easier” (152, Female)

Others felt that eMotion helped them to find ways around barriers to engaging in activities that could improve their mood:

“I think it’s trying to remain positive I guess, trying to find ways around our problem rather than looking at the problem, because it’s all well and good to say I can’t do this, can’t do that, it’s just trying to find ways around it” (106, Female)

7.5.2.5 Mechanisms of impact of behaviour on depression

People mentioned various possible mechanisms responsible for their reduction in depression as a result of routine, pleasurable or necessary or physical activities.

Increased sense of achievement

Many spoke of an increased sense of achievement from engaging in physical activity, experiencing a sense of pride from overcoming the behavioural inertia to re-engage with life. They also felt that this feeling of pride then had a positive effect on their subsequent behaviour.

“I think it was probably more of a psychological thing. I don’t know; you hear if you do more activity, more exercise and it improves your mood, so it’s a psychological thing. But actually I’m doing an activity, I’m doing what I should be doing, so therefore I should be happy with myself doing that. Rather than having it to do with your hormone levels and your serotonin or whatever. Is it to do with that or it is because I’m proud of myself because I’ve managed to do some activity rather than staying in the house or not seeing anybody. So yeah, it’s sort of that really” (129, Female)

“...it felt like a huge achievement because a really big thing to do, and I think almost you know energy breeds energy and I think I felt more able to achieve other things somehow” (158, Female)

Distraction from negative thoughts

Others spoke of physical activity as offering a distraction from negative thoughts, and a chance to 'switch off'. No one mentioned a biochemical effect from engaging in physical activity, and some felt that this aspect was less important than the psychological benefits.

"Yeah I think 'cos you just the focus comes away from, you kind of make a really kind of positive move towards doing something, and I think that takes away the focus from how you are thinking" (152, Female)

"I think sort of just taking your mind off things sometimes. So yeah just sort of there's one, there's one activity where I think I just completely switch off my brain and think about playing because I'm concentrating on myself and not thinking about work, so I think mentally yes, it's mentally sort of giving your mind a rest. Yeah that's where some of the stress buster comes in I guess" (154, Female)

Distraction from negative thoughts

Conversely, some participants, who perceived themselves as already active, did not view physical activity as useful for their depression and even felt worse for doing it. There was a sense that physical activity was something you 'had to do' as opposed to something you 'chose to do'. In this case, participants felt an increased benefit from engaging in activities which were more personally meaningful, even if this meant doing less physical activity:

"As someone who does exercise, but has trouble enjoying it and doing things that are meaningful and when it got to halfway through the modules, and it started talking about things that were necessary and the things that were meaningful that when I really started to engage and I feel that [!] understand this now and it's more addressed to me" (120, Female)

Taking control

Many people attributed the change in mood to a sense of 'taking control' from engaging in the BCTs themselves (e.g. planning). For example, some gained great insight just from understanding how physical activity or routine, pleasurable or necessary activities link with mood. Some also gained benefit

from the idea of using physical activity as a personal tool to improve mood. Others felt that a clear distinction between routine, pleasurable and necessary activities and challenging previous presumptions about depression was one of the most useful aspects.

“I think what also it sort of helped me focus on is that if things are very, very bad, I needed to concentrate on the necessary because the necessary could you know if you don’t do the necessary, then obviously things could get really you know could get really bad. It was also, and that really helped because I had started I had never had that as I say never had that distinction I think before in that way. So it was very good, very useful” (158, Female)

“I think to understand a bit more about, do a bit more exercise, and plan a bit more; it would generally make you feel a bit better.” (146, Female)

“I would say it’s how I started to think about things. And it’s kind of challenged some presumptions that I had before, and I think that that will stay with me more than physically going through the programme. And I think that has been really valuable” (120, Female)

7.6 Discussion

7.6.1 Summary

Behavioural interventions promoting physical activity for depression are rare, and their mechanisms are poorly understood. The pilot RCT (reported in chapter 6) demonstrated that eMotion was feasible and potentially effective for treating depression. The present chapter described a mixed-methods process evaluation exploring how eMotion may have achieved reductions in depression. We found that participant factors (e.g. work commitments, expectations of treatment) may have influenced the engagement and subsequent outcomes of eMotion. eMotion in its current form was potentially acceptable to participants (with suggestions for further refinements) and demonstrated good fidelity regarding receipt and enactment. Furthermore, interviews with participants revealed a number of possible mechanisms by which eMotion may have

changed behaviour (e.g. through increased awareness of mood and activity link) and reduced depression (e.g. through distraction).

7.6.2 Relationship to other literature

7.6.2.1 Participant factors

Regarding participant factors, people had high expectations of eMotion and found it to be potentially more accessible than face-to-face therapy. These findings are comparable with previous findings from qualitative research on peoples' experiences of app-based BA which found that people were curious about managing their depression using a self-delivered format (Ly et al., 2015). People using eMotion also expressed a sense of curiosity for trying something different. However, many found it challenging to fit eMotion into their busy work and family lives due to the need to access a computer for delivery. A qualitative study exploring patient views of face-to-face delivered BA corroborated this finding, showing that work and family commitments were cited as a primary concern (Finning et al., 2017).

7.6.2.2 Acceptability

Most people liked the audio delivery aspect of eMotion, the weekly modular structure and the ease of navigation. However, many felt there was too much information, found the linear weekly structure off-putting and repetitive and felt that more reminders to access the programme (other than by email) would have been useful. Recent studies have found that tailoring to health literacy may not be necessary for positive outcomes (Rowell et al., 2015). As such, a future iteration of eMotion could ensure that all content is written to lower health literacy levels to ensure that fewer people feel overloaded with information. The audio delivery aspect was by far the most liked aspect of eMotion, with people stating that it added a more 'personal feel' than other written programmes. One explanation for this could be that the audio delivery partially replicated a feeling of empathy or compassion, considered to be a crucial component of face-to-face psychological interventions (Moyers & Miller, 2013). Recent studies have explored whether computer-based systems can simulate empathy without the presence of another human using computer-based modes of delivery (Imel, Georgiou, Atkins, & Narayanan, 2016). However, at present, there is no research that has investigated the extent to

which different modes of delivery (e.g. audio, avatar-based) via the internet can affect outcomes of depression (Renton et al., 2014). It is important to note, that other studies of web-based interventions have reported that interactivity and audio-visual presentations may be less important if web-based interventions are delivered iteratively with in-depth feedback from users (Muller et al., 2017).

The lack of therapist support in eMotion was considered a barrier to engagement and outcomes for many, with participants reporting a lack of accountability and motivation for logging into the website. This finding is consistent with a previous systematic review of web-based CBT for depression which has shown that support is positively associated with effectiveness and retention rates (Richards & Richardson, 2012). Participants in other qualitative studies exploring perceptions of BA have also echoed these findings, with all participants perceiving the therapist support as crucial to a positive experience (Ly et al., 2015; Richards et al., 2016). However, in stark contrast to these studies, many participants in the current study felt that a facilitator was not necessary, and may have added further pressure. This echoes findings from the BAcpac study in which some patients worked through the workbook independently and stopped the therapy support sessions (Pentecost et al., 2015). Self-regulation proposes that people's own motivation (in the absence of external factors) influences their behaviour (Bandura, 1991). As such, the lower level of support provided in eMotion may have fostered some people's sense of self-regulation or autonomy. Indeed, in a study by Babyak et al. (2000) people felt that using anti-depressant medication alongside physical activity undermined the self-regulatory benefits that come from physical activity. It is also possible that web-based BA required less human support than other web-based treatments (e.g. cognitive behaviour therapy) due to its less complicated nature. A future trial could test this idea by comparing unsupported web-based BA with CBT.

7.6.2.3 Fidelity

As reported in chapter 6, a median of three out of 13 eMotion modules was accessed (delivery). However, an increase in measures of receipt and enactment were found for the intervention group compared to control. More specifically, there were increases in participants' understanding of eMotion, participants' confidence to identify and plan activities to improve their mood, and

participants' confidence to deal with setbacks. Exploratory analysis also revealed that confidence to deal with setbacks mediated the effect of eMotion on depression outcomes. No significant changes were found for participants' confidence to select activities to improve mood. This lack of change might be due to higher levels of confidence at baseline, leaving less room for change, or it could be that this intervention component was not sufficiently delivered via the eMotion website.

Feedback from participants indicated that people found the process of identifying achievable activities slightly difficult to follow. Learning how to identify and select activities that can improve mood is considered fundamental to BA (as well as planning and dealing with setbacks) (Farrand et al., 2014). Hence, future intervention studies need to ensure that these factors are properly operationalised and understood by participants. One way to do this could be to adopt a similar design fidelity enhancing methodology (as reported in chapter 4), but by using patient and public involvement (PPI) groups rather than intervention designers. For example, PPI groups could be asked to go through the intervention materials and report on what they think the active components are using a checklist. Had more participants enacted all the BCTs as intended, the intervention may have achieved a greater effect on depression. Our findings partially support evidence from a study that showed that a higher number of enacted BCTs was associated with a change in body mass index (Hankonen et al., 2014). Our findings also support a recent article that suggests that measuring fidelity in digital behaviour change intervention involves conceptualising engagement beyond just physical interaction with a website (e.g. use of BCTs in day-to-day settings) (Yardley et al., 2016). Despite offering good design and delivery fidelity, it appears that using an online intervention mode can still have substantial variation in receipt and enactment, supporting the idea that every aspect of fidelity is important for maximising effectiveness. The next challenge for eMotion is to find ways to maximise engagement and retention with the intervention process.

7.6.2.4 *Mechanisms of influencing behaviour*

Participants randomised to eMotion expressed various perspectives regarding mechanisms of change for behaviour, and many people reported positive outcome expectations towards physical activity. However, the

qualitative data revealed that, despite endorsing activity for depression, they were more convinced by learning from experience than the logical ideas. As such, a vital part of the intervention was to elicit and reinforce any positive experiences. Affect or pleasure is considered to be a stimulus that positively reinforces people's future behaviour (Berridge & Kringelbach, 2016). The experience of affect and positive reinforcement is also a fundamental mechanism by which BA is theorised to reduce depression (Hopko et al., 2003; Jacobson et al., 2001). Furthermore, previous literature has found that emphasising the affective benefits is more effective than highlighting the instrumental benefits (e.g. weight loss) for increasing physical activity (Conner, Rhodes, Morris, McEachan, & Lawton, 2011; Ekkekakis, Hargreaves, & Parfitt, 2013), adding weight to this finding.

Other mechanisms of behaviour change reported by people randomised to eMotion included an increased sense of competence to engage in activities as a result of prioritising and planning activities, as well as dealing with setbacks. These were all intended BCTs operationalised in eMotion, and the data also support the underlying theoretical premise of 'building competence' from Self Determination Theory (SDT) (Deci & Ryan, 1985; Ryan & Deci, 2000). This is also consistent with previous research which has found that BCTs based on control theory (and other self-regulation theories) were more effective in changing physical activity (Greaves et al., 2011).

7.6.2.5 *Mechanisms influencing depression*

People had diverging views about the mechanisms of change in depression symptoms, suggesting the changes were either the result of increases in routine, pleasurable and necessary activities or physical activity. For some people, the most crucial part of eMotion was the distraction from negative cognitive thoughts as the result of engaging in physical activity. An important potential mechanism of depression is perseverative negative cognitive processes (e.g. worry, rumination) which have been shown to be associated with depression (Dickens et al., 2012; Trick, Watkins, Winderatt, & Dickens, 2016; Watkins, 2008). Recent laboratory studies have found physical activity to potentially protect against the harmful effects of rumination (Puterman et al., 2012) and distraction has been reported as a key mediator in studies investigating the effects of physical activity on depression (Searle et al., 2011).

Conversely, some people, who perceived themselves to be already physically active, felt that physical activity served as an avoidance strategy and that reducing their physical activity and engaging in more meaningful activities was more beneficial.

There was also some evidence that engaging in physical or routine, pleasurable and necessary activities provided a sense of structure or control as well as feelings of achievement, supporting previous research that proposes that achievement and control are key mechanisms underlying the therapeutic effects of physical activity (Craft & Perna, 2004). A sense of achievement has also been reported as a mechanism in a previous qualitative study, which showed that participants felt a sense of purpose after engaging in physical activity and often preferred the 'self-help' aspect of engaging in physical activity as opposed to the passive nature of taking antidepressant medication (Searle et al., 2011). Furthermore, a previous trial of self-determination based exercise referral schemes found increases in physical activity and reductions in depression (Fortier, Duda, Guerin, & Teixeira, 2012), implying that constructs based on Self-determination Theory may be partly responsible for changes in depressive symptoms.

An interesting finding is that no one attributed his or her reductions in depression to biochemical pathways (despite the presence of text and audio outlining this mechanism in the "rationale" elements of eMotion). This finding contrasts with Searle et al. (2011), who found that patients tended to attribute their improvement in depression to biochemical pathways if they thought their depression was of a biochemical origin. A possible reason for this could be due to the way in which people were recruited. In the study by Searle et al. (2011) participants were recruited from a larger trial which included patients referred through primary care. The current study recruited people from the community who were interested in self-helping for their depression. It is plausible that people recruited via primary care were more likely to attribute their depression to biochemical factors (due to a more salient focus on medication strategies), whereas people in the current study were more likely to attribute their depression to situational (hence changeable) factors.

7.6.3 Strengths and limitations

The process evaluation reported in this chapter had a number of strengths. We adopted a mixed methods approach to explore further domains highlighted by the MRC guidance on process evaluation (Moore et al., 2015). By adopting a mixed methods approach, we were able to obtain richer data relating to process factors, which could be fundamental in planning the next stage of the intervention.

Despite attempting to minimise mentions of physical activity in the recruitment criteria, it may have still been clear to people that the trial had a focus on physical activity due to other factors (e.g. accelerometers). As such it is possible that there was a selection bias towards participants who held favourable views towards physical activity as a treatment for depression. For example, before people entered the trial, they were informed in the participant information sheet that they would be wearing wrist monitors that assess movement. Despite this, many reported in the interviews that they did not think the trial was explicitly about physical activity.

Another limitation is the timing of the telephone calls and the fact that the same person (who also voiced the audio content for the intervention) conducted some of the interviews. A social desirability effect (Podsakoff, MacKenzie, Lee, & Podsakoff, 2003) may have occurred as participants felt they wanted to give the best possible impression of the intervention. However, to mitigate this, seven of the interviews were conducted by a student who had no other involvement with the eMotion intervention, and there appeared to be no noticeable difference from this subset of interviews. Self-report data on the enactment and receipt of intervention components have previously been used in behavioural interventions promoting physical activity (as reported in chapter 2), but such data are subject to a number of limitations (e.g. recall bias) (Podsakoff et al., 2003). Direct monitoring of engagement with the worksheets provided by eMotion could have provided a more objective account of receipt /enactment. However, effective engagement or enactment also involves engaging with the behavioural strategies taught by the intervention in people's day to day lives (Bellg et al., 2004; Resnick, 2005; Yardley et al., 2016). As such, even measuring completion of worksheets would not give an accurate reflection of the extent to which people engaged with the core principles of the intervention.

Finally, only two out of the eleven interviews were conducted on males (reflecting the sample composition in the pilot trial) resembling other qualitative research on people's experiences of face-to-face BA (Finning et al., 2017). However, this stands in contrast to another study looking at a BA app (Ly et al., 2015). Reasons for the low male response could be a reflection of the poor help-seeking behaviours of men in the UK (Oliver, Pearson, Coe, & Gunnell, 2005).

Another limitation is the lack of quantitative data for other process measures used in eMotion. However, the primary aim of eMotion was to assess feasibility and acceptability in a hard-to-reach and vulnerable population. As such it was important to ensure that it was feasible to collect the primary and secondary outcomes (i.e. depression and physical activity) and that people found the questionnaires acceptable (which qualitative data indicated they did) and not too burdensome. The next stage of the trial could, therefore, include the same level of quantitative process measures in a more substantial sample to more precisely identify the theoretical and operational mechanisms at work.

One final limitation, is that my own identity and experiences may have shaped the methodological choices I made, potentially influencing the interpretation of the findings. I have had personal experiences with depression, and hold positive views about the utility of behavioural activation and physical activity as a treatment strategy. These experiences inspired me to conduct research in this area and potentially influenced the data collection and analysis. I also have a background in psychology which may have biased me towards a more scientific/reductionist epistemology.

7.6.4 Conclusion

This process evaluation used mixed methods to explore the acceptability, fidelity, and theoretical mechanisms of eMotion and provide further insight into the relationship between the extent to which people engage with BCTs and outcomes. Overall, most participants found eMotion to be acceptable. Ways to refine the intervention were also identified. Participant engagement with certain key BCTs appeared to mediate depression outcomes, suggesting that further work needs to be done to increase the salience and impact of other proposed change techniques. This study has yielded further insight into how people with

depression engage with behavioural interventions promoting physical activity and provided preliminary data suggesting that a novel approach to implementing BA alongside physical activity promotion could be effective.

Chapter 8 General Discussion

8.1 Chapter outline

This final chapter brings together the findings from each chapter and discusses how they have addressed the thesis aims. More specifically this chapter includes:

- A brief recap of the overall thesis aims
- A summary of findings and how they met the thesis aims
- A discussion of the overall findings in relation to the broader literature
- A summary of the strengths and limitations of the research conducted
- Implications for future research and practice
- Conclusion

8.2 Recap of overarching thesis aims summary of findings

Physical activity may prove a promising treatment for depression. However, there are translational barriers with physical activity not being regularly prescribed as an evidence-based treatment at policy and practitioner level. Reasons could include a lack of agreement on the appropriate methodological strategies needed to effectively evaluate physical activity as a treatment for depression (Faulkner & Biddle, 2001), as well as the inherent challenges in prescribing physical activity for depression (Taylor & Faulkner, 2014). Individual level (one to one and group-based) behavioural interventions are a crucial strategy for increasing physical activity. However, there is considerable variation in their reported effectiveness (Foster et al., 2005; Greaves et al., 2011; Orrow et al., 2012). There is an abundance of studies which investigate the effects of structured exercise, psychological therapies, and anti-depressants on depression (Cooney et al., 2013; Pim Cuijpers et al., 2008). However, there is a lack of research which investigates whether physical activity can be promoted as a treatment for depression. Furthermore, the few existing trials have a range of methodological limitations (complete description of interventions, establishing intervention fidelity, using appropriate control conditions and avoiding potential sample bias regarding baseline physical

activity(attracting pro-exercise/non-representative segments of the population)).

The first overarching aim of the thesis was to therefore:

1. *Develop and pilot a behavioural intervention promoting physical activity for the treatment of depression.*

Fidelity concerns the extent to which behavioural interventions are delivered as intended. At its most broad conceptualisation, fidelity refers to the confirmation that the manipulation of the independent variable occurred as planned. A lack of attention to fidelity can undermine the effectiveness of interventions, and increase the probability of making type 1 (incorrectly concluding an intervention is effective) or type 2 (erroneously concluding an intervention is ineffective) errors. Various frameworks for conceptualising fidelity exist (Carroll et al., 2007; Moncher & Prinz, 1991; Moore et al., 2015). However, the Behaviour Change Consortium (BCC) framework (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005) recommend that researchers assess fidelity at the levels of design, training, delivery, receipt, and enactment. Given its importance in behavioural interventions more generally, fidelity is also a further consideration for behavioural interventions promoting physical activity for treating depression. The second overarching aim of the thesis was therefore to:

2. *Use the BCC framework to focus on issues relating to fidelity throughout the development and pilot/feasibility evaluation of a behavioural intervention promoting physical activity for depression.*

8.3 Summary of findings

This thesis addressed two core thesis aims through six empirical chapters (figure 8.1). This section summarises the findings from each chapter, and how they relate to each of the thesis aims.

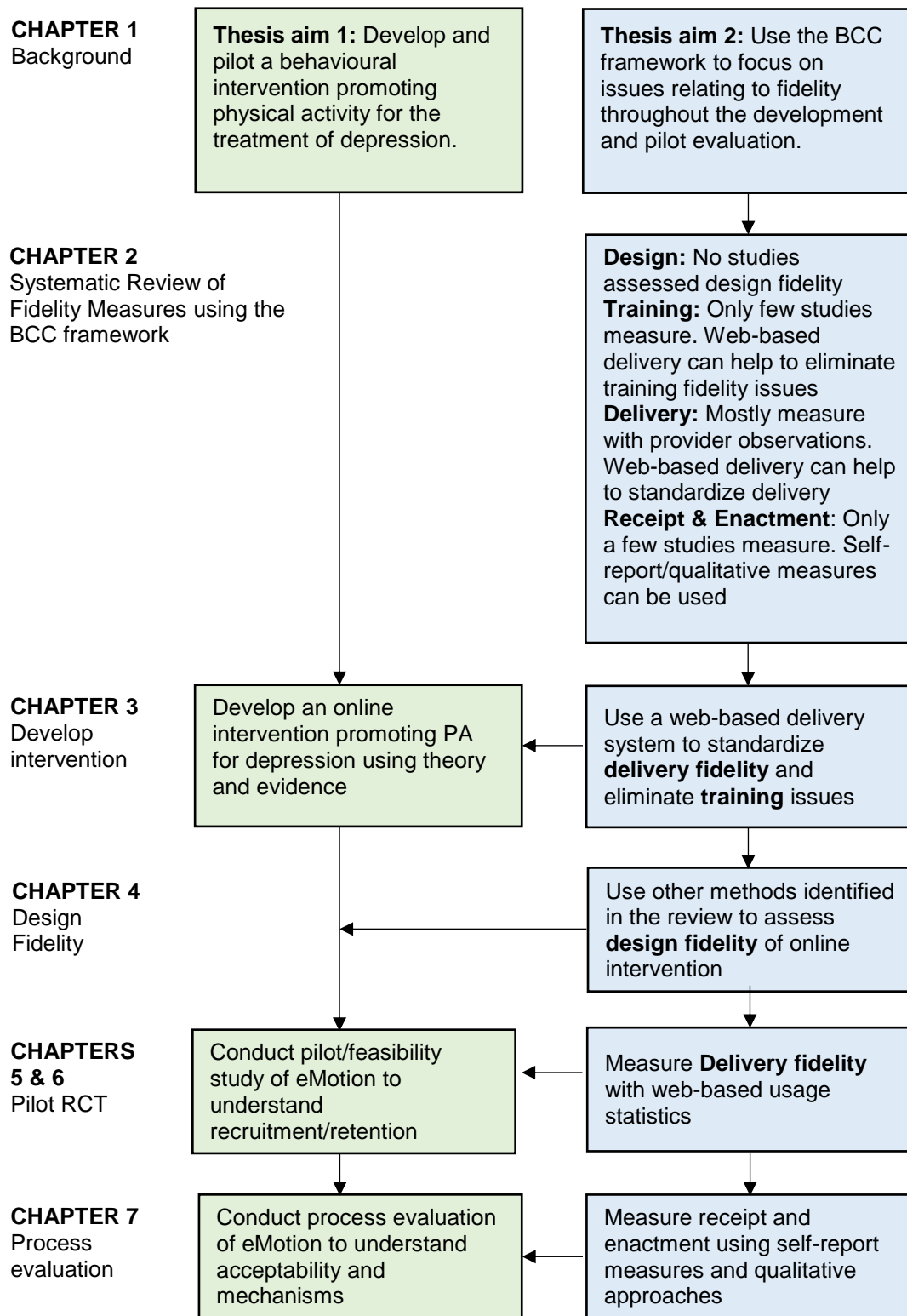


Figure 8.1: Thesis flowchart

8.3.1 Chapter 2: Assessment of fidelity in individual-level behaviour change interventions promoting physical activity among adults: A Systematic Review.

The systematic review only identified 28 studies evaluating 21 interventions, suggesting a lack of attention to this issue in the field. A range of different ways to assess intervention fidelity were identified, with the delivery of intervention components being the most frequent. The concepts measured often deviated from those determined by the BCC Framework (Borrelli, 2011). For example, there was a lack of clear distinction between fidelity of training and fidelity of delivery and no studies assessed every aspect of fidelity. A wide range of approaches were used to measure fidelity, ranging from researcher coding of observational data (using checklists or scales), participant self-report measures and the simple counting of sessions attended. A mixture of provider self-report and audio observation was the most standard approach for delivery fidelity, and participant self-report was most common for receipt and enactment. However, for web-based interventions, delivery was often assessed automatically using electronic methods. There was an overall lack of methodological rigour in the procedures used for data collection (e.g. lack of attention to psychometrics and use of untrained, potentially biased raters) when appraised against a priori quality criteria for fidelity assessment.

8.3.1.1 *How did chapter 2 address the thesis aims?*

Chapter 2 directly addressed the second thesis aim by using the BCC framework to identify, and critique methods used to assess fidelity in behavioural interventions promoting physical activity. Chapter 2 highlighted ways to improve the rigour and replicability of the development and evaluation of behavioural interventions promoting physical activity for reducing depression by enhancing the assessment of intervention fidelity. More specifically, chapter 2 highlighted that there is lack of research assessing design fidelity, and revealed that studies using web-based delivery systems were able to mitigate issues relating to training and delivery by removing the need for a human provider (i.e. by standardising and directly delivering web-based content to the participant). Furthermore, chapter 2 revealed that participant interaction with the intervention could be measured directly using web-based usage statistics (e.g. time spent on modules) and receipt and enactment could be measured using

self-report questionnaires. As such, these findings directly informed the subsequent chapters in the thesis.

8.3.2 Chapter 3: Development of a web-based intervention (eMotion) based on behavioural activation to promote physical activity in people with depression.

Chapter 2 identified that using a web-based programme could be an effective way to standardise intervention delivery fidelity and reduce or eliminate the need for training fidelity. Chapter 3 provided a transparent account of the theory and evidence underpinning the eMotion intervention, as well as a systematic account of how the intervention was adapted for online delivery (using the CeHReS roadmap). A structured approach was taken, which included, identifying key learning objectives, strategically searching the literature and engaging with patient, public involvement (PPI) and experts in the field. Furthermore, chapter 3 provided a detailed, replicable description of the intervention (eMotion). The intervention was systemically developed (Bartholomew et al., 2011; Craig et al., 2008; van Gemert-Pijnen et al., 2011) and reported (Hoffmann et al., 2014) following previous guidelines. The result was a web-based intervention designed to treat depression and simultaneously promote physical activity using behavioural activation (BA) and behaviour change techniques (BCTs) based on Self Determination Theory (Deci & Ryan 1985)

8.3.2.1 *How did chapter 3 address the thesis aims?*

Chapter 3 directly addressed both of the thesis aims. We addressed the first thesis aim by systematically developing a behavioural intervention promoting physical activity for the treatment of depression (eMotion). The second thesis aim was addressed by using findings from chapter 2, to improve the training and delivery fidelity of eMotion.

8.3.3 Chapter 4: Ensuring design fidelity in behavioural interventions: A novel method for assessing design fidelity and its application to the assessment and improvement of the design of eMotion

Chapter 4 used a novel methodology to check intervention design fidelity, using independent coding to systematically verify the presence or absence of intended and non-intended theoretical components. Applying the method to the

development of eMotion identified (post-discussion) discrepancies relating to 12 out of 221 (AC1 =0.91) and 14 out of 221 (AC1 = 0.88) BA and physical activity BCTs respectively. The intervention or its description were then amended to remove all discrepancies. This method can be applied to checking that intervention content is appropriate (regarding its component BCTs) or to checking theoretical integrity (the degree of fit between specified BCTs and proposed processes of change as specified in a logic model). The method can be used either to assess design fidelity (e.g. for systematic reviewing of existing interventions) or in a more iterative mode to help improve design fidelity at the development stage (as exemplified in chapter 4).

8.3.3.1 *How did chapter 4 address the thesis aims?*

Chapter 4 directly addressed the second thesis aim. By addressing issues relating to the first domain of the BCC framework we improved the design fidelity of the intervention.

8.3.4 *Chapter 5 and 6: The eMotion Pilot Trial: Methods and Results*

In chapters 5 and 6, we aimed to provide evidence on the feasibility and acceptability of eMotion, and exploratory data on outcomes with the goal of informing the planning of a full-scale trial. Furthermore, we attempted to improve on the previous methodological limitations, by selecting appropriate control conditions, more accurately measuring physical activity and recruiting a less active baseline sample. Conducting a trial of the eMotion intervention was shown to be feasible with 62 people recruited, and attrition rates of only 19% (95% CI: 11 to 30%) concerning the primary outcome (PHQ-8). At baseline and two months, post-randomisation 85% and 44% provided usable accelerometer data respectively, and the eMotion intervention was shown to be acceptable. We were able to recruit the population of interest with moderately high depression scores (mean at baseline 14.6 (3.2) on the PHQ-8) and low levels of moderate and vigorous physical activity (median of 35.8 (0.0 to 98.6) minutes in at least 10-minute bouts) per week. Regarding engagement with the intervention, the findings from chapter 6 revealed that the mean number of logins, modules accessed and total minutes spent on eMotion was 5.5 (SD=5.7), 3.8 (SD=3.4) and 76.3 (SD = 121.1) respectively. Of all the participants in the intervention group, 55% completed at least the introduction,

week one and week two. An exploratory analysis of outcomes revealed that at two months post-randomisation, study completers in the eMotion group (n=25) had a significantly larger reduction in depressive symptoms than the waiting list control group (n=25) (Adjusted Mean Diff -3.6, 95% CI: -6.1 to -1.1). The findings revealed that we were successfully able to recruit a less active population with depression, maintain acceptable retention rates and measure objective physical activity using GeneACTIV accelerometers. Exploratory analyses revealed a promising signal of depression outcomes which could be tested more definitively in a larger powered trial of eMotion. However, it is critical to note that the eMotion trial only had a two month follow up, and retention rates may have been lower at further follow-up points.

8.3.4.1 *How did chapters 5 and 6 address the thesis aims?*

Chapters 5 and 6 directly addressed both of the thesis aims. The first thesis aim was addressed by successfully piloting the eMotion intervention, which provided valuable data to inform the planning of a full-scale trial. The second thesis aim was addressed by using the BCC framework to focus on delivery fidelity, using web-based usage statistics to give a clear indication of how people engaged with the eMotion intervention.

8.3.5 *Chapter 7: Process Evaluation of the eMotion intervention*

Chapter 7 revealed that participant factors such as work commitments or expectations of treatment might have influenced the engagement and subsequent outcomes of eMotion. Broadly speaking in its current form, eMotion was deemed to be acceptable to participants. However, further refinements may improve this acceptability. We also demonstrated good fidelity of enactment. At two months post-randomisation, participants using eMotion reported significantly higher levels of understanding compared with controls in relation to a) how thoughts feelings and behaviours affect mood, b) confidence to identify, select, and plan achievable activities to improve mood and c) confidence to deal with setbacks. Participants randomised to the eMotion group were significantly more likely to report selecting (OR 5.7, 95% CI: 1.2 to 27.5) and planning (OR 6.3, 95% CI: 1.5 to 26.8) routine, pleasurable or necessary activities, or physical activities to improve their mood over the past two months. Interviews with participants revealed a number of possible mechanisms by which eMotion may

have changed behaviour (e.g. increased awareness of the link between mood and activity) and reduced depression (e.g. distraction). Furthermore, participants reported a number of ways in which they feel eMotion could have improved their experience (e.g. more interactive, available as an app).

8.3.5.1 *How did chapter 7 address the thesis aims?*

Chapter 7 directly addressed both of the thesis aims. The first aim was addressed by including a process evaluation (as recommended by the MRC guidance) providing further data relating to acceptability and mechanisms to inform the utility of conducting a full evaluation. The second thesis aim was addressed by using the BCC framework to focus on participant receipt and enactment of the pilot trial. The findings provided further insight into how people engaged with the eMotion BCTs in day-to-day settings.

8.4 A discussion of the thesis chapters in relation to the wider literature

The lack of attention, consistency and rigour in the conceptualisation and measurement of fidelity in physical activity interventions found in chapter 2 echoes previous findings in other behavioural domains (e.g. diabetes self-management). A recent scoping review found that only 5% of published articles addressed the issue of fidelity in motivational physical activity interventions (Quested et al., 2017). This finding is consistent with findings in other behavioural domains (Gearing et al., 2011; Schinckus et al., 2014; Schoenwald & Garland, 2013). For instance, in a review of fidelity in diabetes self-management interventions, only 15 studies were identified that assessed intervention fidelity, with delivery adherence, again being the most common concept assessed (Schinckus et al., 2014). In contrast, a review of fidelity in after-school programmes to promote behavioural and academic outcomes identified 55 studies (Maynard et al., 2013). However, the review of after-school programmes included strategies used to maintain fidelity (e.g. use of an intervention manual), and under further examination, only 29% of the included studies measured fidelity outcomes. Possible reasons for the lack of attention to fidelity assessment could be a lack of journal space or a lack of definitive guidance requiring the reporting of fidelity data. The recent development of checklists such as the Template for Intervention Description and Replication (TIDieR) (Hoffmann et al., 2014) and (MRC) guidance on process evaluations

(Moore et al., 2014) may help to improve this situation in the future. However, such guidelines do not currently suggest an a priori statement on how fidelity should be assessed. As such, chapter 2 may go further to improve this situation by providing a range of possible measures to assess fidelity.

Rigorous descriptions of the development and content of psychological interventions are lacking, and chapter 3 provided a clear transparent account of the process of developing the eMotion intervention using theory, evidence and stakeholder engagement. Other development frameworks could have been used, such as intervention mapping (Bartholomew et al., 2011), and the MRC framework (Craig et al., 2008). However, intervention mapping can be highly technical and prescriptive, requiring considerable resources (Greaves et al., 2016; Wight, Wimbush, Jepson, & Doi, 2016). The CeHReS roadmap also has an explicit focus on the fit between technology and intervention content, which the other frameworks do not offer (Kelders et al., 2013). There was utility in systematically developing an intervention in this way. However, the process was very time-consuming, an experience shared with other researchers using similar processes (Greaves et al., 2016; Kelders et al., 2013; Lloyd, Logan, Greaves, & Wyatt, 2011). In the context of the PhD, this was a useful exercise but within the context of funded trials and research programmes, the time-consuming nature of this process may be difficult to justify. Intervention mapping and the CeHReS roadmap are both resource intensive and technical (Bartholomew et al., 2011; van Gemert-Pijnen et al., 2011). Researchers have proposed other frameworks (Wight et al., 2016) which are less technical but still provide more detail than the MRC guidance (Craig et al., 2008) which could have been used. However, by providing a thorough account of this process, we have enhanced the transparency and replicability of eMotion and provided other researchers with a way of scrutinising not only the intervention but also the decisions we made to develop it.

In chapter 4, the small percentage of overall content that needed changing following the checking of the design fidelity of the eMotion intervention was encouraging, and indicates that many of the BCTs were indeed 'operationalised as intended'. In a previous study investigating the delivery of a behavioural intervention for physical activity (Proactive), it was found that only 44% of pre-specified BCTs were delivered by facilitators (Hardeman et al.,

2008). Poor delivery may have been due to the facilitators own biases or insufficient training. However, it may also have been a result of inadequate operationalisation of techniques in the manuals and protocol that informed the training, highlighting the many stages at which intervention fidelity can fail (design, training, delivery, receipt enactment) (Borrelli, 2011). It is essential therefore to have robust methods for assessing fidelity at each step, so that process evaluations can determine what factors may have caused an intervention to fail (or succeed) and what aspects researchers could improve for future implementation.

In chapters 5 and 6, The finding that the eMotion intervention was feasible and acceptable to deliver, supports previous findings of interventions promoting physical activity for depression (Chalder et al., 2012; Nyström et al., 2017; Rosenbaum et al., 2015; Vickers et al., 2009). However, the BAcPac study had major problems with intervention delivery (Pentecost et al., 2015) which stands in contrast to the findings of the present study. Possible reasons for this difference are due to the decision to deliver eMotion via an online medium, which has been suggested as a way to help to standardise fidelity and give the researchers further control (Watkins et al., 2016). Another reason could be due to the fact we delivered eMotion to a community sample. This method may have been more likely to attract a pool of able and willing participants. Furthermore, online delivery avoids the kind of provider/implementation issues identified in qualitative data from the BAcPac study (Pentecost et al., 2015). The eMotion trial, although exploratory, showed a promising signal in favour of depression outcomes, which warrants further research. This finding stands in contrast to the TREAD-UK trial which found no evidence that participants offered a physical activity counselling intervention experienced improvement in mood at four months follow-up point compared with usual care (Adjusted Mean Diff -0.54 (95% CI -3.06 to 1.99 ; $P=0.68$) (Chalder et al., 2012). The difference in findings to TREAD-UK could be due to the shorter follow up point in eMotion. However, the limitations of the TREAD-UK trial could also be responsible, such as using an active control group or having potentially poor fidelity.

Delivery is often considered the core issue for intervention fidelity (Borrelli, 2011; Gearing et al., 2011). However, in chapter 7 we showed the utility of capturing other fidelity domains (receipt and enactment). Recent

advances have suggested that attendance or contact time with behaviour change interventions (as indicated by page usage statistics in the case of eMotion) only partially captures participant engagement (Yardley et al., 2016). Unlike pharmacological interventions, behavioural interventions involve ongoing engagement with BCTs in day-to-day settings (e.g. use of action planning, self-monitoring or problem-solving). As such, the amount of exposure a participant has to the intervention itself may not provide a full picture of how someone has engaged. People who stop attending the intervention may sometimes do so because they have quickly understood it and may continue to use the skills and change techniques learned in their day to day lives. Similarly, increased engagement with a web-based system could be the result of higher motivation, or it may indicate that a person is just taking longer to understand the concepts delivered (Yardley et al., 2016). eMotion provided a rationale in the first two modules which intended to provide the core information a participant would need to enact the intervention in their own lives. Furthermore, participants were actively encouraged to engage in eMotion outside of the website by using their own diaries or phone apps. This thesis has added some weight to this hypothesis of effective engagement by showing that people engaged with eMotion in their own time, and did not necessarily spend lots of time on the programme itself. It was also found that contact time with the eMotion was not associated with depression outcomes.

8.5 Strengths and limitations

The collection of work presented in this thesis has a number of strengths as well as some limitations. We have already discussed specific strengths and limitations relating to each study within the discussions sections of each chapter. The present section addresses the broader strengths and limitations of the work comprising the thesis.

8.5.1 Strengths

The main strength of this thesis was a rigorous approach to assess the feasibility of conducting a future evaluation and the conduct of exploratory analyses of the potential efficacy of eMotion. We used objective methods where possible to evaluate physical activity, and validated measures of depression symptoms.

Another considerable strength of this thesis was the focus on all elements of intervention fidelity throughout the design and evaluation of eMotion. Chapter 2 identified a range of potentially good quality methods for assessing fidelity across the NIH BCC framework which fed into the design and evaluation of the eMotion intervention. As a result, we enhanced the fidelity of delivery (and removed the need for training) by delivering the intervention in a web-based format (chapter 3). Improving delivery fidelity in this way has also been proposed as a novel strategy for standardising the fidelity in a recent multifactorial trial evaluating discrete components of psychological therapies (Watkins et al., 2016). We also added a new step to the intervention development process to maximise design fidelity (chapter 4), and we assessed delivery using web-based usage statistics and receipt and enactment using quantitative and qualitative measures (chapters 5, 6 and 7).

Another advantage of web-based delivery is the potential ease of implementation and uptake into routine practice, where resources are scarce. Scalability and accessibility are widely held to be major advantages of digital health interventions and have the potential to reduce the treatment vs demand gap (Andersson, 2010). However, this has to be balanced against the lower potential uptake, particularly amongst lower literacy and older populations, and potentially lower long-term effectiveness compared with face-to-face interventions. Furthermore, if internet interventions become too prolific, existing clinical face-to-face services may lose funding (Andersson, 2010).

Another strength of this work is the fact that it addresses the pragmatic and crucial question of how to promote physical activity in people with depression. There is increasing interest in how to help people with depression to initiate and maintain an increase in physical activity but a lack of work in this area (as highlighted in chapter 1). Little is known about how behaviour change theories can be applied for promoting physical activity in people with depression. This lack of insight represents a significant challenge in translating such research to real-world settings, and it is hoped this thesis represents a step in taking the field forwards.

Finally, another strength to this work is the impact on overall public health and ability to target the large number of those in the community with undiagnosed depression (Kohn et al., 2004). In-house survey figures found that

a leaflet promoting the benefits of physical activity for mental health (on the Royal College of Psychiatrists website) was the third highest scoring leaflet out of a possible 45 and was also highly accessed (based on responses from 161 individuals) (Faulkner & Taylor, 2012). As such, an intervention such as eMotion could further help people in the community self-manage their symptoms and possibly with the assistance of physical activity.

8.5.2 Limitations

Although methods used enhanced design and delivery fidelity, it is possible that web-based delivery can lead to reduced engagement (Andersson, 2010; Richards & Richardson, 2012). However, the process evaluation has identified several ways that we can improve on this (e.g. using app-based mode of delivery, text reminders) which are also supported by other studies (Ly et al., 2014, 2015). Nevertheless, despite these potential limitations eMotion still had a promising effect on depression scores.

The thesis includes a number of other limitations that should be acknowledged. Although we randomised participants, due to a lack of resources for increased staffing, there was no blinding, introducing bias, and potentially inflating the observed effects (Suresh, 2011). However, an absence of face-to-face contact by using online self-report measures may have limited the potential of bias. Despite these issues, the purpose of the eMotion trial was to examine the feasibility of conducting a trial, rather than to make clinical judgements about effectiveness. This methodological issue can be easily addressed in future trials. From a pragmatic perspective, this thesis was able to answer core questions put forward by the MRC framework. For example, for the development stage, we identified the primary outcome, a logic model for bringing about change, the inclusion of a coherent theoretical basis, and a systematic approach to developing the intervention as well as a clear description of the intervention and its components.

It is conventional for research involving complex interventions to conduct a systematic review of similar studies during the development stage. Although an overview of existing studies addressing physical activity promotion for depression is included in chapter 1, it was not systematic. However, a recent systematic review of web-based physical activity interventions for depression

only included two studies (Rosenbaum et al., 2015). Furthermore, a recent Cochrane review of the effect of physical activity for depression found only found two studies had a behavioural component (which they subsequently excluded on this basis) (Chalder et al., 2012; Vickers et al., 2009). As such, we felt that the studies we reviewed in chapter 1 still provided an adequate overview of contemporary research in the field and felt a focus on fidelity would be more useful in improving the rigour of our intervention.

8.6 Implications for future research and practice

Based on the encouraging exploratory data, a larger scale trial of the effectiveness and cost-effectiveness of the eMotion intervention should be conducted after refinement (based on the data presented in chapters 6 and 7). The pilot RCT successfully tested many uncertainties related to the conduct of a full scale RCT, however some changes are recommended (summarised in table 8.1).

Although the eMotion pilot RCT achieved statistical significance, a definitive study powered a priori is required to confirm the results and estimate the mean difference between groups more precisely. A between arm comparison using the PHQ-8, with a minimally clinically important difference of 2.59 (Richards et al., 2016) a standard deviation of 3.2 (from the eMotion baseline sample) at 90% power would require 34 people per arm. Allowing for 19% attrition, 43 people would be needed for each arm.

Qualitative methods helped us to identify key participant barriers to engaging with eMotion, which we would address for the main trial. We would also seek to overcome the logistical barriers relating to data collection which were mainly a result of resource constraints (e.g. by incentivising the return of accelerometers). The full scale trial would also attempt to build on the pilot RCT by expanding the assessments to include more objective ways of collecting fidelity data (e.g. the collection of participant plans/diaries). One issue with expanding data collection is the lack of piloting. However, qualitative data suggested that participants did not find the data collection procedures burdensome. We could also conduct an internal pilot within the context of a larger scale trial to ensure that the changes to data collection remain acceptable to participants, before proceeding to a full scale trial.

Furthermore, with extra funding, more objective data could be collected using GENEActiv accelerometers to ascertain whether changes in physical activity are apparent and what types and intensities of activity help to mediate the effects of the intervention. A more definitive trial could also include an EMA sub-study (as described above). This would not only provide us with data on whether eMotion is cost-effective but also on how (and if) physical activity mediates depressive symptoms. This work was primarily targeted to people the community with elevated depressive symptoms. However, it could also be used to augment existing mental health services. As such it could provide a resource for both upstream (i.e. preventative) and downstream (i.e. treatment) interventions.

Table 8.1: Description of the eMotion pilot RCT and proposed changes for the main RCT

Pilot/feasibility trial	Main changes for main trial
Design	
<ul style="list-style-type: none"> Two-arm, individually randomised, parallel group pilot RCT with a nested process evaluation 	No change
Participants	
<ul style="list-style-type: none"> 18 years old, were living in the UK, had at least moderately severe depressive symptoms 	No change
<ul style="list-style-type: none"> Recruit people from the community 	No change
Sample size	
<ul style="list-style-type: none"> Target sample of at least 62 participants 	Recruit a sample of X participants based on the following
Intervention	
<ul style="list-style-type: none"> Audio/visual content 	No change
<ul style="list-style-type: none"> Linear structure 	Keep structure, but provide new content each week to facilitate engagement
<ul style="list-style-type: none"> Eight week duration 	No change
<ul style="list-style-type: none"> Up to two supportive phone calls 	Provide optional weekly supportive telephone calls
<ul style="list-style-type: none"> Weekly email reminders 	Provide optional text message reminders as people do not always check emails
<ul style="list-style-type: none"> Other (if resources permit) 	Provide app version, more visuals, FAQ page, progress chart, provide printed materials, online discussion forums, link to existing outlook calendars
Control	
<ul style="list-style-type: none"> Waiting list control 	No change
Data collection	
<ul style="list-style-type: none"> Monitor participants' mental health using PHQ-8/GAD-7 	Also confirm depression diagnosis using clinical interview schedule-revised (CIS-R).
<ul style="list-style-type: none"> Measure objective physical activity using GENEActiv accelerometers posted to participants 	Continue to use GENEActiv accelerometers but incentivise their return through the post to reduce data loss
<ul style="list-style-type: none"> Measure self-reported physical activity using IPAQ-SF 	Change measure for one which more accurately assesses 'type' of activity and is more sensitive to change
<ul style="list-style-type: none"> Demographic data 	Also measure 'depression diagnosis'
<ul style="list-style-type: none"> Baseline and two-month follow up 	Add a twelve month follow up assessment
<ul style="list-style-type: none"> Fidelity: Delivery/Usage 	No change
<ul style="list-style-type: none"> Receipt and enactment 	<p>Collect more measures of enactment relating to key processes of the trial</p> <p>Also collect data relating to the type of plans people are setting through online/print worksheets</p>

Researchers, reviewers and practitioners increasingly recognise the importance of understanding issues related to fidelity. This thesis has provided a rich set of ideas for informing the conduct or review of evaluations of behavioural interventions promoting physical activity. Some of the learning is more broadly applicable to other behavioural and clinical domains. We have provided an overview and appraisal of fidelity measures, proposing a new method for addressing design fidelity, and providing a worked example assessing the different dimensions of fidelity in a web-based intervention promoting physical activity for depression. Researchers will hopefully be able to build on the findings from this thesis by developing more robust interventions and evaluation plans that include more methodologically valid fidelity assessments. For reviewers, this thesis provides recommendations and methods for scrutinising the findings of intervention studies in relation to intervention fidelity, giving them increased scientific confidence in the outcomes and how they relate to the intervention. For practitioners and intervention designers, this thesis provides a range of tools to scrutinise their levels of intervention fidelity.

Drawing together the main recommendations outlined in this thesis, future research on promoting physical activity as an adjunct to treatment for depression could consider recruiting patients from primary care as well as the community (and assess whether the findings are different for these populations). Recruiting in this way could not only boost recruitment rates but also indicate how acceptable a web-based intervention would be in the context of primary care, potentially relieving the pressure on the NHS.

Future research should continue to test the optimum methods for promoting physical activity via BA as well as the use of human support vs no support. Data from the process evaluation revealed that people might increase different types of activities depending on what was contextually meaningful in their own lives. As such, different types of activity (including physical activity) may be more or less helpful depending on what they are already doing. Data from the process evaluation also revealed that there was a mixed response from people with regards to the utility of human support. Some participants felt that human support would have motivated them, and others felt the opposite. A

future trial could look at the differences between a supported vs unsupported intervention on effectiveness and cost-effectiveness outcomes.

More mechanistic approaches such as ecological momentary assessment (EMA) could also be used to better understand the dynamics of the relationships between physical activity and depression. EMA involves the collection of data in real time (i.e. continuous measurement of physical activity and depressive symptoms), allowing a more sensitive and precise mapping of any associations. This method may also help to eliminate one of the main limitations associated with self-report measures (recall bias) (Podsakoff et al., 2003).

8.7 Conclusion

The central aim of this thesis was to develop and pilot a behavioural intervention promoting physical activity for the treatment of depression with a focus on issues relating to fidelity. This thesis has successfully addressed the first two stages as outlined by the MRC framework (development and pilot/feasibility) and provided further insight into a number of methodological and clinical implications for the conduct of a fully powered RCT. This thesis has also shown that by applying a rigorous approach to intervention fidelity, we were able to improve the objectivity of the development process (by formative and summative testing of design fidelity), remove the need for training, standardise intervention delivery and capture additional data to further understand how people engage with behavioural interventions.

Appendices

Appendix 1: Search terms with results

Ovid was used to search in PsychINFO, Embase, PsychArticles and MEDLINE

	Searches	Results
1	Exercise\$.ti,ab,kw.	586819
2	Physical activ\$.ti,ab,kw.	204659
3	Swim\$.ti,ab,kw.	75441
4	Walk\$.ti,ab,kw.	222239
5	Jog\$.ti,ab,kw.	4568
6	Run\$.ti,ab,kw.	373908
7	sedentary.ti,ab,kw.	55379
8	fidelity.ti,ab,kw.	44622
9	Process evaluation.ti,ab,kw.	5628
10	(Intervention adj3 integrity).ti,ab,kw.	252
11	Treatment adj3 integrity).ti,ab,kw.	2059
12	(Intervention adj3 adherence).ti,ab,kw.	3718
13	(Treatment adj3 adherence).ti,ab,kw.	28808
14	(Intervention adj3 compliance).ti,ab,kw.	1568
15	(Treatment adj3 compliance).ti,ab,kw.	18421
16	(Intervention adj3 implementation).ti,ab,kw.	5519
17	(Treatment adj3 implementation).ti,ab,kw.	4722
18	(Intervention adj3 delivery).ti,ab,kw.	3522
19	(Treatment adj3 delivery).ti,ab,kw.	13283
20	(Intervention adj3 receipt).ti,ab,kw.	290
21	(Treatment adj3 receipt).ti,ab,kw.	1529
22	(Intervention adj3 enactment).ti,ab,kw.	47
23	(Program\$ adj3 enactment).ti,ab,kw.	54
24	(Treatment adj3 enactment).ti,ab,kw.	89
25	(Intervention adj3 dose).ti,ab,kw.	1732
26	(Program\$ adj3 dose).ti,ab,kw.	1920
27	(Treatment adj3 dose).ti,ab,kw.	61407
28	(Program\$ adj3 integrity).ti,ab,kw.	470
29	(Program\$ adj3 adherence).ti,ab,kw.	3264
30	(Program\$ adj3 compliance).ti,ab,kw.	3076
31	(Program\$ adj3 implementation).ti,ab,kw.	18700
32	(Program\$ adj3 delivery).ti,ab,kw.	5306
33	(Program\$ adj3 receipt).ti,ab,kw.	123
34	1 or 2 or 3 or 4 or 5 or 6 or 7	1325384
35	8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33	219275
36	34 and 35	11464

Appendix 2: Inclusion/Exclusion Criteria

Inclusion Criteria

1. Did the study examine the issue of fidelity (or related terms) of design, training, delivery, receipt or enactment either as a main focus or nested within another study (e.g. trial or feasibility study)?
2. Was the study testing a behavioural intervention designed to increase any type of physical activity at an individual level (i.e. interventions delivered to individuals either singly or in group sessions, but not whole community or whole-population level interventions such as media campaigns or changes in the local environment) as defined as any bodily movement produced by skeletal muscles that requires energy expenditure?
3. Did the intervention focus only on increasing physical activity and no other behaviours (e.g. diet, smoking)?
4. RCTs, observational studies, case-controlled or other quasi-experimental studies. Comparison groups could include usual care, no intervention or other interventions.
5. Was it conducted with adults aged 18 or over;
6. Was it a peer reviewed publication in English?

Exclude if

1. Protocol paper, conference abstract, not peer reviewed
2. Intervention also tackled other behaviours (e.g. diet, smoking, relaxation, skills building etc)
3. Intervention was school based or targeted children
4. Study includes physical activity as part of the intervention in addition to the outcome.
5. Study is looking at behavioural support plus physical activity

Appendix 3: Data extraction table

Author, study design	Population, Outcome	Intervention	Fidelity Measurement ¹	Fidelity Result ¹
(Aittasalo et al., 2012), 2 arm RCT	Population 241 inactive employees from occupational health care units Outcome Self-reported weekly minutes of walking. Increase in minutes of "walking for transportation" at 2 months	Content Intervention: 1 face to face session providing information of health benefits of PA. Pedometers and logbooks given to participants and monthly email message. Control: No intervention Duration 6 months Delivered by Researchers and occupational health care units	What measured Delivery: Delivery, reading and receiving email messages Enactment: Use of pedometers and logbooks How measured Delivery: Researcher notes and participant self-report checklists at 2 and 6 months Enactment: Researcher notes and participant self-report checklists at 2 and 6 months	Fidelity level Delivery: All messages delivered as intended; 80% were read at 6 months. Enactment: 60%, 46% of the participants respectively reported having used pedometers and logbooks regularly. 37% and 47% of the participants respectively in reported having used pedometers and logbooks irregularly Fidelity Level compared with other outcomes (e.g. physical activity) None reported
(Albright et al., 2012, 2015), Parallel 2 arm RCT	Population 115 inactive healthy postpartum women Outcome measure MVPA using Active Australia Survey	Content Intervention: Tailored telephone counselling plus website. Including goal setting, overcoming barriers to MVPA, and the importance of social support. Control: Standard website only Duration 17 calls delivered over 12 months Delivered by Health educator	What measured Delivery: Essential intervention components (e.g. goal, setting, social support and problem-solving, goal review). Number of calls made, and time of call. Number of website log ins, number of pages viewed How measured Delivery: 5% of calls with fidelity checklist of essential components over 12 months	Fidelity Level Delivery: 88% adherence to components. Review pedometer steps asked 68.8%, MVPA resources offered 80% of the time. Because resources were tailored to the woman's barriers and goals, she may not have required MVPA resources after each call. Discussing barriers to MVPA was covered in 96% of the calls, assessing woman's previous MVPA goal in 97% of calls, and setting the woman's next MVPA goal was discussed in 100% of the evaluated calls. Compliance to the scheduled telephone calls was high, with 90.4% receiving ≥ 13 of the 17 scheduled calls, with a mean time per call of 12.7 (± 6.4) minutes. Most (78.3%) of the women in TTCW condition viewed the website at least once. They accessed the website 2,092 times for a mean of 17.7 pages viewed per person (among those who viewed website at least once). Fidelity Level compared with other outcomes (e.g. physical activity) None reported
(Avery et al., 2014, 2016)	Population	Content Intervention:	What measured	Fidelity Level

Appendices

<p>1 arm pilot Trial</p>	<p>30 patients with type 2 diabetes Outcome None reported</p>	<p>Multifaceted behavioural intervention based on the TBP and SCT. Delivered online, and with discussion cards, booklets, activity planners, DVD's, Pedometers, Progress pads and leaflets. Duration 4 face to face appointments over 12 months Delivered by Healthcare professional</p>	<p>Delivery: Delivery of the intervention components How measured Delivery: Video recordings of 32 consultations were assessed independently by two researchers with expertise in health behaviour change. Checklist assessing presence and absence of specific intervention content (behaviour change techniques). Disagreements were resolved via discussion with the third researcher. Cohen's kappa calculated for baseline and 1-month coding was 0.60 and 0.55, respectively.</p>	<p>Delivery: Most techniques (i.e. agenda setting, discussion of pros versus cons for increasing PA, and utilisation of importance and confidence rulers) delivered during baseline and 1-month follow-up appointments most of the time. Agenda setting; discussion of pros versus cons for increasing PA; barrier identification and problem-solving; prompt focus on past success; prompt rewards contingent on progress and time management frequently not delivered. Review behavioural goals, delivered during 15 of the 17 1-month follow-up consultations. Prompt generalisation of PA behaviour was not delivered during baseline or 1-month follow-up consultations.</p> <p>Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>
<p>Bodde et al., (2012) 1 arm Formative pilot evaluation</p>	<p>Population 42 adults with intellectual disabilities Outcome None reported</p>	<p>Content Intervention: Multimedia intervention to increase knowledge, skills, and actual control as well as addressing constructs from the TPB. The curriculum included the concept of PA; physical and emotional benefits of PA; PA guidelines; practical ways to increase PA; participating with others; safety; and nutrition. Duration None reported Delivered by Instructor</p>	<p>What measured Delivery: Script adhered to by provider Receipt: Demonstrate the skill and knowledge they acquired. How measured Delivery: At four random times throughout the program a research assistant assessed the instructor's adherence to the script. Receipt: Following each lesson process measures used by research team to evaluate each participant's ability to independently perform the knowledge or skill outlined in the learning objectives. Seven to 10 days later, each participant was evaluated at the beginning of the class for their retention of a previous lesson's objective.</p>	<p>Fidelity Level Delivery: 100% of the material in the script was followed; however, questions and comments from participants interrupted the script as can be expected. Other typical interruptions common to disability day service centres also occurred and included behavioural issues, nonattendance, and emergency drills. Receipt: 73.5% to 100% of the participants met the learning objectives in any given session (M = 87.7%). Measurement of selected objectives for retention 7 to 10 days later showed rates of 79.2% to 96.4% (M = 89.8%). Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>
<p>(Bombardier et al., 2013) 2 arm RCT</p>	<p>Population 92 community-residing adults with multiple sclerosis Outcome</p>	<p>Content Intervention: Face to face and telephone delivered Motivational interviewing intervention. Control: Wait list Duration</p>	<p>What measured Delivery: Key indicators of MI fidelity: open questions, closed questions, affirmations, reflections, and summaries. MI-inconsistent behaviours (arguing, confronting, and giving</p>	<p>Fidelity Level Delivery: Fidelity to MI-consistent behaviours and spirit was good—72% of questions were open rather than closed, and the ratio of reflections to questions</p>

Appendices

	Significantly higher energy expenditure than control using 7 day physical activity recall	1 face to face session follow by 7 telephone calls lasting 30 minutes. Delivered by MI counsellor	advice without permission). Number of sessions completed and time spent. Subjective ratings were made of the therapist's MI spirit including warmth, understanding, and egalitarianism. How measured Delivery: Random selection of 20% of intervention sessions (n = 65) audio recorded and coded by MI-trained staff using behaviour counts and 7-point scale (from 1, not at all, to 7, very much).	was 2.9:1. Both of these indices exceeded standards for MI competency. Mean (SD) frequency of observed therapist behaviours that were MI inconsistent was 0.26 (0.57) per session. The average number of sessions completed was 6.9 (1.7), and 86.4% of the participants received at least six sessions. The average (SD) time spent in counselling sessions was 138 (59) minutes. Satisfactory for MI spirit (means 5.73–5.88; range 4–7). Fidelity Level compared with other outcomes (e.g. physical activity) None reported
(Brawley, Arbour-Nicitopoulos, & Martin Ginis, 2013b) 1 arm trial	Population 13 Adults with spinal cord injury Outcome Large increase in leisure time PA. Leisure time physical activity questionnaire	Content Intervention: Face to face group-mediated cognitive-behavioural training intervention based on SCT Duration 9 weeks Delivered by Interventionist	What measured Delivery: Satisfaction with intervention delivery. Receipt: Self-regulatory efficacy for scheduling and planning. Understanding of intervention content. Enactment: Action plan agreement. How measured Delivery: Interventionist rated relative accomplishment of session objective and the participation of group members in each of the eight sessions on a one item, 10-point Likert-type scale. An average per session rating was then calculated. Receipt: 11-items measured on a 0 (not at all confident) to 100 (completely confident) percent scale. Mean score was calculated for the scale, with higher scores indicating greater confidence. Internal consistency for the scale was > .80 at both time points. Seven items. Understanding measured on 5 point Likert Scale. Cronbach's alpha $\alpha = .80$. Enactment: 4-item instrument used to measure the extent to which participants agreed with forming detailed plans to engage in self-managed LTPA in addition to their activity. Each item was rated on a 9-point Likert-type scale. Internal consistency was good ($\alpha \geq .97$) at both time points.	Fidelity Level Delivery: The interventionist's ratings of satisfaction for the delivery of the group sessions were high (range = 7 to 10), with a mean rating of 8.38 ± 0.68 . Receipt: Self-regulatory efficacy changed from a mean of 86.20 (10.49) to 89.43 (10.23) post intervention. Regarding post-intervention perceptions of intervention content, participants strongly agreed that the material presented in the program was usable and easy to understand (M = 4.16, SD = 0.51; 5-point scale). Enactment: In terms of their agreement about making action plans for future LTPA, a trend was evident (t (9) = 2.12, p = .06), with an increase about aspects of planning actions for the next four weeks, reflecting a medium- to- large effect (See Table 1). In comparison to baseline, participants more strongly agreed that they had made plans about what, where, when and how they would engage in weekly self-managed LTPA in addition to their supervised, structured LTPA sessions. Relative to the response scale, participants moved from modest disagreement to strong agreement about forming action plans for the upcoming weeks.

Appendices

				Fidelity Level compared with other outcomes (e.g. physical activity) None reported
(Bull & Milton, 2010) 1 Arm Trial	Population 378 patients not achieving recommended PA Outcome General Practice Physical Activity Questionnaire	Content Intervention: Brief intervention, with adapted MI. Included goal-setting, written resources, and follow-up support. Duration 1 Baseline and 1 follow up consultation Delivered by General practitioner	What measured Delivery: Components of the intervention delivered to each patient. Estimated time taken and practitioner views and experiences of implementation. How measured Delivery: Tracked by data recorded in the Egton Medical Information System (EMIS). EMIS captured data on which. Data were entered by practitioners during or directly after each patient consultation. Focus group discussion undertaken with five practitioners and 5 telephone interviews. Semi-structured interview schedule developed to explore apparent differences between practices in delivery. Focus group and telephone discussions recorded on a digital audio device.	Fidelity Level Delivery: Overall each intervention component was provided to the majority of patients, including a discussion on the benefits of physical activity (n = 313), goal setting (n = 295), and signposting to local physical activity opportunities (n = 300). It took on average 20 minutes for patients recruited from the disease registers. These patients received both the screening and BI in the same appointment. Follow-up consultations were estimated to take on average 12 minutes. Practitioner feedback indicated that the delivery of the BI and specifically the use of motivational interviewing varied between practitioners. A lack of confidence and time constraints were cited as the primary barriers to delivering MI consistent consultations. Fidelity Level compared with other outcomes (e.g. physical activity) None reported
(Carr et al., 2013) 2 Arm RCT	Population 40 sedentary overweight adults Outcome Objective sedentary time measured by StepWatch decreased by 58.7 minutes per day compared to control group	Content Intervention: Theory based internet delivered programme. Access to a portable pedal machine at their worksite; and a pedometer to use in conjunction with the website. Control: Wait list Duration 12 weeks Delivered by Self-delivered	What measured Delivery: Number of website logins Enactment: Number of steps logged on the website How measured Assessed objectively at the end of 12 weeks through a backend tracking database made available by the website administrators.	Fidelity Level Delivery: Intervention participants logged on to the website an average of 71.3% (59.8 days) of all days they had access to the website (including weekends; table 4). Fidelity Level compared with other outcomes (e.g. physical activity) None reported
(Castro et al., 2011) 3 Arm RCT	Population 181 inactive adults over 50 years of age Outcome Increase in MVPA at 12 month compared to control measured using the Community Healthy Activities	Content Intervention: Telephone-based physical activity advice delivered by a trained professional staff member. Guided self-management program delivered via one face-to-face session followed by scheduled telephone contacts. Grounded in SCT and TTM.	What measured Delivery: Intervention content delivered in each session. Participant perceived quality and competence of providers. Intervention quantity (length of session). How measured	Fidelity Level Delivery: Relative to professional staff, peer mentors more frequently discussed by phone the balance of pros and cons of physical activity; the perceived benefits of PA, physical activity history and self-rewards. Professional staff more frequently discussed self-efficacy in the

Appendices

	<p>Model Program for Seniors Questionnaire</p>	<p><i>Intervention:</i> Identical advice delivered by a trained volunteer peer mentor Control: Attention control Duration 12 months Delivered by Professional staff and peer mentors</p>	<p>Delivery: Providers completed structured contact sheets to quantify the intervention content delivered in each session. Intervention quality included (self-management concepts discussed, tip sheets sent to participant; goals set) of the intervention delivered. Ten content areas were identified included perceived benefits of physical activity; problem-solving barriers to physical activity; discussion of lessons learned from previous physical activity experiences; “pros” versus “cons” of being active; injury prevention; enhancing enjoyment of physical activity; self-rewards for being active; enhancing self-efficacy through overcoming obstacles and building success; eliciting social support; and implementing relapse prevention. The intervention director verified the intervention fidelity data through weekly review of audio taped sessions and contact sheets. Participants rated perceived quality and competence of providers across both intervention arms using a 39-item scale adapted from previous studies. The scale was comprised of items that assessed participants’ perceived trust, competence, communication, empowerment, and connection to their advisor. Cronbach’s coefficient alpha at baseline was .98, indicating high internal consistency of items.</p>	<p>phone contacts relative to the peer mentors. In rating their perceptions of their advisor’s skill and competency, there were. No significant between group differences or changes over time across the two arms of participants perceived quality and competence of providers. Peer mentors and staff delivered equal amounts of the intervention, completing an average of 11 of 14 planned telephone calls across the year. Average length of the telephone calls was equivalent between arms, averaging approximately 15–16 minutes. Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>
<p>(Goyder et al., 2014) 3 arm, parallel-group, pragmatic, RCT</p>	<p>Population 282 previously sedentary people aged 40–64 years, living in deprived areas of Sheffield, UK Outcome No significant between group differences in TEE</p>	<p>Content <i>Intervention:</i> A ‘full booster’ group receiving two face-to-face physical activity consultations, provided in a MI style, underpinned by self-determination theory. Control: A control group who received no intervention after randomisation. Duration 2 months Delivered by None reported</p>	<p>What measured Delivery: Counts of MI adherent and non-adherent behaviours. Global ratings of evocation, collaboration, autonomy/support, direction and empathy. How measured Delivery: 4 interventionists assessed for after training and at 9 and 18 months using the MITI. Sessions were independently coded by a qualified MITI coder.</p>	<p>Fidelity Level Delivery: The reflection to question ratio increased across the four interventionists who completed delivery of the intervention from phase 1 to phase 2. The use of directional and deeper complex reflections was rated moderate or below competence across all interventionists. Mostly characterised as proficient for direction and competent for other global MI measures. Technical aspects of MI, including the use of open questions, increased across all interventionists from baseline. The global rating of ‘direction’ was consistently high</p>

Appendices

				<p>across all interventionists at phase 1 and phase 2.</p> <p>Fidelity Level compared with other outcomes (e.g. physical activity) MI fidelity was associated with physical activity as measured by mean TEE per day in kcal at 3 months ($p = 0.027$).</p>
<p>(Hardeman et al., 2008; Kinmonth et al., 2008)</p> <p>3 Arm RCT</p>	<p>Population 365 sedentary adults with a parental history of Type 2 Diabetes</p> <p>Outcome Energy expenditure measured by heart rate. Increased in both intervention groups at an equivalent of 20 minutes of brisk walking a day.</p>	<p>Content <i>Intervention:</i> Delivered face to face Participants taught to maximise personal advantages and opportunities, and to minimise disadvantages and obstacles to becoming more physically active. The intervention focused on eight self-regulatory strategies for behavioural change, including goal-setting, action-planning, self-monitoring, using rewards, goal-review, using prompts, building support from family and friends, and prevention of relapses. <i>Intervention:</i> Same as above but over telephone <i>Control:</i> Advice only Duration 12 months Delivered by Facilitator</p>	<p>What measured <i>Delivery:</i> All behaviours specified in the protocol coded under 12 behaviour change techniques and two communication techniques. Delivery of nine techniques (Building motivation, goal setting, action planning, self-monitoring, rewards, goal review, prompts, relapse prevention and habit formation) <i>Receipt:</i> Confidence in using each strategy <i>Enactment:</i> Use of eight self-regulatory strategies How Measured <i>Delivery:</i> Validated checklist expressed as the number of component behaviours within a technique applied by the facilitator, divided by the number of behaviours specified by the protocol. 52 participants selected purposively from both intervention arms. Final sample of 27 participants. Independent blinded rater assessed 108 transcripts and a second rater assessed sessions one and four for all participants. Inter-rater agreement on behaviours in sessions one and four was over 75% for 88% (76/86) of behaviours (range: 63–100%). Median agreement on techniques was 86% (IQR: 79–92%). Levels of agreement were similar for session one and four and intra-class correlation was high at 0.96 for all behaviours across sessions. There was no drift in assessment by the independent rater, with inter-rater agreement over 75% for 16 transcripts randomly selected for review by the first author. Facilitators recorded delivery of each technique ('covered' or 'not covered') after each session. <i>Receipt:</i> Measured with 10 items ($\alpha = 0.93$) on a scale from 1 (not at all confident) to 10 (very confident). Items were summed to calculate overall scores.</p>	<p>Fidelity Level <i>Delivery:</i> Mean adherence to techniques across all sessions ranged from 25% (generalising skills to other behaviours, e.g., healthy eating) to 66% (summarising, defining the agenda), with an overall mean of 45%. General communication skills were used most often, followed by techniques to facilitate initial behaviour change techniques to facilitate maintenance and generalising skills to other behaviours, e.g., healthy eating, were used least frequently, both within and across sessions. Use of techniques by facilitators varied considerably across participants (18–71%), with a median (IQR) of 44% (35–62%). 100% for facilitator-self reported adherence (IQR 97–100%). <i>Enactment:</i> Most participants in the combined intervention groups reported at both 6 and 12 months that they had used the eight behaviour change strategies. More than 75% reported that they had set goals and used action plans and self-monitoring activities, and more than 60% reported they had used family support and techniques for dealing with setbacks. Fidelity Level compared with other outcomes (e.g. physical activity) No significant associations between observed facilitator adherence to individual techniques and all techniques combined, and participants' cognitions about increasing physical activity and confidence in using self-regulatory strategies at 6 months or change in these variables between baseline and 6</p>

Appendices

			<p>Enactment: Questionnaires at baseline and 6 months (93% response) assessed the use of eight self-regulatory strategies (yes/no): Goal setting, action planning, self-monitoring, using rewards, goal review and using prompts (one item each) and building support and relapse prevention (two items each) (0.77 for all 10 items combined).</p>	<p>months. No significant correlations found for observed adherence and change in intention, affective attitude, and levels of objective and self-reported PA.</p>
<p>(Kolt et al., 2006) 2 Arm RCT</p>	<p>Population 186 sedentary older adults (mean age 74).</p> <p>Outcome Auckland Heart Study Physical Activity Questionnaire.</p>	<p>Content <i>Intervention:</i> Telephone counselling and print based intervention based on the TTM, CBT and MI. <i>Control:</i> No treatment.</p> <p>Duration 3 months.</p> <p>Delivered by Motivational counsellor.</p>	<p>What measured <i>Delivery:</i> Participant perception of counsellor support.</p> <p>How measured <i>Delivery:</i> 63 intervention group participants completed and survey focused on counsellor support, which was assessed in terms of counsellor advice being helpful and/or relevant, and whether the counsellor provided a service that was motivating, understanding, supportive and/or professional.</p>	<p>Fidelity Level <i>Delivery:</i> All respondents agreed or strongly agreed that the counsellor was understanding and supportive, and that a good overall level of service and support was provided. 97% agreed or strongly agreed that the service was professional, and 95% reported that the advice provided was helpful and the counsellor was motivating in terms of becoming and remaining physically active. Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>
<p>(Leslie et al., 2005) (Marshall, Leslie, Bauman, Marcus, & Owen, 2003) 2 Arm RT</p>	<p>Population 655 University academic and general staff.</p> <p>Outcome No significant change in IPAQ scores between or within groups.</p>	<p>Content <i>Intervention:</i> Website and email based intervention based on the TTM. <i>Intervention:</i> Print delivery of same intervention.</p> <p>Duration 10 weeks.</p> <p>Delivered by Self-delivered.</p>	<p>What measured <i>Delivery:</i> How many website visits, how long spent on website, how many pages viewed, how many emails received and read and how many modules of the website read.</p> <p>How measured <i>Delivery:</i> Website usage statistics. Specific items given to participants who recalled receiving any e-mails about the project were asked to recall how many e-mails they received, how much of them they read. For the website, participants were asked to rate how many sections of the website they read how often they accessed the website.</p>	<p>Fidelity Level <i>Delivery:</i> 152 participants visited the website at least once, the average time spent browsing the website was 9 min and the average number of pages viewed was 18. 227 received at least one e-mail and 23% of these recalled seeing all four e-mails. 115 of the follow-up sample recalled the website and 27% recalled there were four sections to the website. Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>
<p>(Levy & Cardinal, 2004)</p>	<p>Population 185 adults not achieving PA recommendations.</p>	<p>Content <i>Intervention:</i> Mailed information packet based on SDT. Behavioural and cognitive strategies</p>	<p>What measured <i>Delivery:</i> Received and read information packet.</p>	<p>Fidelity Level <i>Delivery:</i> 83.7% of those providing feedback reported receiving and reading</p>

Appendices

3 Arm RCT	<p>Outcome Increased PA for women indicated by the Leisure time exercise questionnaire.</p>	<p>promoting a sense of autonomy, competence, and relatedness. Intervention: Additional booster card mailed. Control: Informational packet containing American Heart Association (AHA) physical activity and health facts adapted from the AHA website. Duration 2 months Delivered by Self-delivered</p>	<p>Enactment: Completion of worksheets How measured Delivery: Participants reported whether they had received the packet (and, if appropriate, booster postcard) that was mailed to them, whether they had read the packet or postcard. Enactment: Participants reported whether they had completed intervention packet worksheets (in intervention groups only).</p>	<p>their respective packets, with no differences observed across conditions. Enactment: 35.3% and 57.9% of those in the intervention or intervention-plus-booster conditions reported completing the self-help worksheets included with their print materials. Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>
<p>(McCarthy et al., 2015) Pre=post pilot study</p>	<p>Population 20 adults with heart failure. Outcome None reported</p>	<p>Content Intervention: Brief face-to-face exercise counselling followed by weekly telephone follow up based on MI, and the use of a daily diary for self-monitoring. Participants were given an accelerometer to keep track of step-counts, 2-pound hand weights with instructions for upper body exercises, and a diary to record the four self-care activities. Duration 12 weeks. Delivered by MI counsellor.</p>	<p>What measured Delivery: Fidelity to the intervention and use of MI. Quantity or amount of intervention delivered to participants. Enactment: Use of the daily diary. How measured Delivery: All 20 exercise counselling sessions conducted at the beginning of the study were audiotaped. Four audiotapes were sent to an independent expert in MI for review and assessment of the interventionist's use of MI. Each tape was scored for adherence to the principles of MI. Summary scores for each of the four audiotapes included five categories: (1) average of spirit global (use of evocation, collaboration, autonomy/support, direction, and empathy); (2) reflection to question ratio; (3) percent open questions; (4) percent complex reflections; and (5) percent MI-adherent. Evaluation of the dose of the intervention that was delivered consisted of examining the quantity or amount of intervention delivered to participants. Enactment: Engagement with the daily diary was tallied for each of four activities: daily step counts, body weight, use of the hand weights, and the Borg scale. The total number of actual recorded data for each activity was divided by the number of potential diary recordings.</p>	<p>Delivery: Scoring of the tapes from subject 3 and 4 that were sent at revealed an overall low adherence to MI principles (50% and 40%). Percentage of open questions, was 40% and 25%. Reflections-to-questions ratio less than 1:1 (considered beginning MI proficient). Global spirit rating was poor. The initial session, lasted approximately one hour. The mean time was 12.57 minutes. 168 calls (93%) were made successfully and step-count data were collected. The length of each call lasted approximately 5 minutes. The mean number of calls over 12 weeks for each subject was 16.3. Enactment: Participants recorded step-counts 64% of days and body weight 52% of days. The Borg scale was recorded 50% of days and the use of hand weights was recorded 32% of days. These data reflect compliance with the diary recordings, not necessarily what was actually done for that day. Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>
<p>(Pinto et al., 1998) 2 Arm RCT</p>	<p>Population 355 Older adults Outcome None reported</p>	<p>Content Intervention: Activity counselling delivered by community based on a patient-centred model and the stages of change approach Control: No intervention</p>	<p>What measured Training: Confidence in providing activity counselling</p>	<p>Fidelity Level Training: There was a significant difference between groups in summary score change over time with the IG</p>

Appendices

		<p>Duration 1 session plus follow up</p> <p>Delivered by Primary care physicians</p>	<p>Delivery: Extent to which they provided specific components of activity counselling to all their patients</p> <p>How measured</p> <p>Training: Prior to randomisation, physicians were asked to complete a brief questionnaire assessing their confidence in providing activity counselling. A summary score was computed as a mean of the eight items' ratings.</p> <p>Delivery: Physicians were administered a post-intervention questionnaire after completing the follow-up visits, which included a self-reported evaluation of activity counselling. At follow-up interviews, patients were asked a series of questions about the activity counselling that they may have received.</p>	<p>physicians showing increased confidence in providing exercise counselling.</p> <p>Delivery: Most physicians reported counselling 75% of their patients across all counselling behaviours. Ninety-three percent of patients who provided data at 6 weeks reported receiving activity counselling from their physician during the initial visit. Patients reported that the physician spent an average of 8.9 minutes counselling them about exercise.</p> <p>Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>
<p>(Busse et al., 2014; Quinn et al., 2016)</p> <p>2 Arm RCT</p>	<p>Population: 46 participants with genetically confirmed Huntington disease</p> <p>Outcome None reported</p>	<p>Content:</p> <p>Intervention: Programme face to face based on SDT comprising of a purpose developed workbook, and an exercise DVD.</p> <p>Control: Social contact control intervention</p> <p>Duration 14 weeks</p> <p>Delivered by Coaches</p>	<p>What measured</p> <p>Delivery: Whether the content of each of the sessions was consistent with what was specified in the protocol and number of minutes. Extent to which each coach demonstrated efforts to promote a patient's autonomy, relatedness, and competence.</p> <p>How measured</p> <p>Delivery: Self-report checklist after each home visit. Full audio recording of one of the coach home visits and audio-recordings one of their later home visits third of 6 visits). Rated independently rated by a member of the study team, using a 0 to 4 rating scale for the 3 SDT areas and overall impression of the coach's performance. Used to provide coaches with constructive feedback on their interactions and as a mediating factor in analysis. To ensure that the fidelity rating tool could be readily implemented in a clinical setting utilizing relatively novice raters, the study team member (who was a researcher and not involved in delivery of the intervention) and the intervention coordinator independently rated 3 audio files and compared ratings for agreement. The ratings for the 2 raters were within one point of each other, and for 2 of the 3 total scores, there was 100% agreement. Fidelity of the</p>	<p>Fidelity Level</p> <p>Delivery: In 100% of sessions coaches introduced participants to the workbook, gave the participants the exercise DVD and discussed the concept of goal-setting. Sessions lasted on average 72.3 minutes.</p> <p>Overall scores ranged from 7 to 14 out of a possible 16 points, with a mean (standard deviation) score across the coaches of 11.0 (2.4). Coach interactions scored an average of 2.5 for autonomy, 3.0 for relatedness, 2.7 for competence, and 2.8 for the overall impression. Self-assessment scores were 3.1 for autonomy, 3.3 for relatedness, and 3.0 for competence.</p> <p>Fidelity Level compared with other outcomes (e.g. physical activity) Self-assessment scores were on average higher than those assigned by the independent rater.</p>

Appendices

			intervention was further evaluated by asking coaches to complete a self-assessment of their perceived ability to deliver the intervention as intended.	
(Soetens et al., 2014) 3 Arm RT	Population 803 Australian adults Outcome Physical activity measured by the Active Australia Survey improved significantly over time in all groups	Content <i>Intervention:</i> Internet delivered video intervention based on the TPB and TTM <i>Intervention:</i> Internet delivered text intervention based on the TPB and TTM <i>Intervention:</i> Internet delivered text and video intervention based on the TPB and TTM Duration 1 month Delivery by Self-delivered	What measured <i>Delivery:</i> Time spent on the website for each participant during the entire intervention period How measured <i>Delivery:</i> Website user statistics	Fidelity Level <i>Delivery:</i> Participants in the video group spent significantly more time in total on the website during the intervention period (21.4 minutes) than participants in the text group (13.4 minutes) and the combination group (15.1 minutes). Fidelity Level compared with other outcomes (e.g. physical activity) None reported
(R Steele & Mummery, 2007) 3 Arm RT	Population 192 inactive adults Outcome Physical activity measured by the Active Australia Survey	Content <i>Intervention:</i> Health-eSteps intervention based on SCT and included techniques such as; lifestyle activity, benefits and barriers, goal setting, self-monitoring, resistance training, self-talk, self-reinforcement, time and stress management, relapse prevention, and social support. <i>Intervention:</i> FACE group received weekly 1-hour face-to-face contact sessions with a trained program <i>Intervention:</i> Face to face plus internet. Received the same content delivered via the internet, and two additional face-to-face sessions. Duration 10 weeks Delivery by Facilitator	What measured <i>Delivery:</i> Number of face to face sessions and logins to the website How measured <i>Delivery:</i> Web tracking was used to track exposure across both intervention groups.	Fidelity Level <i>Delivery:</i> The mean number of face-to-face sessions (exposure) attended by the FACE group was 6.1 The mean number of logins (exposure) for the IM group was 11.5 and 11.8 for the IO group. Fidelity Level compared with other outcomes (e.g. physical activity) None reported
(JoEllen Wilbur et al., 2016; Joellen Wilbur et al., 2016) 3 Arm RCT	Population 288 African American Women Outcome	Content <i>Intervention (overall):</i> Six 2-hour group meetings. Based on SCT and MI. An easy-to-read participant manual for home use supplemented the group content.	What measured <i>Delivery:</i> Checklist of whether or not the interventionist performed the expected action outlined in the study manual (adherence). Competence (e.g. actively engages women in all discussion)	Fidelity Level <i>Delivery:</i> % of adherence to the group meeting protocol across all 3 conditions averaged greater than 70%, with no differences by condition. Interventionists' competence scores at the group meeting for all 3 conditions were close to the

Appendices

	<p>Physical activity measured by the Community Health Activities Model Programme for Seniors (CHAMPS) and using accelerometers. Main effect for increase in physical activity</p>	<p>Group 1: Above, with Personal motivational calls</p> <p>Group 2: Above with Automated messages</p> <p>Group 3: No calls between meetings</p> <p>Duration 48 weeks</p> <p>Delivered by Delivered predominately by registered nurses who were research staff members.</p>	<p>Enactment: Assessing participants' self-monitoring of their lifestyle PA prescription (steps they walked) using accelerometer.</p> <p>How measured</p> <p>Delivery: Each group meeting recorded with a digital audio recorder by the interventionist and given to clinical psychologist. Sample of group meetings and a combination of observation and digital audio recordings. The goals were to (1) get a reasonable estimate of intervention fidelity; (2) provide feedback to the interventionists based on initial evaluations; and (3) avoid longitudinal effects such as drift. Fidelity was assessed for 3 of the 6 group meetings for each of the 18 cohorts. Adherence: 12 to 16 checklist items. Summed and divided by the total number of items for percent adherence. Above 75% was considered adherent. Selected checklist items included the following: discussed benefits and trade-offs of physical activity, discussed activities women. Competence: 14 scored from 1 to 3. Items summed and divided by 14, with a possible range of 1 to 3. A score above 2.5 was competent. In a community based parenting intervention, the measure showed high interrater agreement for both adherence and competence scales (94% and 85%, respectively) and adequate intraclass correlation coefficients (adherence = 0.69, competence = 0.91). The average of these 3 assessments formed the fidelity score for each cohort.</p> <p>PC implementation fidelity delivery was assessed with the MI Treatment Integrity Code Version 3.0 (MITI). A global rating score and behaviour counts.</p> <p>Interventionists and research assistants entered each participant's attendance at group meetings held in the community into a web based tracking system. Likewise, the PC</p>	<p>maximum score of 3, with no differences across conditions. Examination of MI revealed that the global clinician rating score was close to 4, suggesting competence in delivering MI. The overall percentage of open-ended questions, was a mean of 46% of all questions, and complex reflection was just 2% of all reflections. The ratio of reflections to questions tended to be low (less than 1). A mean of 81% of behaviors were MI-adherent, which is below the threshold for beginning proficiency (90%).</p> <p>Enactment: 71.9% of the women wore their accelerometer more than 24 weeks out of a total of 48 weeks.</p> <p>Fidelity level compared with other outcomes (e.g. physical activity)</p> <p>Adherence in delivering the group meeting showed no significant effects on change in PA. A ceiling effect in the competence of group leaders made it infeasible to assess the impact on outcomes. The global clinician rating for fidelity delivery of PCs showed no significant change in PA.</p>
--	---	---	---	--

Appendices

			<p>interventionists logged their MI calls into a web-based tracking system. The system was programmed to provide reports on attendance at group meetings and completion of PCs by participant, study condition, and cohort. This allowed assessment of intervention receipt or dose. The outcaller of the ATCL was programmed to deliver ACs related to motivational messages during the adoption and maintenance phase of the intervention for the AC condition. All calls were stamped with the date and outcome: (1) voice (connected to a voice) and motivational message selected, (2) busy, (3) no answer, (4) no ring back, (5) no dial tone, (6) answering machine, or (7) hung-up. The incaller of the ATCL was also programmed to stamp the date of all incoming calls that connected to a motivational message. This information was downloaded and stored as Excel data so that the number of PCs from the incaller and outcaller that connected to a motivational message could be counted.</p> <p>Enactment: Data were exported from software at the group meeting for analysis. Thus, it was possible to identify how many weeks the women actually wore their accelerometers.</p>	
<p>(S. L. Williams et al., 2015) 2 Arm Cluster RCT</p>	<p>Population 315 general practice patients</p> <p>Outcome No significant differences in walking measured by pedometer</p>	<p>Content Intervention: Face to face based on self-regulation intervention plus information pack. Control: Patients received the information pack detailed above, and were also offered the opportunity to discuss their own walking with the practice nurse. Duration 6 weeks Delivery by Practice nurse</p>	<p>What measured Training: Provider competence before trial How measured Training: Assessed by research team using a 20-point checklist of the intervention techniques. Practice nurses and HCAs were required to achieve a minimum level of competence of delivery, which was that 12/14 intervention components were delivered correctly.</p>	<p>Fidelity Level None reported Fidelity Level compared with other outcomes (e.g. physical activity) None reported</p>

Appendix 4: Search terms with results for intervention development

Ovid was used to search in PsychINFO, Embase, PsychArticles and MEDLINE

	Searches	Results
1	Web delivered.ti,ab,kw.	211
2	web based.ti,ab,kw.	65762
3	computer delivered.ti,ab,kw.	693
4	computer based.ti,ab,kw.	36983
5	self delivered.ti,ab,kw.	74
6	self help.ti,ab,kw.	21184
7	online.ti,ab,kw.	230764
8	computerised.ti,ab,kw.	20849
9	computerized.ti,ab,kw.	166478
10	self management.ti,ab,kw.	40552
11	bibliotherapy.ti,ab,kw.	1887
12	book.ti,ab,kw.	220697
13	workbook.ti,ab,kw.	2733
14	depression.ti,ab,kw.	889321
15	mental health.ti,ab,kw.	407260
16	Physical activity.ti,ab,kw.	225546
17	Exercise.ti,ab,kw.	568671
18	behavior change.ti,ab,kw.	24475
19	behaviour change.ti,ab,kw.	9534
20	systematic-review.ti.	171646
21	Meta-analysis.ti.	164143
22	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	778739
23	14 or 15 or 16 or 17 or 18 or 19	1952009
24	20 or 21	281961
25	22 and 23 and 24	1919
26	remove duplicates from 25	1118
27	limit 26 to yr="2007 -Current"	1031
28	limit 27 to "all adult (19 plus years)" [Limit not valid in Journals@Ovid,Embase,PsyclINFO; records were retained]	877

Appendix 5: eMotion Intervention Structure

Learning Objective	Core BCTs	Operational strategy
Introduction		
² Believes information being conveyed relating to routine pleasurable and necessary activities	1a. Credible source	Audio/visual: Reference experts and research to increase credibility of information presented
Understand the aetiology of depression/low mood	2a. Information about emotional consequences	Audio/visual: Provide explanation about the interaction of physiological, behavioural and cognitive emotional symptoms and the role of avoidance in maintaining low mood. Prompt person to consider their own examples using worksheet. Worksheet: Cycle of low mood
¹ Understand link between physical (in)activity and low mood	2b. Information about emotional consequences	Audio/visual: Provide explanation about how physical activity and low mood are linked through psychological and physiological mechanisms
² Understands concepts being conveyed relating to physical activity	4b. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible physical activities
Week 1		
² Believes information being conveyed relating to routine pleasurable and necessary activities	1a. Credible source	Audio/visual: Reference experts and research to increase credibility of information presented
² Believes information being conveyed relating to physical activity	1b. Credible source	Audio/visual: Reference experts and research to increase credibility of the idea of using physical activity for low mood
Understand rationale for BA which includes reference to interaction of physiological, behavioural and cognitive emotional symptoms and the role of avoidance in maintaining low mood and the idea of routine, pleasurable and necessary activities	2a. Information about emotional consequences	Audio/visual: Provide information about rationale for BA and the idea of routine, pleasurable and necessary activities
¹ Understand how physical activity fits into the BA rationale (e.g. increasing physical activity promotes positive reinforcement)	2b. Information about emotional consequences	Audio/visual: Provide information of the particular role of physical activity in Behavioural Activation/in improving mood, and identify and address any misconceptions
¹ Understands the other health benefits of physical activity	3b. Information about health consequences	Audio/visual: Provide information about how increasing (physical) activity also has desirable health benefits (e.g. weight loss, reduced risk of disease)
² Understands concepts being conveyed relating to physical activity	4b. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible physical activities

Understand how own current activity (lack of) contributes to low mood and vice versa and has accurate baseline to evaluate change	5a Self-monitoring of behaviour 6a. Monitoring of emotional consequences	Audio/visual: Ask people to keep a record of their activity and mood over the coming week using worksheet Worksheet: My Starting Point Diary
Week 2		
² Believes information being conveyed relating to physical activity	1b. Credible source	Audio/visual: Reference experts and research to increase credibility of the idea of using physical activity for low mood
Understand rationale for BA which includes reference to interaction of physiological, behavioural and cognitive emotional symptoms and the role of avoidance in maintaining low mood and the idea of routine, pleasurable and necessary activities	2a. Information about emotional consequences	Audio/visual: Provide information about rationale for BA and the idea of routine, pleasurable and necessary activities
¹ Understand link between physical (in)activity and low mood	2b. Information about emotional consequences	Audio/visual: Provide explanation about how physical activity and low mood are linked through psychological and physiological mechanisms
² Understands concepts being conveyed relating to routine pleasurable and necessary activities	4a. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible routine pleasurable and necessary activities
² Understands concepts being conveyed relating to physical activity	4b. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible physical activities
Able to feel sense of achievement at completing R,P,N activity	6a. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) activity using worksheet. Worksheets: My next steps diary
Able to identify routine, pleasurable and necessary (or physical) activities (things that they would like to do or try but have stopped doing or not tried since they became depressed) and organise into a hierarchy of difficulty. Should include some of each type of routine, pleasurable and necessary activity	7a. Graded tasks	Audio/visual: Prompt identification of routine, pleasurable and necessary (or physical) activities – things that they would like to do or try but have stopped doing or not tried since they became depressed using worksheet Worksheets: Identify Activities, Organising Activities
¹ Able to identify and organise activities into a hierarchy of most difficult, medium difficulty, easiest.	7b. Graded tasks	Audio/visual: Prompt identification of routine, pleasurable and necessary (or physical) activities – things that they would like to do or try but have stopped doing or not tried since they became depressed using worksheet
Should include some type of physical activity.		Worksheets: Identify Activities, Organising Activities

<p>Able to schedule some activities into their week, using a blank diary to specify a mixture of the easiest routine, pleasurable and necessary activities. Activities should be detailed precisely: what, where, when, and who with. Small and regular activities are better in the early stages</p>	<p>8a. Action planning 9a. Goal setting (behaviour) 10a. Problem-solving</p>	<p>Audio/visual: Prompt planning the performance of the routine pleasurable necessary or physical activities ranked as easy on the 'Organising Activities' worksheet for a particular time on a certain day of the week using the worksheet.</p> <p>Agree on a goal to achieve the routine pleasurable necessary or physical activity ranked as easy on the 'Organising Activities' worksheet using the worksheet</p> <p>Prompt the identification of barriers preventing them from finding an easy activity by going to the problem-solving module</p>
<p>Able to reflect on previous week and identify when depression occurs and what the accompanying behaviour was</p>	<p>12a. Review behavioural goal</p>	<p>Worksheets: Organising Activities, My next steps diary Audio/visual: Prompt review of routine pleasurable and necessary activities and how they linked to mood using worksheet from week 1</p>
<p>¹Able to reflect on previous week and identify when depression occurs and whether was physically active or not</p>	<p>12b. Review behavioural goal</p>	<p>Worksheets: My starting point diary Audio/visual: Prompt review of physical activities and how they linked to mood using My starting point diary worksheet</p>
<p>Week 3</p>		
<p>Understand rationale for BA which includes reference to interaction of physiological, behavioural and cognitive emotional symptoms and the role of avoidance in maintaining low mood and the idea of routine, pleasurable and necessary activities</p>	<p>2a. Information about emotional consequences</p>	<p>Audio/visual: Provide information about rationale for BA and the idea of routine, pleasurable and necessary activities</p>
<p>¹Understand link between physical (in)activity and low mood</p>	<p>2b. Information about emotional consequences</p>	<p>Audio/visual: Provide explanation about how physical activity and low mood are linked through psychological and physiological mechanisms</p>
<p>Able to link mood to performing or not performing routine, pleasurable and necessary activities</p>	<p>6a. Monitoring of emotional consequences</p>	<p>Audio/visual: Ask person to record how they feel after performing (not performing) activity using worksheet</p> <p>Worksheets: My next steps diary</p>
<p>Able to select easier, harder or the same routine pleasurable and necessary activities based on previous week</p>	<p>7a. Graded tasks</p>	<p>Audio/visual: Prompt the setting of easy-to-perform routine pleasurable and necessary activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet</p>
<p>¹Able to select easier, harder or the same physical activities based on previous week</p>	<p>7b. Graded tasks</p>	<p>Worksheets: Organising Activities, Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet</p>

<p>Able to schedule some activities into their week, using a blank diary to specify a mixture of the easiest routine, pleasurable and necessary activities. Activities should be detailed precisely: what, where, when, and who with. Small and regular activities are better in the early stages</p>	<p>8a. Action planning 9a. Goal setting (behaviour)</p>	<p>Worksheets: Organising Activities, Audio/visual: Prompt planning the performance of the routine pleasurable necessary or physical activities ranked as easy on the 'Organising Activities' worksheet for a particular time on a certain day of the week using the worksheet. Agree on a goal to achieve the routine pleasurable necessary or physical activity ranked as easy on the 'Organising Activities' worksheet using the worksheet</p>
<p>Able to reflect constructively on failures of R,P,N activity goals without feeling demotivated Able to reflect on and take ownership their previous week of planned activities</p>	<p>10a. Problem-solving 12a. Review behavioural goal</p>	<p>Worksheets: Organising Activities, My next steps diary Audio/visual: Prompt the identification of barriers preventing them from finding an easy activity by going to the problem solving module Audio/visual: Prompt review of routine, pleasurable and necessary activities and how they linked to mood in the 'My next steps diary' using worksheet</p>
<p>Able to reflect and build on successful completion of R,P,N activity</p>	<p>14a. Social reward</p>	<p>Worksheets: Reviewing My Activities Audio/visual: Congratulate the person for each day they achieved their goal of doing a routine, pleasurable or necessary activity</p>
<p>Week 4</p>		
<p>²Understands concepts being conveyed relating to physical activity</p>	<p>4b. Demonstration of the Behaviour</p>	<p>Audio/visual: Provide images demonstrating possible physical activities</p>
<p>Able to self-regulate and consciously take ownership of (not) achieving routine pleasurable and necessary activities</p>	<p>5a. Self-monitoring of behaviour</p>	<p>Audio/visual: Ask person to record whether or not they achieve their goals relating to routine, pleasurable and necessary activities using worksheet</p>
<p>Able to link mood to performing or not performing routine, pleasurable and necessary activities</p>	<p>6a. Monitoring of emotional consequences</p>	<p>Worksheets: My next steps diary Audio/visual: Ask person to record how they feel after performing (not performing) activity using worksheet</p>
<p>¹Able to link mood to performing or not performing physical activity</p>	<p>6b. Monitoring of emotional consequences</p>	<p>Worksheets: My next steps diary Audio/visual: Ask person to record how they feel after performing (not performing) physical activity using worksheet</p>
<p>Able to select easier, harder or the same routine pleasurable and necessary activities based on previous week</p>	<p>7a. Graded tasks</p>	<p>Worksheets: My next steps diary Audio/visual: Prompt the setting of easy-to-perform routine pleasurable and necessary activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet</p>
<p>Worksheets: Organising Activities,</p>		

Appendices

¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet
Able to schedule some activities into their week, using a blank diary to specify a mixture of the easiest routine, pleasurable and necessary activities. Activities should be detailed precisely: what, where, when, and who with. Small and regular activities are better in the early stages	8a. Action planning 9a. Goal setting (behaviour)	Worksheets: Organising Activities, Audio/visual: Prompt planning the performance of the routine pleasurable necessary or physical activities ranked as easy on the 'Organising Activities' worksheet for a particular time on a certain day of the week using the worksheet. Agree on a goal to achieve the routine pleasurable necessary or physical activity ranked as easy on the 'Organising Activities' worksheet using the worksheet
Able to reflect constructively on failures of R,P,N activity goals without feeling demotivated Able to reflect on and take ownership their previous week of planned activities	10a. Problem-solving 12a. Review behavioural goal	Worksheets: Organising Activities, My next steps diary Audio/visual: Prompt the identification of barriers preventing them from finding an easy activity by going to the problem solving module Audio/visual: Prompt review of routine, pleasurable and necessary activities and how they linked to mood in the 'My next steps diary' using worksheet
Able to reflect and build on successful completion of R,P,N activity	14a. Social reward	Worksheets: Reviewing My Activities Audio/visual: Congratulate the person for each day they achieved their goal of doing a routine, pleasurable or necessary activity
¹ Able to reflect and build on successful completion of physical activity	14b. Social reward	Audio/visual: Congratulate the person for each day they achieved their goal of doing a physical activity
Week 5 (Unlocks 'Moving on with physical activity')		
² Understands concepts being conveyed relating to physical activity	4b. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible physical activities
Able to self-regulate and consciously take ownership of (not) achieving routine pleasurable and necessary activities	5a. Self-monitoring of behaviour	Audio/visual: Ask person to record whether or not they achieve their goals relating to routine, pleasurable and necessary activities using worksheet Worksheets: My next steps diary
Able to link mood to performing or not performing routine, pleasurable and necessary activities	6a. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) activity using worksheet Worksheets: My next steps diary
¹ Able to link mood to performing or not performing physical activity	6b. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) physical activity using worksheet Worksheets: My next steps diary

Appendices

Able to select easier, harder or the same routine pleasurable and necessary activities based on previous week	7a. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform routine pleasurable and necessary activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet Worksheets: Organising Activities,
¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet Worksheets: Organising Activities,
Able to schedule some activities into their week, using a blank diary to specify a mixture of the easiest routine, pleasurable and necessary activities. Activities should be detailed precisely: what, where, when, and who with. Small and regular activities are better in the early stages	8a. Action planning 9a. Goal setting (behaviour)	Audio/visual: Prompt planning the performance of the routine pleasurable necessary or physical activities ranked as easy on the 'Organising Activities' worksheet for a particular time on a certain day of the week using the worksheet. Agree on a goal to achieve the routine pleasurable necessary or physical activity ranked as easy on the 'Organising Activities' worksheet using the worksheet Worksheets: Organising Activities,
Able to reflect constructively on failures of R,P,N activity goals without feeling demotivated Able to reflect on and take ownership their previous week of planned activities	10a. Problem-solving 12a. Review behavioural goal	My next steps diary Audio/visual: Prompt the identification of barriers preventing them from finding an easy activity by going to the problem solving module Audio/visual: Prompt review of routine, pleasurable and necessary activities and how they linked to mood in the 'My next steps diary' using worksheet
Able to reflect and build on successful completion of R,P,N activity	14a. Social reward	Worksheets: Reviewing My Activities Audio/visual: Congratulate the person for each day they achieved their goal of doing a routine, pleasurable or necessary activity
¹ Able to reflect and build on successful completion of physical activity	14b. Social reward	Audio/visual: Congratulate the person for each day they achieved their goal of doing a physical activity
Week 6 (Unlocks 'Monitoring your physical activity')		
² Understands concepts being conveyed relating to routine pleasurable and necessary activities	4a. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible routine pleasurable and necessary activities
Able to self-regulate and consciously take ownership of (not) achieving routine pleasurable and necessary activities	5a. Self-monitoring of behaviour	Audio/visual: Ask person to record whether or not they achieve their goals relating to routine, pleasurable and necessary activities using worksheet Worksheets: My next steps diary
Able to link mood to performing or not performing routine, pleasurable and necessary activities	6a. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) activity using worksheet Worksheets: My next steps diary

Appendices

¹ Able to link mood to performing or not performing physical activity	6b. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) physical activity using worksheet Worksheets: My next steps diary
Able to select easier, harder or the same routine pleasurable and necessary activities based on previous week	7a. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform routine pleasurable and necessary activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet Worksheets: Organising Activities,
¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet Worksheets: Organising Activities,
Able to schedule some activities into their week, using a blank diary to specify a mixture of the easiest routine, pleasurable and necessary activities. Activities should be detailed precisely: what, where, when, and who with. Small and regular activities are better in the early stages	8a. Action planning 9a. Goal setting (behaviour)	Audio/visual: Prompt planning the performance of the routine pleasurable necessary or physical activities ranked as easy on the 'Organising Activities' worksheet for a particular time on a certain day of the week using the worksheet. Agree on a goal to achieve the routine pleasurable necessary or physical activity ranked as easy on the 'Organising Activities' worksheet using the worksheet Worksheets: Organising Activities, My next steps diary
Able to reflect constructively on failures of R,P,N activity goals without feeling demotivated Able to reflect on and take ownership their previous week of planned activities	10a. Problem-solving 12a. Review behavioural goal	Audio/visual: Prompt the identification of barriers preventing them from finding an easy activity by going to the problem solving module Audio/visual: Prompt review of routine, pleasurable and necessary activities and how they linked to mood in the 'My next steps diary' using worksheet Worksheets: Reviewing My Activities
Able to reflect and build on successful completion of R,P,N activity	14a. Social reward	Audio/visual: Congratulate the person for each day they achieved their goal of doing a routine, pleasurable or necessary activity
¹ Able to reflect and build on successful completion of physical activity	14b. Social reward	Audio/visual: Congratulate the person for each day they achieved their goal of doing a physical activity
Week 7 (Unlocks 'Increasing your physical activity')		
² Understands concepts being conveyed relating to physical activity	4b. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible physical activities
Able to self-regulate and consciously take ownership of (not) achieving routine pleasurable and necessary activities	5a. Self-monitoring of behaviour	Audio/visual: Ask person to record whether or not they achieve their goals relating to routine, pleasurable and necessary activities using worksheet Worksheets: My next steps diary

Appendices

Able to link mood to performing or not performing routine, pleasurable and necessary activities	6a. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) activity using worksheet Worksheets: My next steps diary
¹ Able to link mood to performing or not performing physical activity	6b. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) physical activity using worksheet Worksheets: My next steps diary
Able to select easier, harder or the same routine pleasurable and necessary activities based on previous week	7a. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform routine pleasurable and necessary activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet Worksheets: Organising Activities
¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet Worksheets: Organising Activities,
Able to schedule some activities into their week, using a blank diary to specify a mixture of the easiest routine, pleasurable and necessary activities. Activities should be detailed precisely: what, where, when, and who with. Small and regular activities are better in the early stages	8a. Action planning 9a. Goal setting (behaviour)	Audio/visual: Prompt planning the performance of the routine pleasurable necessary or physical activities ranked as easy on the 'Organising Activities' worksheet for a particular time on a certain day of the week using the worksheet. Agree on a goal to achieve the routine pleasurable necessary or physical activity ranked as easy on the 'Organising Activities' worksheet using the worksheet
Able to reflect constructively on failures of R,P,N activity goals without feeling demotivated Able to reflect on and take ownership their previous week of planned activities	10a. Problem-solving 12a. Review behavioural goal	Worksheets: Organising Activities, My next steps diary Audio/visual: Prompt the identification of barriers preventing them from finding an easy activity by going to the problem solving module Audio/visual: Prompt review of routine, pleasurable and necessary activities and how they linked to mood in the 'My next steps diary' using worksheet
Able to reflect and build on successful completion of R,P,N activity	14a. Social reward	Worksheets: Reviewing My Activities Audio/visual: Congratulate the person for each day they achieved their goal of doing a routine, pleasurable or necessary activity
¹ Able to reflect and build on successful completion of physical activity	14b. Social reward	Audio/visual: Congratulate the person for each day they achieved their goal of doing a physical activity
Week 8		
Understand rationale for BA which includes reference to interaction of physiological, behavioural and	2a. Information about emotional consequences	Audio/visual: Provide information about rationale for BA and the idea of routine, pleasurable and necessary activities

cognitive emotional symptoms and the role of avoidance in maintaining low mood and the idea of routine, pleasurable and necessary activities		
¹ Understand link between physical (in)activity and low mood	2b. Information about emotional consequences	Audio/visual: Provide explanation about how physical activity and low mood are linked through psychological and physiological mechanisms
¹ Understands the other health benefits of physical activity	3b. Information about health consequences	Audio/visual: Provide information about how increasing (physical) activity also has desirable health benefits (e.g. weight loss, reduced risk of disease)
Able to self-regulate and consciously take ownership of (not) achieving routine pleasurable and necessary activities	5a. Self-monitoring of behaviour	Audio/visual: Ask person to record whether or not they achieve their goals relating to routine, pleasurable and necessary activities using worksheet Worksheets: My next steps diary
Able to link mood to performing or not performing routine, pleasurable and necessary activities	6a. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) activity using worksheet Worksheets: My next steps diary
¹ Able to link mood to performing or not performing physical activity	6b. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) physical activity using worksheet Worksheets: My next steps diary
¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet Worksheets: Organising Activities,
Able to reflect constructively on failures of R,P,N activity goals without feeling demotivated	10a. Problem-solving	Audio/visual: Prompt the identification of barriers preventing them from finding an easy activity by going to the problem solving module
Able to reflect on and take ownership their previous week of planned activities	12a. Review behavioural goal	Audio/visual: Prompt review of routine, pleasurable and necessary activities and how they linked to mood in the 'My next steps diary' using worksheet Worksheets: Reviewing My Activities
Able to recognise symptoms of low mood, cueing the planning of routine, pleasurable and necessary activities	13a. Internal prompts/cues	Audio/visual: Prompt person to recognise when feeling down to cue being active using worksheet Worksheet: Low Mood Alarm
Able to reflect and build on successful completion of R,P,N activity	14a. Social reward	Audio/visual: Congratulate the person for each day they achieved their goal of doing a routine, pleasurable or necessary activity
¹ Able to reflect and build on successful completion of physical activity	14b. Social reward	Audio/visual: Congratulate the person for each day they achieved their goal of doing a physical activity

Moving on with physical activity (unlocked after week 5)

² Believes information being conveyed relating to physical activity	1b. Credible source	Audio/visual: Reference experts and research to increase credibility of the idea of using physical activity for low mood
¹ Understand link between physical (in)activity and low mood	2b. Information about emotional consequences	Audio/visual: Provide explanation about how physical activity and low mood are linked through psychological and physiological mechanisms
¹ Understands the other health benefits of physical activity	3b. Information about health consequences	Audio/visual: Provide information about how increasing (physical) activity also has desirable health benefits (e.g. weight loss, reduced risk of disease)
² Understands concepts being conveyed relating to physical activity	4b. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible physical activities
¹ Able to link mood to performing or not performing physical activity	6b. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) physical activity
¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed using worksheet Worksheet: Thinking about physical activity, My next steps diary
¹ Able to schedule routine pleasurable and necessary activities precisely (i.e. what, where, when, and who with) Small and regular activities are better in the early stages	8b. Action planning	Audio/visual: Prompt planning the performance of physical activities ranked as easy on the 'Thinking about physical activity' worksheet for a particular time on a certain day of the week using the worksheet Worksheet: Thinking about physical activity, My next steps diary
¹ Able to set a goal in relation to an intention to achieve a routine pleasurable and necessary activity	9b. Goal setting (behaviour)	Audio/visual: Agree on a goal to achieve physical activity ranked as easy on the 'Thinking about physical activity' worksheet using the worksheet Worksheet: Thinking about physical activity, My next steps diary
¹ Able to reflect constructively on failures of physical activity goals without feeling demotivated	10b. Problem-solving	Audio/visual: Prompt the identification of barriers preventing them from finding an easy activity by going to the problem solving module
¹ Able to identify different types of physical activity	17b. Instruction on how to perform a behaviour	Audio/visual: Providing information about how to be more physically active using the (Frequency, Intensity, Time, Type) FITT principle

Monitoring your physical activity (unlocked after week 6)

¹ Understand link between physical (in)activity and low mood	2b. Information about emotional consequences	Audio/visual: Provide explanation about how physical activity and low mood are linked through psychological and physiological mechanisms
---	--	--

² Understands concepts being conveyed relating to physical activity	4b. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible physical activities
¹ Able to self-regulate and consciously take ownership of (not) physical activity	5b. Self-monitoring of behaviour	Audio/visual: Ask person to record whether or not they achieve their goals relating to physical activity using worksheet
¹ Able to link mood to performing or not performing physical activity	6b. Monitoring of emotional consequences	Audio/visual: Ask person to record how they feel after performing (not performing) physical activity
¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed
¹ Able to schedule routine pleasurable and necessary activities precisely (i.e. what, where, when, and who with) Small and regular activities are better in the early stages	8b. Action planning	Audio/visual: Prompt planning the performance of physical activities ranked as easy on the 'Thinking about physical activity' worksheet for a particular time on a certain day of the week using the worksheet
¹ Able to link mood to performing or not performing physical activity	11b. Behavioural experiments	Audio/visual: Asking person to do some physical activity rather than be sedentary and to note whether they feel better or worse

Worksheet: Monitoring physical activity

Increasing your physical activity (unlocked after week 7)

¹ Understands the other health benefits of physical activity	3b. Information about health consequences	Audio/visual: Provide information about how increasing (physical) activity also has desirable health benefits (e.g. weight loss, reduced risk of disease)
² Understands concepts being conveyed relating to physical activity	4b. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible physical activities
¹ Able to self-regulate and consciously take ownership of (not) physical activity	5b. Self-monitoring of behaviour	Audio/visual: Ask person to record whether or not they achieve their goals relating to physical activity using worksheet
¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed
¹ Able to identify different types of physical activity	17b. Instruction on how to perform a behaviour	Audio/visual: Providing information about how to be more physically active using the (Frequency, Intensity, Time, Type) FITT principle

Problem Solving

² Understands concepts being conveyed relating to routine pleasurable and necessary activities	4a. Demonstration of the Behaviour	Audio/visual: Provide images demonstrating possible routine pleasurable and necessary activities
Able to select easier, harder or the same routine pleasurable and	7a. Graded tasks	Audio/visual: Prompt the setting of easy-to-perform routine pleasurable and necessary activities, making

Appendices

necessary activities based on previous week	10a. Problem Solving	them increasingly difficult, but achievable, until behaviour is performed using worksheet Prompt person to identify barriers preventing them from starting a new routine, pleasurable or necessary activity using worksheet Worksheet: Breaking down activities
¹ Able to select easier, harder or the same physical activities based on previous week	7b. Graded tasks 10b. Problem Solving	Audio/visual: Prompt the setting of easy-to-perform physical activities, making them increasingly difficult, but achievable, until behaviour is performed Prompt person to identify barriers preventing them from starting a new physical activity using worksheet Worksheet: Breaking down activities

Appendix 6: Design Fidelity Coding Manual

The aim of this coding manual is to facilitate the reliable identification of core intervention components in the audio visual content of eMotion. This manual enables coders to identify content that conveys particular types of information or prompts specific actions which are theoretically essential to the interventions success. The coding categories are mutually exclusive and based on theory based constructs used to increase physical activity and reduce depression.

Coding procedure

Analysis should take place for **all content** including the introductory, core and unlockable and problem-solving modules. All coders should read through this manual and ensure they understand all categories especially the nuances between similar categories. Below are the steps a coder should go through when analysing each eMotion module.

1. Go through the entire intervention to get an idea of the common categories which may be present.
2. Go back through each module separately and rate 'present' or 'absent' for each category based on the combined audio/visual content.
3. Repeat step 2, making any changes necessary.

Tips for coders:

- A category should be marked as 'present' as soon as the module has fulfilled that definition.
- A category should only be marked as 'present' or 'absent' once per module.
- A **module** will be the basic unit of analysis.
- All BCT's referring to routine, pleasurable and necessary activities should be coded under **A** and all BCT's referring to physical activities should be coded under **B**
- Each module can have the same BCT for the both behaviours (e.g. goal setting for physical activity and routine, pleasurable and necessary activities), if this is the case then code for both.
- If you are not sure whether a technique is present, then please rate 'unsure'
- Each technique should specifically be in reference to the target behaviour (i.e. physical activities or routine pleasurable and necessary)
- Each technique contains the term "**behaviour**" referring to a single action or sequence of actions that includes the performance of **wanted**

behaviour(s) and/or **inhibition** (non-performance) of **unwanted** behaviour(s)

No.	Technique	Definition	Example Content
1 (a/b)	Credible source	Present verbal or visual communication from a credible source in favour of or against the behaviour	Present information given by an expert to emphasise the importance of following subsequent advice about (physical) activity
2(a/b)	Information about emotional consequences	Provide information (e.g. written, verbal, visual) about emotional consequences of performing the behaviour	Explain that increasing (physical) activity increases happiness and life satisfaction
3(a/b)	Information about health consequences	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	Explain that increasing (physical) activity decreases risk of type 2 diabetes
4(a/b)	Demonstration of the behaviour	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate	Demonstrate to participant how to be more (physically) active via a case study/example
5(a/b)	Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change/therapeutic strategy	Prompt patient to keep a record of their (physical) activity over the coming week
6(a/b)	Monitoring of emotional consequences	Prompt assessment of feelings after attempts at performing the behaviour	Agree that the person will record how they feel after (physical) activity
7(a/b)	Graded tasks	Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behaviour is performed	Ask the person to walk for 100 yards a day for the first week, then half a mile a day after they have successfully achieved 100 yards, then two miles a day after they have successfully achieved one mile
8(a/b)	Action planning	Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive) (includes 'Implementation Intentions') Note: evidence of action planning does not necessarily imply goal setting,	Prompt planning the performance of a particular (physical) activity (e.g. running/going to the shops) at a particular time (e.g. before work) on certain days of the week

		only code latter if sufficient evidence)	
9(a/b)	Goal setting (behaviour)	Set or agree on a goal defined in terms of the behavior to be achieved Note: only code goal-setting if there is sufficient evidence that goal set as part of intervention; if goal unspecified or a behavioral outcome, code Goal setting (outcome); if the goal defines a specific context, frequency, duration or intensity for the behaviour, also code Action planning	Agree on a daily (physical) activity goal (e.g. 3 miles / go to friends house) with the person and reach agreement about the goal
10(a/b)	Problem-solving	Analyse , or prompt the person to analyse, factors influencing the behavior and generate or select strategies that include overcoming barriers and/or increasing facilitators (includes 'Relapse Prevention' and 'Coping Planning')	Prompt the patient to identify barriers preventing them from starting a new (physical) activity e.g., lack of motivation, and discuss ways in which they could help overcome them e.g., going to the gym with a buddy
11(a/b)	Behavioural experiments	Advise on how to identify and test hypotheses about the behaviour, its causes and consequences, by collecting and interpreting data	Ask participant to do some (physical) activity rather than be sedentary and to note whether they feel better or worse
12(a/b)	Review behavioural goal	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change	Examine how well a person's performance corresponds to agreed goals e.g. whether they were (physically) active at least twice this week and consider modifying future behavioural goals accordingly e.g. by increasing or decreasing physical activity target or changing type of physical activity
13(a/b)	*Internal prompts/cues	Introduce or define internal stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance Note: when a stimulus is linked to a specific action in an if-then plan including one or more of frequency, duration or intensity also code Action planning.	Recognise when feeling down to cue being (physically) active

14(a/b)	Social reward	Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing the behaviour (includes 'Positive reinforcement')	Congratulate the person for each day they were (physically) active
15(a/b)	Framing/reframing	Suggest the deliberate adoption of a perspective or new perspective on behaviour (e.g. its purpose) in order to change cognitions or emotions about performing the behaviour (includes 'Cognitive structuring'); If information about consequences then code 5.1, Information about health consequences, 5.6, Information about emotional consequences	Suggest that the person might think of the tasks as reducing sedentary behaviour rather than increasing (physical) activity
16(a/b)	Associative learning	Present a neutral stimulus jointly with a stimulus that already elicits the behaviour repeatedly until the neutral stimulus elicits that behaviour (includes 'Classical/Pavlovian Conditioning')	Repeatedly pair (physical) activity with an increase in mood to encourage increase in physical activity
17(a/b)	Instruction on how to perform a behaviour	Advise or agree on how to perform the behaviour (includes 'Skills training')	Advise the person how to be more (physically) active by increasing the frequency

Appendix 7 : eMotion Participant Information Sheet

Version 4 27/05/2016

Participant information Sheet**A study to assess the feasibility and acceptability of an online Behavioural Activation (BA) programme for people with low mood****Invitation and brief summary**

Thank you for taking an interest in this research study. It is important you understand what you will be asked to do and why before you agree to take part. Please ask us if you are not sure about anything. Behavioural Activation (BA) therapy, seeks to restore the number of everyday activities people with depression or low mood do in their day-to-day lives. This is because depression often reduces the things people do as part of their normal daily lives and this can lead to further lowering of their mood. We would like to know how an enhanced online version of BA therapy affects depressive symptoms for people with low mood.

Why have I been asked to take part?

You have expressed an interest by responding to one of our study advertisements because you may have low mood or symptoms of depression.

What will happen if I want to take part?

If you are interested in taking part, or would like to ask some questions about the research or your participation, please contact the researcher using the contact details below. The researcher will ask you some basic questions to confirm eligibility. If you are still interested, please tick the box on the online consent form.

Start of Study (All groups)

Once we have received your consent form, you will be allocated (at random) to receive the enhanced BA programme straight away, or to receive it in two months. Regardless of which arm you are randomised to, you will receive an online questionnaire pack via email and possible telephone call at the start of the study, after you have completed the programme (two months and five months after the start of the study). You may also be asked to wear a monitor for seven days. The monitor is a device a bit like a wrist watch that measures the wearer's physical activity. You will be asked to return the device (in a stamped addressed package that we will supply) after wearing it for seven days.

8-week programme delivery period

If you are allocated to the intervention group, you will receive an email, which will include instructions and a website link to the online BA programme (which is called eMotion) You may also receive a telephone call from the researcher to confirm that you have received this. You are then free to access the website as you see fit – instructions on how to use the website will be provided. Each time you complete a module a few basic questions may be asked to check your understanding of each module. This is not to test you, but to make sure that we have made the materials as easy to understand as possible. Over the 8 weeks, a facilitator (a person with knowledge of eMotion and how it works) may conduct two further telephone calls with you to support you, see how you are getting on and assist with any questions you have about using the website. However, this will not include clinical support as the facilitators are not trained to deliver treatments for depression or low mood. The timing and contact time of each call will vary depending on your needs, and whether they are able to get hold of you, but it is expected to be around 10-20 minutes.

After eight week period

Once eight weeks has passed, you may receive a telephone call from the researcher to go over the next stage of the study. They will also send you the online questionnaire pack to complete via email. These should again take no longer than ten minutes. You may also be asked to wear the wrist monitor again for seven days which you will be asked to return in a stamp addressed package.

If you have not had access to the programme, you will now be given access to it.

3 months after finishing the programme

Three months after you have completed the programme, you will receive a final call and email from the researcher. As part of their assessment, you will be asked to complete a one more set of online questions and may for a final time be asked to wear a monitor. At the end of the study, you may be asked by the researcher to participate in a short telephone interview to ask what you thought about the enhanced BA intervention you have received. This will be over the phone at a time arranged between you and the researcher and will (with your permission) be recorded. Your personal details will remain confidential and your name will not be used when reporting any findings. Once the study is officially finished, you will be sent a debrief of the study by email.

Duration

It is expected that you will be involved in the study for approximately 6 months between the initial approach and the final telephone call. In total, we estimate that total participation would amount to no more than eight hours of your time (including interviews and your use of the website).

Tell me more about the eMotion Behavioural Activation programme

You will have access to an online intervention, which will provide you with a series of weekly modules. Each module takes roughly 15 to 20 minutes to complete. The online intervention will help you increase your daily activities in a way that should help to lift your mood. This is done via the online system and by using a combination of written materials that you can print off to read at your leisure. You will be asked to complete a brief diary of the tasks and activities that you choose. Where appropriate you may be prompted to add more physical movement to activities that you are already doing as part of your daily routine, such as increasing time spent walking. All activities will be chosen by you.

Why should I take part?

The information you provide may help us to develop better support for people with depression or low mood in the future.

Are there any risks involved in taking part?

As part of the study, you may be asked to increase activities that involve some light to moderate physical activity. If you already have any physical difficulties doing your normal activities you will be advised to talk to your doctor for advice.

Do I have to take part?

Please remember that participation in this study is entirely voluntary. It is up to you to decide whether you would like to take part or not and if you decide to take part you are free to leave the study at any time without giving a reason as to why you wish to do so. If you do decide to participate in this study you will be asked to complete an online consent form before you start. You will be given a copy of the consent form and this information sheet for your own records.

What if I change my mind?

If you start the study and then change your mind, it is not a problem. You will be able to withdraw at any time. You may be asked why you do not want to continue, but you do not have to give any reasons if you do not want to.

Will my information be kept confidential?

Yes. No information about you will be shared with anyone else outside the research team. All your information will be safely stored, in line with guidelines for good clinical practice. Study reports will not contain any information that can identify you.

What will happen to the results of this study?

The results will increase our understanding of using the internet to deliver psychological therapies to help low mood. We will aim to publish the findings in research journals and to present them at conferences in the UK or abroad. Your data will always remain anonymous and your name will not appear on any results.

Who has reviewed this study?

This study has been approved by the Ethics Committee of Sport and Health Sciences, College of Life and Environmental Sciences at the University of Exeter.

Could the study be stopped for any reason?

Like all studies, if the research team think it is necessary, they will stop the study in the interest of the health and safety of those people taking part. Also, if you become unwell to the point that you are not able to decide if you wish to continue to take part or not we will stop collecting data from you. In either of these cases the information we have collected from you for the purpose of the study will remain strictly confidential. It is important to note that this study is research in nature and does not overlap with any clinical services. If you are having any thoughts about suicide or self-harm, you are strongly advised to contact your GP and not take part in this study. In addition, if we believe at any point during the study that you are at risk of self-harm or suicide, we will operate a risk policy which will involve contacting your GP or the emergency services if we deem it necessary.

What should I do if something goes wrong during the study?

If you feel unwell at any time, you should contact your GP in the normal way. If you have a medical emergency you should dial 999 and ask for an ambulance.

Anything that makes it hard for you to continue should be reported to Jeff Lambert using the contact details below.

What shall I do if I have a complaint?

If you feel you have been treated unfairly or if you have a complaint about any aspect of taking part in the study you are encouraged to contact:

Associate Professor Colin Greaves,

University of Exeter Medical School

Room 105, Smeall Building

St Luke's Campus

Magdalen Road

Exeter EX1 2LU

Telephone number: 01392 262751

E-mail: C.J.Greaves@exeter.ac.uk

Who can I contact to get more information about the study?

Jeff Lambert

Room 207 College House, St Luke's Campus, University of Exeter, Heavitree Road,

EX1 2LU

Telephone number: 01392 262751

E-mail: jdl212@exeter.ac.uk

Are you experiencing thoughts of suicide or self-harm?

These kinds of thoughts can vary a lot. This may have just been a brief passing thought or reflect a sense of feeling trapped, but without any intention to do anything. These thoughts are relatively common and not that unusual in people who feel stressed. If you would like support with these thoughts, please contact your GP; if you feel at high risk to yourself or others, please contact your GP immediately.

However, you may have been thinking about your own death a lot, having persistent thoughts about killing yourself, experiencing suicidal intentions and urges, or be making plans to end your life. In any of these cases or if you have any other thoughts of suicide, we strongly recommend that you contact your general practitioner or family doctor RIGHT AWAY for advice and tell them how you are feeling.

As this internet treatment has not been designed to address these particular difficulties, it would not be helpful to offer this treatment to you. For these difficulties, talking with a professional or trained helper is recommended.

To help you as best we can, alternative sources of help and support are provided below:

Throughout the UK, please contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call.

You can also phone 111 to access the NHS 111 service, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year. Details for out of hours services and support across the UK can be found in this leaflet. If you would find it helpful to talk confidentially about your feelings, you also can contact the Samaritans at Samaritans.org or Befrienders.org .

In addition, if you live in Cornwall, during normal working hours you can also contact Cornwall Community Mental Health team for help and advice. Further details and the right number to call for your area can be found on their web page:www.cornwallfoundationtrust.nhs.uk/cft/OurServices/CommunityServices/CommunityMentalHealthTeams.asp

The out of hours services available in Cornwall can be found on Cornwall Foundation NHS's Trust out of hours leaflet here. You can access an up to date version of this leaflet by clicking www.cornwallfoundationtrust.nhs.uk/cft/OurServices/HowToGetHelp/UsefulLinksAndContacts and scrolling down to find the 'out of hours leaflet' on the left hand side of the page in the Download section.

If you don't think you can stay safe, please go to the nearest hospital accident and emergency room. If none of these options are available, please contact a family member or a trusted friend, so that you won't be alone right now. If you have already made a plan, then please try and get rid of the means to harm yourself, whilst keeping yourself safe. It can also be helpful to focus on anything that may stop you from harming yourself at the moment, such as thinking about your faith, loved ones, family and pets. It is important to remember that these feelings and urges do pass, and when individuals feel better, they are glad that they did not act on them. There are effective treatments that can help, and there is no need to struggle alone. Getting help may make it easier to manage your symptoms and to live the kind of life you would like to live. We hope that you are able to find the help that you need and are sorry that we are unable to provide

that help. We hope that the suggested alternative advice and resources we have provided above are useful to you at this difficult time.

For more information about depression and what might be helpful to deal with depression, it may be useful to visit the Royal College of Psychiatrists website.

Appendix 8: eMotion Consent Form

Study: A study to assess the feasibility and acceptability of an online Behavioural Activation (BA) programme for people with low mood

Principal Investigator: Jeff Lambert

Primary Supervisor: Assoc Prof Colin Greaves

Organisation: The University of Exeter

Version: 4. 27.05.16: reviewed by The University of Exeter ethics committee

Participant Identification Number:

Consent Item	Please tick box	
	Yes	No
I confirm that I have read and understood the participant information (Version 4 27/05/2016) for the above study and have had the opportunity to ask questions and have had these answer to my satisfaction.		
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, without my usual care or legal rights being affected.		
I understand that I may not be eligible to take part in the study.		
I understand that details of my participation will be stored anonymously on file and may be used in the final analysis of data.		
I agree to take part in the study.		
If I am experiencing problems or feel that something is going wrong with the study I realise I should contact Jeff Lambert (University of Exeter, Room 207 College House, St Lukes Campus, Heavitree Road, EX1 2LU; Telephone: 01392 725705; Email:jdl212@exeter.ac.uk) or one of the research team members.		

I agree to allow digital recordings of the support sessions with the facilitator to be made.		
I agree to being approached to part in an interview with a researcher (if selected) after using the web-based programme.		
I would like to receive information about the findings of this study. I am happy for my contact details to be kept until after the study so I can be sent this information. You do not need to tick yes to participate in this study.		

Print Name: _____ Tel.

number: _____

Date: _____

Signed (University of Exeter) _____ Date: -

Appendix 9: Randomisation list

id	randomiser	group	randomised_date	randomised_time
102	jdl212@exeter.ac.uk	A	25 May 2016	06:11 PM
101	jdl212@exeter.ac.uk	A	8 June 2016	10:47 AM
103	jdl212@exeter.ac.uk	B	8 June 2016	10:48 AM
106	jdl212@exeter.ac.uk	A	15 June 2016	03:03 PM
109	jdl212@exeter.ac.uk	B	15 June 2016	03:17 PM
105	jdl212@exeter.ac.uk	B	15 June 2016	03:20 PM
110	jdl212@exeter.ac.uk	A	6 July 2016	01:39 PM
111	jdl212@exeter.ac.uk	B	19 July 2016	10:13 AM
115	jdl212@exeter.ac.uk	B	11 August 2016	03:21 PM
113	jdl212@exeter.ac.uk	B	11 August 2016	03:56 PM
116	jdl212@exeter.ac.uk	A	12 August 2016	02:19 PM
123	jdl212@exeter.ac.uk	A	25 August 2016	08:28 AM
122	jdl212@exeter.ac.uk	B	25 August 2016	08:37 AM
118	jdl212@exeter.ac.uk	A	25 August 2016	02:01 PM
128	jdl212@exeter.ac.uk	B	31 August 2016	08:50 AM
125	jdl212@exeter.ac.uk	B	31 August 2016	08:55 AM
120	jdl212@exeter.ac.uk	A	31 August 2016	09:04 AM
130	jdl212@exeter.ac.uk	B	31 August 2016	09:14 AM
129	jdl212@exeter.ac.uk	A	2 September 2016	11:55 AM
126	jdl212@exeter.ac.uk	A	8 September 2016	09:54 AM
127	jdl212@exeter.ac.uk	B	8 September 2016	11:46 AM
133	jdl212@exeter.ac.uk	A	19 September 2016	04:27 PM
132	jdl212@exeter.ac.uk	B	19 September 2016	04:39 PM

131	jdl212@exeter.ac.uk	B	26 September 2016 09:20 AM
134	jdl212@exeter.ac.uk	A	3 October 2016 03:19 PM
136	jdl212@exeter.ac.uk	A	3 October 2016 03:22 PM
135	jdl212@exeter.ac.uk	A	3 October 2016 03:28 PM
141	jdl212@exeter.ac.uk	B	7 October 2016 09:25 AM
137	jdl212@exeter.ac.uk	B	10 October 2016 01:46 PM
121	jdl212@exeter.ac.uk	A	17 October 2016 04:03 PM
139	jdl212@exeter.ac.uk	A	17 October 2016 04:12 PM
140	jdl212@exeter.ac.uk	B	17 October 2016 04:18 PM
138	jdl212@exeter.ac.uk	B	20 October 2016 09:48 AM
142	jdl212@exeter.ac.uk	B	26 October 2016 02:01 PM
146	jdl212@exeter.ac.uk	A	1 November 2016 10:41 AM
143	jdl212@exeter.ac.uk	A	3 November 2016 11:19 AM
144	jdl212@exeter.ac.uk	A	3 November 2016 11:22 AM
145	jdl212@exeter.ac.uk	B	7 November 2016 04:07 PM
148	jdl212@exeter.ac.uk	B	7 November 2016 04:11 PM
147	jdl212@exeter.ac.uk	B	11 November 2016 04:37 PM
150	jdl212@exeter.ac.uk	A	11 November 2016 04:53 PM
149	jdl212@exeter.ac.uk	A	14 November 2016 06:23 PM
152	jdl212@exeter.ac.uk	A	17 November 2016 02:14 PM
154	jdl212@exeter.ac.uk	A	28 November 2016 12:12 PM
151	jdl212@exeter.ac.uk	A	28 November 2016 03:16 PM
153	jdl212@exeter.ac.uk	B	7 December 2016 01:21 PM
155	jdl212@exeter.ac.uk	B	12 December 2016 05:18 PM
156	jdl212@exeter.ac.uk	B	12 December 2016 05:20 PM

157	jdl212@exeter.ac.uk	A	20 December 2016	12:44 PM
162	jdl212@exeter.ac.uk	A	17 January 2017	06:40 PM
160	jdl212@exeter.ac.uk	B	19 January 2017	05:07 PM
165	jdl212@exeter.ac.uk	B	27 January 2017	01:48 PM
166	jdl212@exeter.ac.uk	A	27 January 2017	01:49 PM
158	jdl212@exeter.ac.uk	A	28 January 2017	01:25 PM
161	jdl212@exeter.ac.uk	B	28 January 2017	01:37 PM
164	jdl212@exeter.ac.uk	B	28 January 2017	01:43 PM
163	jdl212@exeter.ac.uk	B	31 January 2017	06:14 PM
168	jdl212@exeter.ac.uk	A	7 February 2017	05:40 PM
159	jdl212@exeter.ac.uk	A	10 February 2017	04:03 PM
167	jdl212@exeter.ac.uk	B	19 February 2017	12:55 PM
169	jdl212@exeter.ac.uk	A	28 February 2017	05:03 PM
170	jdl212@exeter.ac.uk	A	2 March 2017	05:06 PM

Appendix 10: Questionnaire Items

What is your gender?

Male	
Female	
Prefer not to say	

What is your address?

Address Line 1	
Address Line 2	
Town/City	
County	
Postcode	

What is the name and address of your registered GP practice?

Name of Surgery

Name of GP

Telephone

Number

Address

What is your age in years?

--

What is your telephone number?

What is your ethnicity?

White or Caucasian	
African or Afro-American or Afro-Caribbean	
Asian or Asian American or Asian British	
Hispanic or Latino	
Mixed	
Other	
Not stated	

How did you hear about this study?

Facebook	
Twitter	
Recovery Devon	
Other Charity website	
Newspaper	
Word of Mouth	
Google Search	
Other (please specify)	

*Please indicate which of the following options best describes your current status:

Employed full-time (30 hours or more per week)	
Employed part-time	
Unemployed	
Full-time student	
Retired	
Full-time homemaker or carer	

Please indicate your highest educational level?

GCSE/O Level	
A Levels	
Degree (e.g. BSc, BA, BEng)	
Postgraduate Degree (e.g. MSc, MA, MEng)	
Doctoral Degree (e.g. PhD)	

Are you currently receiving anti-depressant medication?

Yes	
No	

Are you currently receiving any form of psychotherapy?

Yes	
No	

* Over the past **2 weeks**, how often have you been bothered by any of the following problems? **(PHQ-8)**

	Not at all	Several days	More Than Half the Days	Nearly Every Day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3
Trouble falling asleep, staying asleep, or sleeping too much	0	1	2	3
Feeling tired or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself – or that you’re a failure or have let yourself or your family down	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
Moving or speaking so slowly that other people could have noticed. Or, the opposite – being so fidgety or restless that have been moving around a lot more than usual	0	1	2	3

Can you walk unaided for at least 5 minutes?

Yes	
No	

*IAPT minimum data set

* Over the past **2 weeks**, how often have you been bothered by any of the following problems? **(GAD-7)**

	Not at all	Several days	More Than Half the Days	Nearly Every Day
Feeling nervous, anxious or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Worrying too much about different things	0	1	2	3
Trouble relaxing	0	1	2	3
Being so restless that it is hard to sit still	0	1	2	3
Becoming easily annoyed or irritable	0	1	2	3
Feeling afraid as if something awful might happen	0	1	2	3

Fidelity

Based on measures from the Pro-Active Study (Hankonen et al., 2014; Hardeman et al., 2008).

Understanding (Receipt)

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I understand how emotions, behaviours, thoughts and physical feelings affect each other to maintain depression over time?	1	2	3	4	5
I believe that doing 30 minutes of moderate physical activity (e.g. brisk walk) can make a big difference on my mood	0	1	2	3	4

Please write down three examples of how you think physical activity might improve your mood

Example 1

Example 2

Example 3

The International Physical Activity Questionnaire – Short Form (IPAQ – SF)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the vigorous activities that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

No vigorous physical activities? **Skip to question 3**

How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours and**

_____ **minutes per day**

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**.

Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

No moderate physical activities **Skip to question 5**

How much time did you usually spend doing moderate physical activities on one of those days?

_____ **hours and**

_____ **minutes per day**

Don't know/Not sure

Think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

_____ **days per week**

No walking **Skip to question 7**

How much time did you usually spend walking on one of those days?

_____ **hours and**

_____ **minutes per day**

Don't know/Not sure

The last question is about the time you spent sitting on weekdays during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours and**

_____ **minutes per day**

Don't know/Not sure

The Client Satisfaction Questionnaire (CSQ)

Please help us improve our programme by answering some questions about the online treatment you received. We are interested in your honest opinions, whether they are positive or negative. Please answer all of the questions. We also welcome your comments and suggestions. Thank you very much, we appreciate your help.

Please tick the relevant answer

1. To what extent has our program met your needs?

4	3	2	1
Almost all of my needs have been met	Most of my needs have been met	Only a few of my needs have been met	None of my needs have been met

2. In an overall, general sense, how satisfied are you with the service you received?

4	3	2	1
Very satisfied	Mostly Satisfied	Indifferent or mildly dissatisfied	Quite dissatisfied

3. If you were to seek help again, would you come back to our programme?

1	2	3	4
No, definitely not	No, I don't think so	Yes, I think so	Yes definitely

4. Please write any comments below

Appendix 11: Suicide Risk Protocol (over the telephone)

MOOD DISORDERS CENTRE

PROTOCOL FOR ASSESSING AND REPORTING RISK

The following principles and procedures govern risk assessment and reporting in the Mood Disorders Centre (MDC). The MDC does not manage risk.

General principles

MDC clinical academic faculty are responsible for risk assessment in their research programmes. This includes ensuring that staff, students and interns working with them receive adequate induction and training prior to participant contact in which risk could be disclosed and ongoing supervision during their research work.

Many of the research projects in the MDC will include supplementary and more detailed protocols for risk assessment.

The AccEPT Clinic has its own risk protocol.

General procedures

Background training materials are available on the shared directory. All staff should attend training in the use of this protocol as soon as is reasonably possible and attend training normally at least annually. If they undertake any work where risk may be an issue prior to receiving formal training, it is the PI's responsibility to ensure that they have reviewed all the materials and have received bespoke training.

Whenever any significant risk is identified a risk assessment should be completed and (counter-) signed by the responsible member of staff. If at all possible this should be done at the time of the assessment, or as soon afterwards as possible. This record should be kept on file in line with the Centre's or study's data storage procedures.

Any significant, but not imminent risk should be reported to the person's GP and, if appropriate, other health care professionals, as soon as is reasonably possible.

For research outside of the local area, PIs / supervisors should familiarise themselves with the local providers' risk procedures, and researchers should hold the relevant contact details needed in the case of immediate risk.

When clinical academic staff are away from the Centre they should ensure appropriate cover is arranged for any risk issues that might arise in their absence.

When conducting telephone interviews in which risk may be disclosed, the interviewer should establish the telephone number and location of the participant at the start of the call, and clarify the boundaries of confidentiality (as per trial / clinic protocol).

Exeter emergency contact numbers

- Crisis Resolution Home Treatment Team (East and Mid Devon)
07968 845048

Please note, this number is to make an urgent referral to the Crisis Team and should not be given out to participants / clients / members of the public under any circumstances. The participant's / client's GP can also make an urgent referral to the Crisis Team and should be the first port of call.

- Exeter Accident and Emergency Department

This is located at the Royal Devon and Exeter Hospital (Wonford),
Barrack Road, Exeter, EX2 5DW

- Student Health Services – The Streatham Campus Student Health Centre is located in Reed Mews and is run solely for students. Phone: 01392 676606 (Streatham) or, 01392 211511 (St Luke's)

If you need a doctor urgently out of Student Health Centre opening hours,
phone the Devon Doctors on Call Patient line: 0845 6710 270

Exploring Risk in Research Interviews

THOUGHTS

“I see that you’ve said / you mentioned that..... These are thoughts / feelings that people suffering from depression often have, but it’s important to make sure you are receiving the right kind of support. So I would now like to ask you some more questions that will explore these feelings in a little more depth.”

PLANS

- 1 Do you know how you would kill yourself? Yes / No

If **yes** – details

- 2 Have you made any actual plans to end your life? Yes / No

If **yes** – details

ACTIONS

- 3 Have you made any actual preparations to kill yourself? Yes / No

If **yes** – details

- 4 Have you ever attempted suicide in the past? Yes / No

If **yes** – details

PREVENTION

5 Is there anything stopping you killing or harming yourself
at the moment? Yes / No

If **yes** – details

6 Do you feel that there is any immediate danger that you
will harm or kill yourself? Yes / No

Details:

FOLLOW-UP FROM PREVIOUS CONTACT

7 **If Action B was enacted at previous assessment and level B risk is identified at current assessment:** Last time we met I suggested that you spoke to your GP about these thoughts, and I also wrote to your GP about this. Have you been able to speak with your GP about these thoughts since we last met? Yes / No

See risk table overleaf for appropriate actions

Researcher Risk Protocol To be used following any indication of risk from questionnaire items, responses to interview questions or any other sources.
Look at answers from the sheet to determine the level of risk, A B or C:

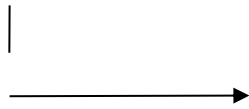
Actions by Researcher

Tell Participant

All answers 'no' apart from Q5
 'yes':



A



I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see your GP to talk about these feelings (as per trial protocol).

'Yes' for any **one** of Qs 1-4; plus
 'yes' for Q5 and 'no' for Q6



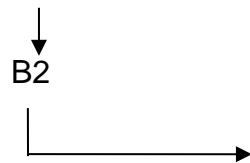
B1



Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. I will be writing to your GP to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see your GP to talk about these feelings. (as per trial protocol).

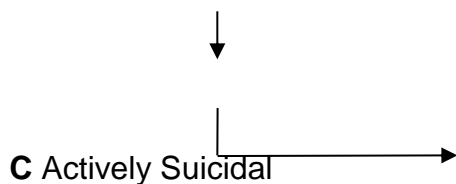
I think it's important that your GP knows how difficult things are for you right now. I

'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6 **and** 'no' to Q7



will be telephoning your GP to speak with him/her and suggest that you meet with one another. I also advise that you make an appointment to see your GP to talk about these feelings. (as per trial protocol). N.B: telephone call to GP to be followed up by letter. The letter should include the statement “the clinical management of this patient remains your responsibility, but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan.”

Scoring 'no' to Q5 or 'yes' to Q6



I am very concerned about your safety at this moment, I am not a clinician but I would like you to talk to one right now. I am going to make some telephone calls now to your GP Care Co-ordinator / Crisis Management team/the emergency services to let them know how you are feeling and to arrange for you to receive immediate help.

Action to take in the case of immediate risk:

Participant needs immediate help – **do not leave them alone, or if on telephone, do not hang up.** Follow your trial’s chain of supervisory clinical contact in order to involve supervisory clinician right away. Then either yourself or the supervisory clinician* should follow the chain of contact below:

1. **GP / out of hours GP; if not**
2. **Crisis team; if not**

3. Call ambulance; if this does not result in ambulance attending

4..Clinician accompanies to A&E (by taxi rather than private car)

**Individual projects should determine in advance whether clinician or researcher (with clinician support) enacts steps 1-4*

Risk Report

Patient name: _____

DOB:

*Suicide risk information:**Include whether the participant has reported any of the following:*

- *History of previous suicide attempts*
- *Current suicidal ideation*
- *Relevant inventory scores (e.g., BDI item 9)*
- *Suicide plans / preparations*
- *Protective factors*
- *Regular contact with GP?*

Date reported: ___/___/___

Additional notes / actions taken:

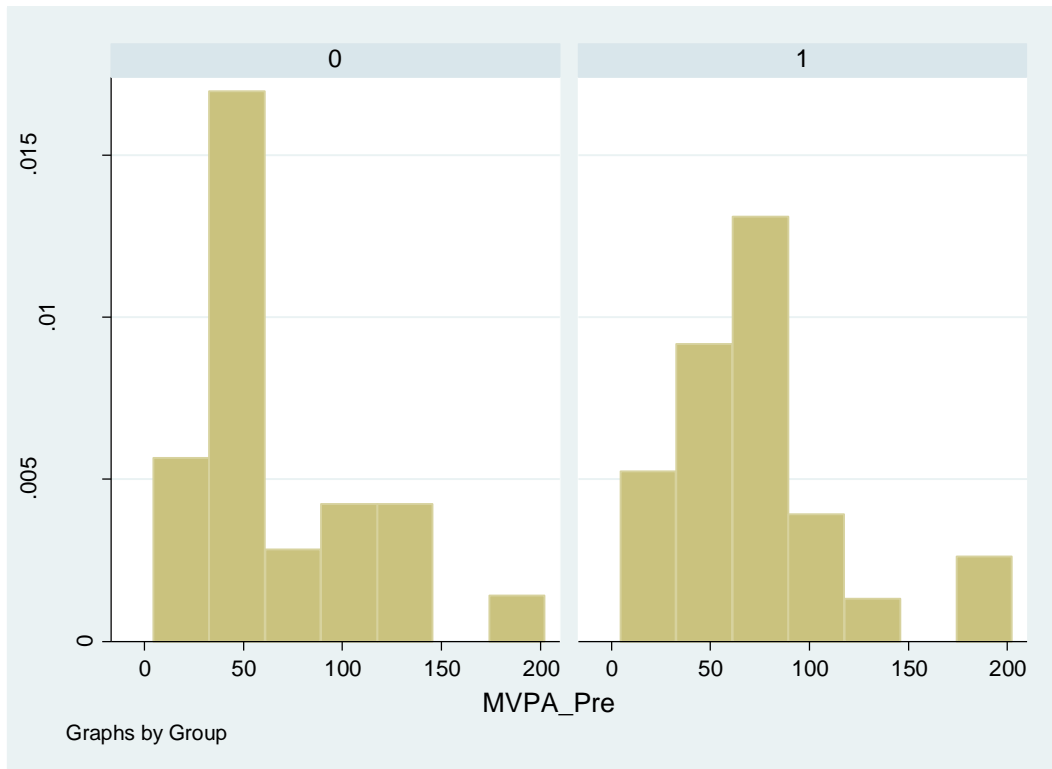
As part of the MDC risk protocol, suicide risk is **managed** by the patient's GP.

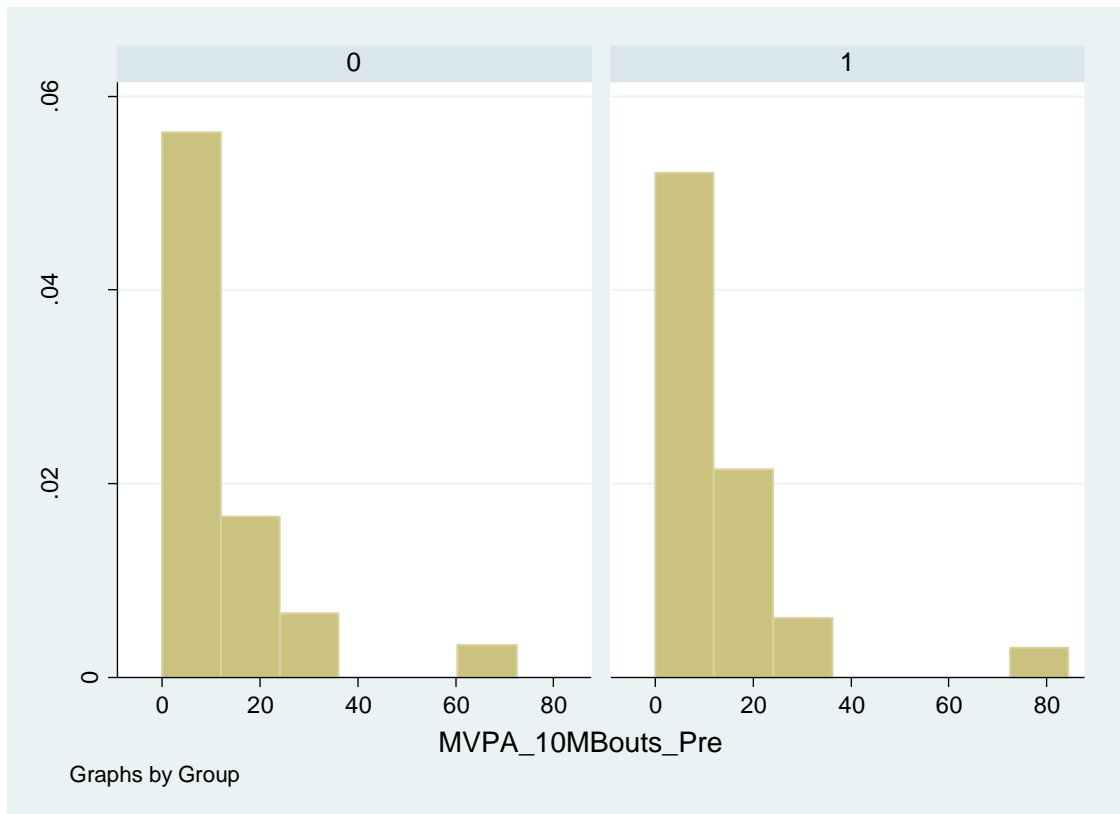
Date action taken: ___/___/___

Researcher / assessor: _____ Signed: _____ Date:
___/___/___

Supervisor: _____ Signed: _____ Date:
____/____/____

Appendix 12: Example histograms for physical activity data





Appendix 13: Stata 'Do' file

```

*Import Data from Excel eMotion_FinalDataSet created on 19th July 2017"
version 14.0
capture log close
clear
set more off
cd "C:\eMotion Stata"
import excel "eMotion_FinalDataSet_V3.xlsx", firstrow clear
*Create Log File*
log using "eMotion_PilotOutPut.log", replace
*CONVERT ALL STRING TO NUMERIC*
destring Registered LogIns GAD7_PRE IPAQ_Vigdays_Pre IPAQ_VigMins_Pre
IPAQ_Modda
> ys_Pre IPAQ_ModMins_Pre IPAQ_Walkdays_Pre IPAQ_WalkMins_Pre
IPAQ_Sitmins_Pre I
> PAQ_Category_Pre IPAQ_WeeklyMETS_Pre ValidWEdays_Pre ValidWKdays_Pre
LPA_Pre M
> PA_Pre VPA_Pre MVPA_Pre LMVPA_Pre MVPA_10MBouts_Pre Understand_Pre
Believe_Pre
> Confident_Identify_Pre Enactment_Identify_Pre Confident_Select_Pre Enactment_
Select_Pre Confident_Plan_Pre Enactment_Plan_Pre Confident_Setback_Pre
Enactme
> nt_Setback_Pre PHQ-8_Post GAD7_Post IPAQ_VigDays_Post IPAQ_Moddays_Post
IPAQ_Wa
> lkdays_Post IPAQ_VigMins_Post IPAQ_ModMins_Post IPAQ_WalkMins_Post
IPAQ_Sitmin
> s_Post IPAQ_Category_Post IPAQ_WeeklyMETS_Post ValidWEdays_Post
ValidWKdays_Po
> st LPA_Post MPA_Post VPA_Post MVPA_Post LMVPA_Post
MVPA_10MBouts_Post Understa
> nd_Post Believe_Post Confident_Identify_Post Enactment_Identify_Post Confident
_Select_Post Enactment_Select_Post Confident_Plan_Post Enactment_Plan_Post Con
fident_Setback_Post Enactment_Setback_Post IPAQ_DailyMVPA_Pre
IPAQ_DailyMVPA_P
> ost, replace force
*GENERATE NEW VARIABLES*
*Generate change scores*
generate PHQ-8_Change = PHQ-8_Post - PHQ-8_Pre
generate LPA_Change = LPA_Post - LPA_Pre
generate MPA_Change = MPA_Post - MPA_Pre
generate VPA_Change = VPA_Post - VPA_Pre
generate MVPA_Change = MVPA_Post - MVPA_Pre
generate LMVPA_Change = LMVPA_Post - LMVPA_Pre

```



```

generate MVPA_10MBouts_Change = MVPA_10MBouts_Post -
MVPA_10MBouts_Pre
generate IPAQ_WeeklyMETS_Change = IPAQ_WeeklyMETS_Post -
IPAQ_WeeklyMETS_Pre
generate IPAQ_Sitmins_Change = IPAQ_Sitmins_Post - IPAQ_Sitmins_Pre
generate IPAQ_DailyMVPA_Change = IPAQ_DailyMVPA_Post -
IPAQ_DailyMVPA_Pre
encode Gender, gen(Gender_num)
encode Employment, gen(Employment_num)
encode Education, gen(Education_num)
generate weeklymvpa10mbouts_Pre = MVPA_10MBouts_Pre * 7
generate weeklymvpa10mbouts_Post = MVPA_10MBouts_Post * 7
generate mvpa150m10mbouts_Pre = weeklymvpa10mbouts_Pre
recode mvpa150m10mbouts_Pre (min/149=1)(150/max=2)
generate IPAQ_daysmin_MVPA_Pre = IPAQ_VigMins_Pre + IPAQ_VigMins_Post
generate Less10PHQ-8_Pre = PHQ-8_Pre
recode Less10PHQ-8_Pre (min/9=1)(10/max=0)
generate Less10PHQ-8_Post = PHQ-8_Post
recode Less10PHQ-8_Post (min/9=1)(10/max=0)
encode Needsmet, gen(needsmet_num)
encode Satisfaction, gen(satisfaction_num)
encode Comeback, gen(comeback_num)
generate confident_Setback_Change = Confident_Setback_Post - Confident_Setback_P
> re
generate Confident_Plan_Change = Confident_Plan_Post - Confident_Plan_Pre
generate Confident_Select_Change = Confident_Select_Post - Confident_Select_Pre
generate Confident_Identify_Change = Confident_Identify_Post - Confident_Identif
> y_Pre
generate Understand_Change = Understand_Post - Understand_Pre
generate Believe_Change = Believe_Post - Believe_Pre
*Baseline tests of normality*
hist Age, by(Group)
hist PHQ-8_Pre, by(Group)
hist GAD7_PRE, by(Group)
hist LPA_Pre, by(Group)
hist MPA_Pre, by(Group)
hist VPA_Pre, by(Group)
hist MVPA_Pre, by(Group)
hist LMVPA_Pre, by(Group)
hist MVPA_10MBouts_Pre, by(Group)
hist IPAQ_WeeklyMETS_Pre, by (Group)
hist IPAQ_Sitmins_Pre, by (Group)
hist IPAQ_DailyMVPA_Pre, by (Group)
hist Understand_Pre, by(Group)
hist Believe_Pre, by(Group)

```

```

hist Confident_Identify_Pre, by(Group)
hist Confident_Select_Pre, by(Group)
hist Confident_Plan_Pre, by(Group)
hist Confident_Setback_Pre, by(Group)
*Baseline differences*
ttest Age, by(Group)
ttest PHQ-8_Pre, by(Group)
tab Group Less10PHQ-8_Pre, chi2 row
ttest GAD7_PRE, by(Group)
ttest mvpa_134mg_10mbouts_Pre, by(Group)
tab Group mvpa150m10mbouts_Pre, chi2 row
tab mvpa150m10mbouts_Pre
summarize ValidWEdays_Pre, detail
summarize ValidWKdays_Pre, detail
summarize ValidWEdays_Post, detail
summarize ValidWKdays_Post, detail
bysort Group: summarize LPA_Pre, detail
ttest LPA_Pre, by(Group)
regress LPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg LPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize MPA_Pre, detail
ttest MPA_Pre, by(Group)
regress MPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg MPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize VPA_Pre, detail
ttest VPA_Pre, by(Group)
regress VPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg VPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize MVPA_Pre, detail
ttest MVPA_Pre, by(Group)
regress MVPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg MVPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize LMVPA_Pre, detail
ttest LMVPA_Pre, by(Group)
regress LMVPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg LMVPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize MVPA_10MBouts_Pre, detail
ttest MVPA_10MBouts_Pre, by(Group)
regress MVPA_10MBouts_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg MVPA_10MBouts_Pre Group

```

matrix list e(ci_bca
 summarize LPA_Pre, detail
 summarize MPA_Pre, detail
 summarize VPA_Pre, detail
 summarize MVPA_Pre, detail
 summarize LMVPA_Pre, detail
 summarize MVPA_10MBouts_Pre, detail
 bysort Group: summarize weeklymvpa10mbouts_Pre, detail
 summarize weeklymvpa10mbouts_Pre, detail
 ttest IPAQ_Sitmins_Pre, by (Group)
 bysort Group: summarize IPAQ_Sitmins_Pre, detail
 summarize IPAQ_Sitmins_Pre, detail
 ttest Understand_Pre, by(Group)
 ttest Believe_Pre, by(Group)
 ttest Confident_Identify_Pre, by(Group)
 ttest Confident_Select_Pre, by(Group)
 ttest Confident_Plan_Pre, by(Group)
 ttest Confident_Setback_Pre, by(Group)
 tab Group Howheardaboutstudy, chi2 row
 tab Group Gender, chi2 row
 tab Group Therapy, chi2 row
 tab Group Antidepressants, chi2 row
 tab Group Education, chi2 row
 tab Group Employment, chi2 row
 tab Group Location, chi2 row
 tab Group Ethnicity, chi2 row
 differences between total drop out
 ttest Age, by(POST)
 tab POST Gender, chi2 row
 ttest PHQ-8_Pre, by(POST)
 ttest GAD7_PRE, by(POST)
 tab POST Therapy, chi2 row
 tab POST Antidepressants, chi2 row
 tab POST Howheardaboutstudy, chi2 row
 tab POST Education, chi2 row
 tab POST Employment, chi2 row
 tab POST Group, chi2 row
 tab POST Location, chi2 row
 tab POST Ethnicity, chi2 row
 differences between lost GENEActive drop out
 ttest PHQ-8_Pre, by(POSTGENEACTIVE)
 ttest GAD7_PRE, by(POSTGENEACTIVE)
 ttest Age, by(POSTGENEACTIVE)
 ttest mvpa_134mg_Pre, by(POSTGENEACTIVE)
 ttest Understand_Pre, by(POSTGENEACTIVE)

```

ttest Believe_Pre, by(POSTGENEACTIVE)
ttest Confident_Identify_Pre, by(POSTGENEACTIVE)
ttest Confident_Select_Pre, by(POSTGENEACTIVE)
ttest Confident_Plan_Pre, by(POSTGENEACTIVE)
ttest Confident_Setback_Pre, by(POSTGENEACTIVE)
tab POSTGENEACTIVE Gender, chi2 row
tab POSTGENEACTIVE Therapy, chi2 row
tab POSTGENEACTIVE Antidepressants, chi2 row
tab POSTGENEACTIVE Howheardaboutstudy, chi2 row
tab POSTGENEACTIVE Education, chi2 row
tab POSTGENEACTIVE Employment, chi2 row
tab POSTGENEACTIVE Group, chi2 row
tab POSTGENEACTIVE Location, chi2 row
tab POSTGENEACTIVE Ethnicity, chi2 row
*Post tests of normality (with bootstapping)*
hist PHQ-8_Post, by(Group)
hist GAD7_Post, by(Group)
hist mvpa_134mg_Post, by(Group)
hist mvpa_134mg_10mbouts_Post, by(Group)
hist LPA_Post, by(Group)
hist MPA_Post, by(Group)
hist VPA_Post, by(Group)
hist MVPA_Post, by(Group)
hist LMVPA_Post, by(Group)
hist MVPA_10MBouts_Post, by(Group)
hist weeklymvpa10mbouts_Post, by(Group)
hist IPAQ_WeeklyMETS_Post, by (Group)
hist IPAQ_Sitmins_Post, by (Group)
hist Understand_Post, by(Group)
hist Believe_Post, by(Group)
hist Confident_Identify_Post, by(Group)
hist Confident_Select_Post, by(Group)
hist Confident_Plan_Post, by(Group)
hist Confident_Setback_Post, by(Group)
*Mean differences post depression*
ttest PHQ-8_Post, by(Group)
regress PHQ-8_Post PHQ-8_Pre i.Group
*Mean difference post depression with covariates*
regress PHQ-8_Post PHQ-8_Pre Therapy i.Group
regress PHQ-8_Post PHQ-8_Pre Therapy Age i.Group
regress PHQ-8_Post PHQ-8_Pre Therapy Age Gender_num i.Group
regress PHQ-8_Post PHQ-8_Pre Therapy Age Gender_num Employment_num i.Group
regress PHQ-8_Post PHQ-8_Pre Therapy Age Gender_num Employment_num
Education_num i
> .Group

```

```

regress PHQ-8_Post PHQ-8_Pre Therapy Age Gender_num Employment_num
Education_num A
> ntidepressants i.Group
*Mean difference post depression with usage*
regress PHQ-8_Change ModulesAccessed
regress PHQ-8_Change LogIns
regress PHQ-8_Change Totalmins
*Under 10 on PHQ-8 at post*
logistic Less10PHQ-8_Post Less10PHQ-8_Pre i.Group
*GENEACTIV post*
bysort Group: summarize LPA_Post, detail
ttest LPA_Post, by(Group)
regress LPA_Post LPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg LPA_Post LPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize MPA_Post, detail
ttest MPA_Post, by(Group)
regress MPA_Post MPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg MPA_Post MPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize VPA_Post, detail
ttest VPA_Post, by(Group)
regress VPA_Post VPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg VPA_Post VPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize MVPA_Post, detail
ttest MVPA_Post, by(Group)
regress MVPA_Post MVPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg MVPA_Post MVPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize LMVPA_Post, detail
ttest LMVPA_Post, by(Group)
regress LMVPA_Post LMVPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg LMVPA_Post LMVPA_Pre Group
matrix list e(ci_bca)
bysort Group: summarize MVPA_10MBouts_Post, detail
ttest MVPA_10MBouts_Post, by(Group)
regress MVPA_10MBouts_Post MVPA_10MBouts_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg MVPA_10MBouts_Post
MVPA_10MBouts_P
> re Group
matrix list e(ci_bca)
bysort Group: summarize weeklymvpa10mbouts_Post, detail
ttest weeklymvpa10mbouts_Post, by(Group)
regress weeklymvpa10mbouts_Post weeklymvpa10mbouts_Pre Group

```

```

bootstrap, reps(2000) strata(Group) bca: reg weeklymvpa10mbouts_Post weeklymvpa
> 10mbouts_Pre Group
matrix list e(ci_bca)
*Mean difference post depression with Self report PA*
regress PHQ-8_Post PHQ-8_Pre IPAQ_WeeklyMETS_Pre i.Group
regress PHQ-8_Post PHQ-8_Pre IPAQ_Sitmins_Pre i.Group
regress PHQ-8_Post PHQ-8_Pre IPAQ_DailyMVPA_Pre i.Group
*Change in depression regress with Objective PA*
ttest LPA_Change, by (Group)
bysort Group: regress PHQ-8_Change PHQ-8_Pre LPA_Change
bysort Group: regress PHQ-8_Change PHQ-8_Pre MPA_Change
bysort Group: regress PHQ-8_Change PHQ-8_Pre VPA_Change
bysort Group: regress PHQ-8_Change PHQ-8_Pre MVPA_Change
bysort Group: regress PHQ-8_Change PHQ-8_Pre LMVPA_Change
bysort Group: regress PHQ-8_Change PHQ-8_Pre MVPA_10MBouts_Change
*Change in depression regress with Self report PA*
bysort Group: regress PHQ-8_Change PHQ-8_Pre IPAQ_WeeklyMETS_Change
bysort Group: regress PHQ-8_Change PHQ-8_Pre IPAQ_Sitmins_Change
bysort Group: regress PHQ-8_Change PHQ-8_Pre IPAQ_DailyMVPA_Change
*Hist of logins*
hist LogIns
hist ModulesAccessed
hist Totalmins
summarize LogIns ModulesAccessed Totalmins, detail
*Change in Objective physical activity regress with delivery*
bysort Group: regress LPA_Change LPA_Pre LogIns
bysort Group: regress MPA_Change MPA_Pre LogIns
bysort Group: regress VPA_Change VPA_Pre LogIns
bysort Group: regress MVPA_Change MVPA_Pre LogIns
bysort Group: regress LMVPA_Change LMVPA_Pre LogIns
bysort Group: regress MVPA_10MBouts_Change MVPA_10MBouts_Pre LogIns
bysort Group: regress LPA_Change LPA_Pre ModulesAccessed
bysort Group: regress MPA_Change MPA_Pre ModulesAccessed
bysort Group: regress VPA_Change VPA_Pre ModulesAccessed
bysort Group: regress MVPA_Change MVPA_Pre ModulesAccessed
bysort Group: regress LMVPA_Change LMVPA_Pre ModulesAccessed
bysort Group: regress MVPA_10MBouts_Change MVPA_10MBouts_Pre Totalmins
bysort Group: regress LPA_Change LPA_Pre Totalmins
bysort Group: regress MPA_Change MPA_Pre Totalmins
bysort Group: regress VPA_Change VPA_Pre Totalmins
bysort Group: regress MVPA_Change MVPA_Pre Totalmins
bysort Group: regress LMVPA_Change LMVPA_Pre Totalmins
bysort Group: regress MVPA_10MBouts_Change MVPA_10MBouts_Pre Totalmins
*Change in self physical activity regress with delivery*

```

```

bysort Group: regress IPAQ_WeeklyMETS_Change IPAQ_WeeklyMETS_Pre
Totalmins
bysort Group: regress IPAQ_Sitmins_Change IPAQ_Sitmins_Pre Totalmins
bysort Group: regress IPAQ_DailyMVPA_Change IPAQ_DailyMVPA_Pre Totalmins
bysort Group: regress IPAQ_WeeklyMETS_Change IPAQ_WeeklyMETS_Pre
ModulesAccessed
bysort Group: regress IPAQ_Sitmins_Change IPAQ_Sitmins_Pre ModulesAccessed
bysort Group: regress IPAQ_DailyMVPA_Change IPAQ_DailyMVPA_Pre
ModulesAccessed
bysort Group: regress IPAQ_WeeklyMETS_Change IPAQ_WeeklyMETS_Pre LogIns
bysort Group: regress IPAQ_Sitmins_Change IPAQ_Sitmins_Pre LogIns
bysort Group: regress IPAQ_DailyMVPA_Change IPAQ_DailyMVPA_Pre LogIns
*Change in self depression regress with delivery*
bysort Group: regress PHQ-8_Change PHQ-8_Pre Totalmins
bysort Group: regress PHQ-8_Change PHQ-8_Pre ModulesAccessed
bysort Group: regress PHQ-8_Change PHQ-8_Pre LogIns
bysort Group: regress PHQ-8_Change PHQ-8_Pre FacilitationCall
regress PHQ-8_Change FacilitationCall
*Mean difference post anxiety*
ttest GAD7_Post, by(Group)
regress GAD7_Post GAD7_PRE i.Group
*Mean difference post IPAQ*
bysort Group: summarize IPAQ_DailyMVPA_Post, detail
ttest IPAQ_DailyMVPA_Post, by(Group)
regress IPAQ_DailyMVPA_Post IPAQ_DailyMVPA_Pre Group
bootstrap, reps(2000) strata(Group) bca: reg IPAQ_DailyMVPA_Post
IPAQ_DailyMVPA
> _Pre Group
matrix list e(ci_bca)
bysort Group: summarize IPAQ_WeeklyMETS_Post, detail
ttest IPAQ_WeeklyMETS_Post, by (Group)
regress IPAQ_WeeklyMETS_Post IPAQ_WeeklyMETS_Pre i.Group
bysort Group: summarize IPAQ_Sitmins_Post, detail
ttest IPAQ_Sitmins_Post, by (Group)
regress IPAQ_Sitmins_Post IPAQ_Sitmins_Pre i.Group
*Reasons for not returning GENEACTIV*
logistic POSTGENEACTIVE PHQ-8_Pre
logistic POSTGENEACTIVE MVPA_Pre
logistic POSTGENEACTIVE Age
logistic POSTGENEACTIVE GAD7_PRE
*Acceptabilty*
tab Group needsmet_num, chi2 row
tab Group satisfaction_num, chi2 row
tab Group comeback_num, chi2 row
ttest mvpa_134mg_Post, by(Group)

```

Appendix 14: eMotion Telephone interview Topic Guide

Aims:

- Explore acceptability of the study procedures (e.g. data collection);
- Explore any barriers/facilitators participants experienced when using eMotion;
- Explore beliefs about the usefulness of eMotion – did they increase (physical) activity and did it help?
- What could be improved?

Hi, my name is [name], and I am calling you just to talk about your recent experience of using the eMotion intervention website. We really appreciate your time.

Previously I mentioned that it would be useful for us and you to talk through your time while completing several tasks proposed by the website. The main purpose of this interview is to understand your experience of eMotion and any impact it may have had so that we can learn for future development. Please say anything you wish, we want to hear all types of feedback and are keen to hear your views on how things might be done differently to improve the study.

This interview will take approximately 30 minutes and will be audiotaped to make sure we don't miss anything vital. All information you provide will be anonymized; if we use any quotes from you, we will not give your name but use a false name.

Before we begin, do you have any questions about doing the interview?

When we are ready to start I will switch the recorder on, say your name and the date; is that OK?

OK, so the recorder is now going on....

Name:

Date:

Questions

- 1. How acceptable were the study procedures overall?**
 - a. What were your initial thoughts about the study?
 - b. How clear was the information provided?
 - c. How did you find the data collection (questionnaires, activity watches, mood text messages)?
- 2. Did you use the introduction module?**
 - a. If yes, how did you find it?
 - b. How useful was it?
 - c. If no, was there anything that made you skip this module?
- 3. How did you find the weekly proposed tasks in each module?**
 - a. Did you complete all of them
 - b. How well did they help you with your symptoms
 - c. How easy did you find it to plan and select the activities that will enhance your mood?
 - d. What helped you?
 - e. What do you think would help you more?
 - f. Were any of the activities you have chosen to enhance your mood, to do with physical activity?
 - g. If yes, how well did physical activity enhance your mood?
- 4. Did you complete the unlockable modules?**
 - a. If yes, do you feel that you gained anything from going through them
 - b. If no, what were your reasons for disengaging with them
 - c. If no, did you get to unlock the modules
- 5. How did the audio explanation in each module make you feel?**

- a. How helpful did you find it
- b. What would your preferred way of delivery be?

6. What were your thoughts about the length of the intervention?

- a. Too long?
- b. Too short?

7. How easy to use was the website overall?

- a. What would you improve?

8. If you had to choose the best thing about your experience with eMotion

- a. Please explain your choice

9. Did you add more routine, pleasurable or necessary activities to your weekly schedule?

- a. What kind of activities were they?
- b. Did adding more routine, pleasurable or necessary activities help?
- c. How do you feel they helped you?

10. Did you add more physical activities to your schedule?

- a. What kind of physical activities?
- b. Did you find doing more (physical) activities helped?
- c. If so how?
- d. If not, why not?

11. How would you improve eMotion?

12. Do you have anything you would like to add?

References

- Abraham, C., & Michie, S. (2008). A taxonomy of behavior change techniques used in interventions. *Health Psychology, 27*(3), 379.
- Abraham, C., Wood, C. E., Johnston, M., Francis, J., Hardeman, W., Richardson, M., & Michie, S. (2015). Reliability of Identification of Behavior Change Techniques in Intervention Descriptions. *Annals of Behavioral Medicine, 49*(6), 885–900. <https://doi.org/10.1007/s12160-015-9727-y>
- Aittasalo, M., Rinne, M., Pasanen, M., Kukkonen-Harjula, K., & Vasankari, T. (2012). Promoting walking among office employees — evaluation of a randomized controlled intervention with pedometers and e-mail messages. *BMC Public Health, 12*(1), 403. <https://doi.org/10.1186/1471-2458-12-403>
- Ajzen, I. (1991). The Theory of Planned Behaviour. *Organisational Behaviour and Human Decision Processes, 50*, 179–211.
- Ajzen, I. (2011). The theory of planned behaviour : Reactions and reflections. <https://doi.org/10.1080/08870446.2011.613995>
- Albright, C. L., Saiki, K., Steffen, A. D., & Woekel, E. (2015). What barriers thwart postpartum women’s physical activity goals during a 12-month intervention? A process evaluation of the Nā Mikimiki Project. *Women & Health, 55*(1), 1–21. <https://doi.org/10.1080/03630242.2014.972014>
- Albright, C. L., Steffen, A. D., Novotny, R., Nigg, C. R., Wilkens, L. R., Saiki, K., ... Brown, W. J. (2012). Baseline results from Hawaii’s Nā Mikimiki Project: a physical activity intervention tailored to multiethnic postpartum women. *Women & Health, 52*(3), 265–91. <https://doi.org/10.1080/03630242.2012.662935>
- Alderman, B. L., Olson, R. L., Brush, C. J., & Shors, T. J. (2016). MAP training: combining meditation and aerobic exercise reduces depression and rumination while enhancing synchronized brain activity. *Translational Psychiatry, 6*(2), e726. <https://doi.org/10.1038/tp.2015.225>
- Ali, S., Stone, M. A., Peters, J. L., Davies, M. J., & Khunti, K. (2006). The prevalence of co-morbid depression in adults with Type 2 diabetes: a systematic review and meta-analysis. *Diabetic Medicine, 23*(11), 1165–299

1173. <https://doi.org/10.1111/j.1464-5491.2006.01943.x>
- Alkhaldi, G., Hamilton, F. L., Lau, R., Webster, R., Michie, S., & Murray, E. (2016). The Effectiveness of Prompts to Promote Engagement With Digital Interventions: A Systematic Review. *Journal of Medical Internet Research*, *18*(1), e6. <https://doi.org/10.2196/jmir.4790>
- Anderson, R. J., Freedland, K. E., Clouse, R. E., & Lustman, P. J. (2001). The prevalence of comorbid depression in adults with diabetes a meta-analysis. *Diabetes Care*, *24*(6), 1069–1078.
- Andersson, G. (2010). The promise and pitfalls of the internet for cognitive behavioral therapy. *BMC Medicine*, *8*, 82. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=cmedm&AN=21138574&site=ehost-live>
- Andersson, G., & Cuijpers, P. (2009). Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. *Cognitive Behaviour Therapy*, *38*, 196–205.
- Arroll, B., Elley, C. R., Fishman, T., Goodyear-Smith, F. A., Kenealy, T., Blashki, G., & MacGillivray, Sa. (2009). Antidepressants versus placebo for depression in primary care. *The Cochrane Library*.
- Association, A. P. (2013). *DSM 5*. American Psychiatric Association.
- Avery, L., Charman, S. J., Taylor, L., Flynn, D., Mosely, K., Speight, J., ... Trenell, M. I. (2016). Systematic development of a theory-informed multifaceted behavioural intervention to increase physical activity of adults with type 2 diabetes in routine primary care: Movement as Medicine for Type 2 Diabetes. *Implementation Science : IS*, *11*, 99. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=27430648>
- Avery, L., Sniehotta, F. F., Denton, S. J., Steen, N., McColl, E., Taylor, R., & Trenell, M. I. (2014). Movement as Medicine for Type 2 Diabetes: protocol for an open pilot study and external pilot clustered randomised controlled trial to assess acceptability, feasibility and fidelity of a multifaceted behavioural intervention targeting physical activity in. *Trials*, *15*, 46. Retrieved from

<http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=24491134>

- Babyak, M., Blumenthal, J. A., Herman, S., Khatri, P., Doraiswamy, M., Moore, K., ... Krishnan, K. R. (2000). Exercise treatment for major depression: maintenance of therapeutic benefit at 10 months. *Psychosomatic Medicine*, 62(5), 633–638.
- Bandura, A. (1991). Social Cognitive Theory of Self Regulation.
- Barnes, M., Sofie, S., Thomas, L., Kessler, D., Kuyken, W., Owen-Smith, A., ... Turner, K. (2013). No pain, no gain: Depressed clients' experiences of cognitive behavioural therapy. *British Journal of Clinical Psychology*, 52(4), 347–364. <https://doi.org/10.1111/bjc.12021>
- Baron, R. M., & Kenny, D. a. (1986). The Moderator-Mediator Variable Distinction in Social The Moderator-Mediator Variable Distinction in Social Psychological Research: Conceptual, Strategic, and Statistical Considerations. *Journal of Personality and Social Psychology*, 51(6), 1173–1182. <https://doi.org/10.1037/0022-3514.51.6.1173>
- Bartholomew, LK, Parcel GS, K. G. (1998). Intervention mapping: a process for developing theory- and evidence-based health education programs. *Health Education and Behaviour*, 25(5), 545–563.
- Bartholomew, L. K., Parcel, G. S., Kok, G., Gottlieb, N. H., & Fernandez, M. E. (2011). *Planning health promotion programs. An intervention mapping approach* (3rd ed.). San Francisco: John Wiley & Sons, Ltd.
- Baskin, T. W., Tierney, S. C., Minami, T., & Wampold, B. E. (2003). Establishing specificity in psychotherapy: a meta-analysis of structural equivalence of placebo controls. *Journal of Consulting and Clinical Psychology*, 71(6), 973–979. <https://doi.org/10.1037/0022-006X.71.6.973>
- Baumeister, H., Nowoczin, L., Lin, J., Seifferth, H., Seufert, J., Laubner, K., & Ebert, D. D. (2014). Impact of an acceptance facilitating intervention on diabetes patients' acceptance of Internet-based interventions for depression: A randomized controlled trial. *Diabetes Research and Clinical Practice*, 105(1), 30–39. <https://doi.org/10.1016/j.diabres.2014.04.031>

- Beatty, L., & Binnion, C. (2016). A Systematic Review of Predictors of, and Reasons for, Adherence to Online Psychological Interventions. *International Journal of Behavioral Medicine, 23*(6), 776–794. <https://doi.org/10.1007/s12529-016-9556-9>
- Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., ... Czajkowski, S. (2004). Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23*(5), 443.
- Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., ... Treatment Fidelity Workgroup of the, N. I. H. B. C. C. (2004). Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol, 23*(5), 443–451. <https://doi.org/10.1037/0278-6133.23.5.443>
- Berridge, K., & Kringelbach, M. (2016). Pleasure systems in the brain. *Neuron, 86*(3), 646–664.
- Blumenthal, J. A., Babyak, M. A., Moore, K. A., Craighead, W. E., Herman, S., Khatri, P., ... Appelbaum, M. (1999). Effects of exercise training on older patients with major depression. *Archives of Internal Medicine, 159*(19), 2349.
- Bodde, A. E., Seo, D.-C., Frey, G. C., Lohrmann, D. K., & Van Puymbroeck, M. (2012). Developing a physical activity education curriculum for adults with intellectual disabilities. *Health Promotion Practice, 13*(1), 116–123. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=21444920>
- Bodde, A. E., Seo, D.-C., Frey, G. C., Lohrmann, D. K., Van Puymbroeck, M., A.E., B., ... Van Puymbroeck, M. (2012). Developing a physical activity education curriculum for adults with intellectual disabilities. *Health Promotion Practice, 13*(1), 116–123. <https://doi.org/10.1177/1524839910381698>
- Bollen, J., Trick, L., Llewellyn, D., & Dickens, C. (2017). The effects of acute inflammation on cognitive functioning and emotional processing in humans:

- A systematic review of experimental studies. *Journal of Psychosomatic Research*, 94, 47–55. <https://doi.org/10.1016/j.jpsychores.2017.01.002>
- Bombardier, C. H., Ehde, D. M., Gibbons, L. E., Wadhvani, R., Sullivan, M. D., Rosenberg, D. E., & Kraft, G. H. (2013). Telephone-based physical activity counseling for major depression in people with multiple sclerosis. *Journal of Consulting and Clinical Psychology*, 81(1), 89–99. <https://doi.org/10.1037/a0031242>
- Booth, F. W., Roberts, C. K., & Laye, M. J. (2012). Lack of exercise is a major cause of chronic diseases. *Comprehensive Physiology*, 2(2), 1143–1211. <https://doi.org/10.1002/cphy.c110025.Lack>
- Borek, A. J., Abraham, C., Smith, J. R., Greaves, C. J., & Tarrant, M. (2015). A checklist to improve reporting of group-based behaviour-change interventions. *BMC Public Health*, 15, 963. <https://doi.org/10.1186/s12889-015-2300-6>
- Borrelli, B. (2011a). The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *Journal of Public Health Dentistry*, 71(Supplement 1), S52–S63. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=eoh&AN=23438184&site=ehost-live>
- Borrelli, B. (2011b). The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *Journal of Public Health Dentistry*, 71 Suppl 1, S52-63.
- Borrelli, B., Sepinwall, D., Ernst, D., Bellg, A. J., Czajkowski, S., Breger, R., ... Orwig, D. (2005). A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *Journal of Consulting and Clinical Psychology*, 73(5), 852–860. <https://doi.org/10.1037/0022-006x.73.5.852>
- Boutron, I., Moher, D., Altman, D. G., Schulz, K. F., & Ravaud, P. (2008). Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Annals of Internal Medicine*, 148(4), 295–309.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology.

- Qualitative Research in Psychology*, 3, 77–101. [https://doi.org/The publisher's URL is: http://dx.doi.org/10.1191/1478088706qp063oa](https://doi.org/The_publisher's_URL_is:_http://dx.doi.org/10.1191/1478088706qp063oa)
- Brawley, L. R., Arbour-Nicitopoulos, K. P., & Martin Ginis, K. A. (2013a). Developing physical activity interventions for adults with spinal cord injury. Part 3: A pilot feasibility study of an intervention to increase self-managed physical activity. *Rehabilitation Psychology*, 58(3), 316–321. <https://doi.org/10.1037/a0032814.1037/a0032814.suppl> (Supplemental)
- Brawley, L. R., Arbour-Nicitopoulos, K. P., & Martin Ginis, K. A. (2013b). Developing physical activity interventions for adults with spinal cord injury. Part 3: A pilot feasibility study of an intervention to increase self-managed physical activity. *Rehabilitation Psychology*, 58(3), 316–321. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed15&NEWS=N&AN=369702988>
- Breckon, J. D., Johnston, L. H., & Hutchison, A. (2008). *Physical activity counseling content and competency: a systematic review*. *Journal of physical activity & health*. 5 (3) (pp 398-417), 2008. Date of Publication: May 2008. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=emed8&AN=18579918>
- Brosse, A. L., Sheets, E. S., Lett, H. S., & Blumenthal, J. A. (2002). Exercise and the treatment of clinical depression in adults: recent findings and future directions. *Sports Med*, 32(12), 741–760. <https://doi.org/321201> [pii]
- Brouwer, W., Kroeze, W., Crutzen, R., Nooijer, N., Vries, N., Brug, J., & Oenema, A. (2011). Which Intervention Characteristics are Related to More Exposure to Internet-Delivered Healthy Lifestyle Promotion Interventions? A Systematic Review. *Journal of Medical Internet Research*, 13(1).
- Bull, F. C., & Milton, K. E. (2010). A process evaluation of a “physical activity pathway” in the primary care setting. *BMC Public Health*, 10, 463. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medc&NEWS=N&AN=20696030>
- Busse, M., Quinn, L., Dawes, H., Jones, C., Kelson, M., Poile, V., ... Hood, K.

- (2014). Supporting physical activity engagement in people with Huntington's disease (ENGAGE-HD): study protocol for a randomized controlled feasibility trial. *Trials*, *15*, 487. <https://doi.org/10.1186/1745-6215-15-487>
- Butler, A. C., Chapman, J. E., Forman, E. M., & Beck, A. T. (2006). The empirical status of cognitive-behavioral therapy: A review of meta-analyses. *Clinical Psychology Review*, *26*(1), 17–31. <https://doi.org/10.1016/j.cpr.2005.07.003>
- Butler, K., Klaus, K., Edwards, L., & Pennington, K. (2017). Elevated cortisol awakening response associated with early life stress and impaired executive function in healthy adult males. *Hormones and Behavior*, *95*(November 2016), 13–21. <https://doi.org/10.1016/j.yhbeh.2017.07.013>
- Cane, J., O'Connor, D., & Michie, S. (2012). Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science*, *7*(1), 37. <https://doi.org/10.1186/1748-5908-7-37>
- Carlbring, P., Lindner, P., Martell, C., Hassmén, P., Forsberg, L., Ström, L., & Andersson, G. (2013). The effects on depression of Internet-administered behavioural activation and physical exercise with treatment rationale and relapse prevention: study protocol for a randomised controlled trial. *Trials*, *14*(1), 35.
- Carr, L. J., Karvinen, K., Peavler, M., Smith, R., & Cangelosi, K. (2013). Multicomponent intervention to reduce daily sedentary time: a randomised controlled trial. *BMJ Open*, *3*(10), e003261. <https://doi.org/10.1136/bmjopen-2013-003261>
- Carroll, C., Patterson, M., Wood, S., Booth, A., Rick, J., & Balain, S. (2007). A conceptual framework for implementation fidelity. *Implementation Science : IS*, *2*, 40. <https://doi.org/10.1186/1748-5908-2-40>
- Caspersen, C. J., Powell, K. E., & Christenson, G. M. (1985). Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. *Public Health Reports (Washington, D.C. : 1974)*, *100*(2), 126–31. <https://doi.org/10.2307/20056429>

- Castro, C., Pruitt, L., Buman, M., & King, A. (2011). Physical Activity Program Delivery by Professionals Versus Volunteers: The TEAM Randomized Trial. *Health Psychology, 30*(3), 285–294. <https://doi.org/10.1037/a0021980>
- Cataldo, R., John, J., Chandran, L., Pati, S., & Shroyer, A. (2013). Impact of Physical Activity Intervention Programs on Self-Efficacy in Youths: A Systematic Review. *ISRN Obesity, 2013*, 11. <https://doi.org/10.1155/2013/586497>
- Cepeda, M. S., Stang, P., & Makadia, R. (2016). Depression Is Associated With High Levels of C-Reactive Protein and Low Levels of Fractional Exhaled Nitric Oxide: Results From the 2007–2012 National Health and Nutrition Examination Surveys. *J Clin Psychiatry, 77*(12), 1666–1671. <https://doi.org/10.4088/JCP.15m10267>
- Chalder, M., Wiles, N. J., Campbell, J., Hollinghurst, S. P., Searle, A., Haase, A. M., ... Lewis, G. (2012). A pragmatic randomised controlled trial to evaluate the cost-effectiveness of a physical activity intervention as a treatment for depression: the treating depression with physical activity (TREAD) trial. *Health Technology Assessment, 16*(10), 1. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=2011527918&site=ehost-live>
- Chatterjee, S., & Price, A. (2009). Healthy Living with Persuasive Technologies: Framework, Issues, and Challenges. *Journal of the American Medical Informatics Association, 16*(2), 171–178. <https://doi.org/10.1197/jamia.M2859>
- Conner, M., Rhodes, R. E., Morris, B., McEachan, R., & Lawton, R. (2011). Changing exercise through targeting affective or cognitive attitudes. *Psychology & Health, 26*(2), 133–149. <https://doi.org/10.1080/08870446.2011.531570>
- Cooney, G. M., Dwan, K., Greig, C. A., Lawlor, D. A., Rimer, J., Waugh, F. R., ... Mead, G. E. (2013). Exercise for depression. *Cochrane Database Syst Rev, 12*(9).
- Coull, G., & Morris, P. G. (2011). The clinical effectiveness of CBT-based guided self-help interventions for anxiety and depressive disorders: a

- systematic review. *Psychological Medicine*, 41(11), 2239–2252.
<https://doi.org/10.1017/S0033291711000900>
- Cowpertwait, L., & Clarke, D. (2013). Effectiveness of Web-based Psychological Interventions for Depression: A Meta-analysis. *International Journal of Mental Health and Addiction*, 11(2), 247–268.
<https://doi.org/10.1007/s11469-012-9416-z>
- Craft, L. L., & Perna, F. M. (2004). The Benefits of Exercise for the Clinically Depressed. *Primary Care Companion to the Journal of Clinical Psychiatry*, 6(3), 104–111. <https://doi.org/10.4088/PCC.v06n0301>
- Craig, C. L., Marshall, A. L., Sjöström, M., Bauman, A. E., Booth, M. L., Ainsworth, B. E., ... Oja, P. (2003). International physical activity questionnaire: 12-Country reliability and validity. *Medicine and Science in Sports and Exercise*, 35(8), 1381–1395.
<https://doi.org/10.1249/01.MSS.0000078924.61453.FB>
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*, 337. <https://doi.org/10.1136/bmj.a1655>
- Cuijpers, P., De Wit, L., & Taylor, A. (2014). The effects of psychological treatments for adult depression on physical activity: A systematic review. *Mental Health and Physical Activity*, 7(1), 6–8.
<https://doi.org/10.1016/j.mhpa.2014.01.002>
- Cuijpers, P., Sijbrandij, M., Koole, S. L., Andersson, G., Beekman, A. T., & Reynolds, C. F. (2013). The efficacy of psychotherapy and pharmacotherapy in treating depressive and anxiety disorders: A meta-analysis of direct comparisons. *World Psychiatry*, 12(2), 137–148.
<https://doi.org/10.1002/wps.20038>
- Cuijpers, P., van Straten, A., Andersson, G., & van Oppen, P. (2008). Psychotherapy for depression in adults: a meta-analysis of comparative outcome studies. *Journal of Consulting and Clinical Psychology*, 76(6), 909.
- Cuijpers, P., van Straten, A., Bohlmeijer, E., Hollon, S. D., & Andersson, G. (2010). The effects of psychotherapy for adult depression are

- overestimated: a meta-analysis of study quality and effect size. *Psychological Medicine*, 40(2), 211–223. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=ovftk&AN=00006826-201002000-00005>
- Dantzer, R., O'Connor, J., Freund, G., Johnson, R., & Kelley, K. (2008). From inflammation to sickness and depression: when the immune system subjugates the brain. *Nat Rev Neurosci*, 9(1), 46–56.
- Davies, C. a, Spence, J. C., Vandelanotte, C., Caperchione, C. M., & Mummery, W. (2012). Meta-analysis of internet-delivered interventions to increase physical activity levels. *International Journal of Behavioral Nutrition and Physical Activity*, 9(1), 52. <https://doi.org/10.1186/1479-5868-9-52>
- Davies, E. B., Morriss, R., & Glazebrook, C. (2014). Computer-delivered and web-based interventions to improve depression, anxiety, and psychological well-being of university students: A systematic review and meta-analysis. *Journal of Medical Internet Research*, 16(5), 1–22. <https://doi.org/10.2196/jmir.3142>
- Deci, E. L., & Ryan, R. M. (2000). The “What” and “Why” of Goal Pursuits: Human Needs and the Self-Determination of Behavior. *Psychological Inquiry*, 11(4), 227–268. https://doi.org/10.1207/S15327965PLI1104_01
- Deci, E. L., & Ryan, R. M. (2000). The what and why of human goal pursuits: Human needs and the self-determination of behavior. *Psychological Inquiry*, 11, 227–268.
- Deci & Ryan, R. M., E. L. (1985). *Intrinsic motivation and self-determination in human behaviour*. New York: Plenum.
- Dennison, L., Morrison, L., Lloyd, S., Phillips, D., Stuart, B., Williams, S., ... Yardley, L. (2014). Does brief telephone support improve engagement with a web-based weight management intervention? Randomized controlled trial. *J Med Internet Res*, 16(3). Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4004138/?report=classic>
- Department of Health. (2011a). *Physical activity guidelines for adults (19-64 years)*.

- Department of Health. (2011b). UK physical activity guidelines. Retrieved from <https://www.gov.uk/government/publications/uk-physical-activity-guidelines>
- Dickens, C. (2015). Depression in People with Coronary Heart Disease: Prognostic Significance and Mechanisms. *Current Cardiology Reports*, 17(10). <https://doi.org/10.1007/s11886-015-0640-6>
- Dickens, C., Coventry, P., Khara, A., Bower, P., Mansell, W., & Bakerly, N. D. (2012). Perseverative negative cognitive processes are associated with depression in people with long-term conditions. *Chronic Illness*, 8(2), 102–111. <https://doi.org/10.1177/1742395311433058>
- Dishman, R. K., & O'Connor, P. J. (2009). Lessons in exercise neurobiology: The case of endorphins. *Mental Health and Physical Activity*, 2(1), 4–9. <https://doi.org/http://dx.doi.org/10.1016/j.mhpa.2009.01.002>
- Doherty, A., Jackson, D., Hammerla, N., Plötz, T., Olivier, P., Granat, M. H., ... Wareham, N. J. (2017). Large scale population assessment of physical activity using wrist worn accelerometers: The UK biobank study. *PLoS ONE*, 12(2), 1–14. <https://doi.org/10.1371/journal.pone.0169649>
- Donkin, L., Christensen, H., Naismith, S., Neal, B., Hickie, I., & Glozier, N. (2011). A Systematic Review of the Impact of Adherence on the Effectiveness of e-Therapies. *Journal of Medical Internet Research*, 13(3).
- Dusenbury, L., Brannigan, R., Falco, M., & Hansen, W. B. (2003). A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Education Research*, 18(2), 237–256.
- Eaton, L. H., Doorenbos, A. Z., Schmitz, K. L., Carpenter, K. M., & McGregor, B. A. (2011). Establishing Treatment Fidelity in a Web-Based Behavioral Intervention Study. *Nursing Research*, 60(6), 430.
- Ekers, D., Richards, D., McMillan, D., Bland, J. M., & Gilbody, S. (2011). Behavioural activation delivered by the non-specialist: phase II randomised controlled trial. *The British Journal of Psychiatry*, 198(1), 66–72.
- Ekers, D., Webster, L., Van Straten, A., Cuijpers, P., Richards, D., & Gilbody, S. (2014). Behavioural activation for depression; An update of meta-analysis of effectiveness and sub group analysis. *PLoS ONE*, 9(6).

- <https://doi.org/10.1371/journal.pone.0100100>
- Ekkekakis, P. (2015). Honey, I shrunk the pooled SMD! Guide to critical appraisal of systematic reviews and meta-analyses using the Cochrane review on exercise for depression as example. *Mental Health and Physical Activity*, 8, 21–36. <https://doi.org/10.1016/j.mhpa.2014.12.001>
- Ekkekakis, P., Hargreaves, E. A., & Parfitt, G. (2013). Invited Guest Editorial: Envisioning the next fifty years of research on the exercise-affect relationship. *Psychology of Sport and Exercise*, 14(5), 751–758. <https://doi.org/10.1016/j.psychsport.2013.04.007>
- Elliott, L. R., White, M. P., Taylor, A. H., & Abraham, C. (2016). How do brochures encourage walking in natural environments in the UK? A content analysis. *Health Promotion International*, 1–12. <https://doi.org/10.1093/heapro/daw083>
- Esliger, D., Rowlands, A., Hurst, T., Catt, M., Murray, P., & Eston, R. (2011). Validation of the GENE Accelerometer. *Medicine & Science in Sports & Exercise*, 43(6), 1088–1093.
- Euteneuer, F., Dannehl, K., Del Rey, A., Engler, H., Schedlowski, M., & Rief, W. (2017). Immunological effects of behavioral activation with exercise in major depression: an exploratory randomized controlled trial. *Translational Psychiatry*, 7(5), e1132. <https://doi.org/10.1038/tp.2017.76>
- Evans, J., Macrory, I., & Randall, C. (2016). *Measuring national well-being: Life in the UK*.
- Farmer, C. S., Farrand, P., & O'Mahen, H. (2012). "I am not a depressed person": How identity conflict affects help-seeking rates for major depressive disorder. *BMC Psychiatry*, 12(1), 164. <https://doi.org/10.1186/1471-244X-12-164>
- Farrand, P., Pentecost, C., Greaves, C., Taylor, R. S., Warren, F., Green, C., ... Taylor, A. H. (2014). A written self-help intervention for depressed adults comparing behavioural activation combined with physical activity promotion with a self-help intervention based upon behavioural activation alone: study protocol for a parallel group pilot randomised co. *Trials*, 15(1), 196. <https://doi.org/10.1186/1745-6215-15-196>

- Farrand, P., & Woodford, J. (2013). Impact of support on the effectiveness of written cognitive behavioural self-help: A systematic review and meta-analysis of randomised controlled trials. *Clinical Psychology Review, 33*(1), 182–195. <https://doi.org/10.1016/j.cpr.2012.11.001>
- Faulkner, G., & Biddle, S. (2001). Exercise and mental health: it's just not psychology!e. *Journal of Sports Sciences, 19*(6), 433–44.
- Faulkner, G., & Taylor, A. (2009). Promoting physical activity for mental health: A complex intervention? *Mental Health and Physical Activity, 2*(1), 1–3. <https://doi.org/http://dx.doi.org/10.1016/j.mhpa.2009.04.001>
- Faulkner, G., & Taylor, A. H. (2012). Translating theory and evidence into practice: What is the role of health professionals? *Mental Health and Physical Activity, 5*(1), 1–3. <https://doi.org/10.1016/j.mhpa.2012.04.002>
- Finning, K., Richards, D. A., Moore, L., Ekers, D., McMillan, D., Farrand, P. A., ... Wray, F. (2017). Cost and outcome of behavioural activation versus cognitive behavioural therapy for depression (COBRA): a qualitative process evaluation. *BMJ Open, 7*(4), e014161. <https://doi.org/10.1136/bmjopen-2016-014161>
- Fluharty, M., Taylor, A. E., Grabski, M., & Munafo, M. R. (2017). The association of cigarette smoking with depression and anxiety: A systematic review. *Nicotine and Tobacco Research, 19*(1), 3–13. <https://doi.org/10.1093/ntr/ntw140>
- Fortier, M. S., Duda, J. L., Guerin, E., & Teixeira, P. J. (2012). Promoting physical activity: development and testing of self-determination theory-based interventions. *International Journal of Behavioral Nutrition and Physical Activity, 9*(1), 20.
- Foster, C., Hillsdon, M., Thorogood, M., Kaur, A., & Wedatilake, T. (2009). Interventions for promoting physical activity. *The Cochrane Library*. [https://doi.org/DOI: 10.1002/14651858.CD003180.pub2](https://doi.org/DOI:10.1002/14651858.CD003180.pub2)
- Foster, C., Hillsdon, M., Thorogood, M., Kaur, A., & Wedatilake, T. (2012). Interventions for promoting physical activity (Review). *Cochrane Database of Systematic Reviews*. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003180.pub2/pdf/st>

andard

- Fournier, J. C., DeRubeis, R. J., Hollon, S. D., Dimidjian, S., Amsterdam, J. D., Shelton, R. C., & Fawcett, J. (2013). Antidepressant Drug effects and Depression Severity: A Patient- Level Meta-Analysis. *Jama*, *303*(1), 47–53. <https://doi.org/10.1001/jama.2009.1943.Antidepressant>
- Fox, K. R. (1999). The influence of physical activity on mental well-being. *Public Health Nutrition*, *2*(3A), 411–418. <https://doi.org/10.1017/S1368980099000567>
- Freeman, A., Tyrovolas, S., Koyanagi, A., Chatterji, S., Leonardi, M., Ayuso-Mateos, J. L., ... Haro, J. M. (2016). The role of socio-economic status in depression: results from the COURAGE (aging survey in Europe). *BMC Public Health*, *16*(1), 1098. <https://doi.org/10.1186/s12889-016-3638-0>
- Gearing, R. E., El-Bassel, N., Ghesquiere, A., Baldwin, S., Gillies, J., & Ngeow, E. (2011). Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. *Clinical Psychology Review*, *31*(1), 79–88. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=eoh&AN=22735089&site=ehost-live>
- Gelenberg, A. J., Laukes, C., McGahuey, C., Okayli, G., Moreno, F., Zentner, L., & Delgado, P. (2000). Mirtazapine substitution in SSRI-induced sexual dysfunction. *Journal of Clinical Psychiatry*.
- Gellatly, J., Bower, P., Hennessy, S., Richards, D., Gilbody, S., & Lovell, K. (2007). What makes self-help interventions effective in the management of depressive symptoms? Meta-analysis and meta-regression. *Psychological Medicine*, *37*(9), 1217–1228. <https://doi.org/10.1017/S0033291707000062>
- Gibala, M. J., Little, J. P., Macdonald, M. J., & Hawley, J. A. (2012). Physiological adaptations to low-volume, high-intensity interval training in health and disease. *The Journal Of Physiology*, *590*(Pt 5), 1077–1084. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=cmedm&AN=22289907&site=ehost-live>
- Gibson, K., Cartwright, C., & Read, J. (2016). “In my life antidepressants have

- been...”: a qualitative analysis of users’ diverse experiences with antidepressants. *BMC Psychiatry*, 16(1), 135.
<https://doi.org/10.1186/s12888-016-0844-3>
- Gotlib IH, J. J. (2010). Cognition and depression: current status and future directions. *Revista de Neurologia*, 27, 581–584.
<https://doi.org/10.1146/annurev.clinpsy.121208.131305>.Cognition
- Goyder, E., Hind, D., Breckon, J., Dimairo, M., Minton, J., Everson-Hock, E., ... Cooper, C. (2014). A randomised controlled trial and cost-effectiveness evaluation of “booster” interventions to sustain increases in physical activity in middle-aged adults in deprived urban neighbourhoods. *Health Technology Assessment*, 18(13), 1–209. <https://doi.org/10.3310/hta18130>
- Greaves, C. J., Sheppard, K. E., Abraham, C., Hardeman, W., Roden, M., Evans, P. H., & Schwarz, P. (2011). Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health*, 11(1), 119.
- Greaves, C. J., Sheppard, K. E., Abraham, C., Hardeman, W., Roden, M., Evans, P. H., & Schwarz, P. (2011). Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health*. C.J. Greaves, University of Exeter, Peninsula Medical School, Smeall Building, St Luke’s Campus, Magdalen Road, Exeter EX1 2LU, UK. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed13&NEWS=N&AN=362043557>
- Greaves, C. J., Wingham, J., Deighan, C., Doherty, P., Elliott, J., Armitage, W., ... Taylor, R. S. (2016). Optimising self-care support for people with heart failure and their caregivers: development of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention using intervention mapping. *Pilot and Feasibility Studies*, 2(1), 37.
<https://doi.org/10.1186/s40814-016-0075-x>
- Grist, R., & Cavanagh, K. (2013). Computerised cognitive behavioural therapy for common mental health disorders, what works, for whom under what circumstances? A systematic review and meta-analysis. *Journal of*

- Contemporary Psychotherapy*, 43(4), 243–251.
<https://doi.org/10.1007/s10879-013-9243-y>
- Haase, A. M., Taylor, A. H., Fox, K. R., Thorp, H., & Lewis, G. (2010). Rationale and development of the physical activity counselling intervention for a pragmatic TRial of Exercise and Depression in the UK (TREAD-UK). *Mental Health and Physical Activity*, 3(2), 85–91.
<https://doi.org/10.1016/j.mhpa.2010.09.004>
- Hankonen, N., Sutton, S., Prevost, A. T., Simmons, R. K., Griffin, S. J., Kinmonth, A. L., & Hardeman, W. (2014). Which Behavior Change Techniques are Associated with Changes in Physical Activity, Diet and Body Mass Index in People with Recently Diagnosed Diabetes? *Annals of Behavioral Medicine*, 1–11.
- Hans, E., & Hiller, W. (2013). Effectiveness of and dropout from outpatient cognitive behavioral therapy for adult unipolar depression: A meta-analysis of nonrandomized effectiveness studies. *Journal of Consulting and Clinical Psychology*, 81(1), 75–88.
<https://doi.org/10.1037/a0031080>.supp (Supplemental)
- Hardcastle, S. J., Fortier, M., Blake, N., & Hagger, M. S. (2016). Identifying content-based and relational techniques to change behaviour in motivational interviewing. *Health Psychology Review*, 7199(May), 1–16.
<https://doi.org/10.1080/17437199.2016.1190659>
- Hardeman, W., Michie, S., Fanshawe, T., Prevost, A. T., McLoughlin, K., & Kinmonth, A. L. (2008). Fidelity of delivery of a physical activity intervention: Predictors and consequences. *Psychology & Health*, 23(1), 11–24. Retrieved from
<http://search.ebscohost.com/login.aspx?direct=true&db=sph&AN=27639106&site=ehost-live>
- Harmer, C. J., Goodwin, G. M., & Cowen, P. J. (2009). Why do antidepressants take so long to work? A cognitive neuropsychological model of antidepressant drug action. *British Journal of Psychiatry*, 195(2), 102–108.
<https://doi.org/10.1192/bjp.bp.108.051193>
- Hartmann-Boyce, J., Aveyard, P., Koshiaris, C., & Jebb, S. A. (2016).

- Development of tools to study personal weight control strategies: OxFAB taxonomy. *Obesity*, 24(2), 314–320. <https://doi.org/10.1002/oby.21341>
- Harvey, S. B., Øverland, S., Hatch, S. L., Wessely, S., Psych, F. R. C., Mykletun, A., & Hotopf, M. (2017). Exercise and the Prevention of Depression: Results of the HUNT Cohort Study. *American Journal of Psychiatry*. <https://doi.org/10.1176/appi.ajp.2017.16111223>
- Heim, C., & Binder, E. B. (2012). Current research trends in early life stress and depression: Review of human studies on sensitive periods, gene-environment interactions, and epigenetics. *Experimental Neurology*, 233(1), 102–111. <https://doi.org/10.1016/j.expneurol.2011.10.032>
- Helgadóttir, B., Forsell, Y., & Ekblom, Ö. (2015). Physical Activity Patterns of People Affected by Depressive and Anxiety Disorders as Measured by Accelerometers: A Cross-Sectional Study. *Plos One*, 10(1), e0115894. <https://doi.org/10.1371/journal.pone.0115894>
- Helgadottir, B., Owen, N., Dunstan, D. W., Ekblom, O., Hallgren, M., & Forsell, Y. (2017). Changes in physical activity and sedentary behavior associated with an exercise intervention in depressed adults. *Psychology of Sport and Exercise*, 30, 10–18. <https://doi.org/10.1016/j.psychsport.2017.01.006>
- Helmrich, S., Ragland, D., Leung, R., & Paffenbarger, R. (1991). Physical activity and reduced occurrence of non-insulin-dependant diabetes mellitus. *New England Journal of Medicine*, 325(3), 147.
- Higgins, J. P. T., Altman, D. G., Gotzsche, P. C., Juni, P., Moher, D., Oxman, a. D., ... Sterne, J. a. C. (2011). The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *Bmj*, 343(oct18 2), d5928–d5928. <https://doi.org/10.1136/bmj.d5928>
- Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., ... Michie, S. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ (Clinical Research Ed.)*, 348(March), g1687. <https://doi.org/10.1136/bmj.g1687>
- Hofmann, S. G., Asnaani, A., Vonk, I. J. J., Sawyer, A. T., & Fang, A. (2012). The efficacy of cognitive behavioral therapy: a review of meta-analyses.

- Cognitive Therapy Research*, 36(5), 427–440.
<https://doi.org/10.1007/s10608-012-9476-1>.The
- Hopko, D. R., Lejuez, C. W., Ruggiero, K. J., & Eifert, G. H. (2003). Contemporary behavioral activation treatments for depression: Procedures, principles, and progress. *Clinical Psychology Review*, 23(5), 699–717.
[https://doi.org/10.1016/S0272-7358\(03\)00070-9](https://doi.org/10.1016/S0272-7358(03)00070-9)
- Imel, Z. E., Georgiou, P., Atkins, D., & Narayanan, S. (2016). Computational Analysis and Simulation of Empathic Behaviors: A Survey of Empathy Modeling with Behavioral Signal Processing Framework. *Current Psychiatry Reports*, 17(7), 796–808. <https://doi.org/10.1038/nm.2399>.The
- Imel, Z. E., Malterer, M. B., McKay, K. M., & Wampold, B. E. (2008). A meta-analysis of psychotherapy and medication in unipolar depression and dysthymia. *Journal of Affective Disorders*, 110(3), 197–206.
<https://doi.org/10.1016/j.jad.2008.03.018>
- Jacobson, N. S., Martell, C. R., & Dimidjian, S. (2001). Behavioral Activation Treatment for Depression: Returning to Contextual Roots. *Clinical Psychology: Science and Practice*, 8(3), 255–270.
<https://doi.org/10.1093/clipsy.8.3.255>
- Joseph, R., Durant, N., Benitez, T., & Pekmezi, D. (2014). Internet-Based Physical Activity Interventions. *American Journal of Lifestyle Medicine*, 8(1), 1–26. <https://doi.org/10.1177/1559827613498059>.Internet-Based
- Karyotaki, E., Kleiboer, a., Smit, F., Turner, D. T., Pastor, a. M., Andersson, G., ... Cuijpers, P. (2015). Predictors of treatment dropout in self-guided web-based interventions for depression: an “individual patient data” meta-analysis. *Psychological Medicine*, 45(13), 2717–2726.
<https://doi.org/10.1017/S0033291715000665>
- Kelders, S., Kok, R., Ossebaard, H., & van Gemert-Pijnen, J. E. W. C. (2012). Persuasive System Design Does Matter: A Systematic Review of Adherence to Web-Based Interventions. *Journal of Medical Internet Research*, 14(6).
- Kelders, S. M., Pots, W. T. M., Oskam, M. J., Bohlmeijer, E. T., & van Gemert-Pijnen, J. E. W. C. (2013). Development of a web-based intervention for the

- indicated prevention of depression. *BMC Medical Informatics and Decision Making*, 13(1), 26. <https://doi.org/10.1186/1472-6947-13-26>
- Keller, C., Fleury, J., Sidani, S., Ainsworth, B., C., K., J., F., & S., S. (2009). Fidelity to theory in PA intervention research. (B. Anshel Baranowski, Baranowski, Baranowski, Baranowski, Becker, Bellg, Blissmer, Blue, Bock, Brawley, Brug, Conn, Conn, Conn, Conn, Conn, Fahrenwald, Griffin-Blake, Hallam, Kahn, Keele-Smith, King, Marshall, Marshall, Michie, Nigg, Noar, Pinto, Pinto, Plo, Ed.), *Western Journal of Nursing Research*. Keller, Colleen, colleen.keller@asu.edu: Sage Publications. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed12&N EWS=N&AN=354277311>
- Kendler, K. S., Karkowski, L. M., & Prescott, C. A. (1999). Causal relationship between stressful life events and the onset of major depression. *American Journal of Psychiatry*, 156(6), 837–841. <https://doi.org/10.1176/ajp.156.6.837>
- Kessler, R., Berglund, P., Demler, O., Jin, R., Koretz, D., Merikangas, K., ... Wang. (2003). The Epidemiology of Major Depressive Disorder. *Jama*, 2003(23), 186–187.
- Kinmonth, A. L., Wareham, N. J., Hardeman, W., Sutton, S., Prevost, A. T., Fanshawe, T., ... Griffin, S. J. (2008). Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial. *The Lancet*, 371(9606), 41–48. [https://doi.org/10.1016/S0140-6736\(08\)60070-7](https://doi.org/10.1016/S0140-6736(08)60070-7)
- Kinsella, M. T., & Monk, C. (2009). Impact of Maternal Stress, Depression & Anxiety on Fetal Neurobehavioral Development. *Clinical Obstetrics and Gynecology*, 52(3), 425–440. <https://doi.org/10.1097/GRF.0b013e3181b52df1>.Impact
- Kirsch, I., Deacon, B. J., Huedo-Medina, T. B., Scoboria, A., Moore, T. J., & Johnson, B. T. (2008). Initial severity and antidepressant benefits: A meta-analysis of data submitted to the food and drug administration. *PLoS Medicine*, 5(2), 0260–0268. <https://doi.org/10.1371/journal.pmed.0050045>
- Knekt, P., Lindfors, O., Sares-Jäske, L., & Laaksonen, M. (2012). [The

- effectiveness of psychotherapy on depression in the long term]. *Duodecim; Lääketieteellinen Aikakauskirja*, 128(3), 267–274. Retrieved from <http://search.ebscohost.com/login.aspx?direct=true&db=cmedm&AN=22428380&site=ehost-live>
- Kohn, R., Saxena, S., Levav, I., & Saraceno, B. (2004). The treatment gap in mental health care 2004. *Bulletin of the World Health Organization*, 82(3), 858–866. <https://doi.org/S0042-96862004001100011>
- Kok, G., Schaalma, H., Ruiters, R. A. C., Van Empelen, P., & Brug, J. (2004). Intervention mapping: protocol for applying health psychology theory to prevention programmes. *Journal of Health Psychology*, 9(1), 85–98.
- Kolt, G. S., Oliver, M., Schofield, G. M., Kerse, N., Garrett, N., Latham, Nick; ORCID: <http://orcid.org/0000-0001-9289-9743>, Latham, Nancy K.; ORCID: <http://orcid.org/0000-0002-8516-0016>, N. K. A. I.-O. <http://orcid.org/Garret>, ... N., G. (2006). An overview and process evaluation of Tele Walk: A telephone-based counseling intervention to encourage walking in older adults. (A. Adams Ashworth, Ball, Beck, Britt, Castro, Conn, DiPietro, Elley, Humpel, Jackson, Kerse, King, King, Marcus, Marshall, Miller, Prochaska, Stewart, Taylor, van der Bij, Ware, Zimmerman, Ed.), *Health Promotion International*. G.S. Kolt, Centre for Physical Activity and Nutrition Research, Faculty of Health and Environmental Sciences, Auckland University of Technology, Private Bag 92006, Auckland 1020, New Zealand. E-mail: gregory.kolt@aut.ac.nz: Oxford University Press. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed10&N=EWS=N&AN=44306051>
- Kroenke, K., & Spitzer, R. L. (2002). The PHQ-9: A New Depression Diagnostic and Severity Measure. *Psychiatric Annals*, 32(9), 509–515. <https://doi.org/10.3928/0048-5713-20020901-06>
- Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine*, 16(9), 606–613. <https://doi.org/10.1046/j.1525-1497.2001.016009606.x>
- Kroenke, K., Strine, T. W., Spitzer, R. L., Williams, J. B. W., Berry, J. T., &

- Mokdad, A. H. (2009). The PHQ-8 as a measure of current depression in the general population. *Journal of Affective Disorders*, 114(1–3), 163–173. <https://doi.org/10.1016/j.jad.2008.06.026>
- Lambert, J. D., Greaves, C. J., Farrand, P., Cross, R., Haase, A. M., & Taylor, A. H. (2017). Assessment of fidelity in individual level behaviour change interventions promoting physical activity among adults: a systematic review. *BMC Public Health*, 17(1), 765. <https://doi.org/10.1186/s12889-017-4778-6>
- Lambert, K. G. (2006). Rising rates of depression in today's society: Consideration of the roles of effort-based rewards and enhanced resilience in day-to-day functioning. *Neuroscience and Biobehavioral Reviews*, 30(4), 497–510. <https://doi.org/10.1016/j.neubiorev.2005.09.002>
- Landis, J. R., & Koch, G. G. (2008). The Measurement of Observer Agreement for Categorical Data Published by : International Biometric Society Stable URL : <http://www.jstor.org/stable/2529310>. *Society*, 33(1), 159–174. <https://doi.org/10.2307/2529310>
- Lee, P. H., Macfarlane, D. J., Lam, T., & Stewart, S. M. (2011). Validity of the international physical activity questionnaire short form (IPAQ-SF): A systematic review. *International Journal of Behavioral Nutrition and Physical Activity*, 8(1), 115. <https://doi.org/10.1186/1479-5868-8-115>
- Lejuez, C. W., Hopko, D. R. , & Hopko, S. D. (2001). A Brief Behavioral Activation. *Behavior Modification*, 25(2), 255–286.
- Leslie, E., Marshall, A. L., Owen, N., & Bauman, A. (2005). Engagement and retention of participants in a physical activity website. *Preventive Medicine*, 40(1), 54–59. <https://doi.org/10.1016/j.ypmed.2004.05.002>
- Levy, S. S., & Cardinal, B. J. (2004). Effects of a Self-determination Theory-based Mail-mediated Intervention on Adults' Exercise Behavior. (D. Baron Fox, Godin, Ingledew, Li, Marcus, Markland, Markland, Ryan, Ryan, Sallis, Ed.), *American Journal of Health Promotion*. Levy, Susan S.: Department of Exercise and Nutritional Sciences, San Diego State University, 5500 Campanile Dr, San Diego, CA, US, 92182-7251, slevy@mail.sdsu.edu: American Journal of Health Promotion. Retrieved from

- <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc4&NEWS=N&AN=2004-95170-003>
- Leydon, G. M., Rodgers, L., & Kendrick, T. (2007). A qualitative study of patient views on discontinuing long-term selective serotonin reuptake inhibitors. *Family Practice, 24*(6), 570–575. <https://doi.org/10.1093/fampra/cmm069>
- Lloyd, J. J., Logan, S., Greaves, C., & Wyatt, K. (2011). Evidence, theory and context - using intervention mapping to develop a school-based intervention to prevent obesity in children. *International Journal of Behavioral Nutrition and Physical Activity, 8*, 1–15. <https://doi.org/10.1186/1479-5868-8-73>
- Lorencatto, F., Gould, N. J., McIntyre, S. A., During, C., Bird, J., Walwyn, R., ... Francis, J. J. (2016). A multidimensional approach to assessing intervention fidelity in a process evaluation of audit and feedback interventions to reduce unnecessary blood transfusions: a study protocol. *Implementation Science, 11*(1), 163. <https://doi.org/10.1186/s13012-016-0528-x>
- Ly, K. H., Janni, E., Wrede, R., Sedem, M., Donker, T., Carlbring, P., & Andersson, G. (2015). Experiences of a guided smartphone-based behavioral activation therapy for depression: A qualitative study. *Internet Interventions, 2*(1), 60–68. <https://doi.org/10.1016/j.invent.2014.12.002>
- Ly, K. H., Trüschel, A., Jarl, L., Magnusson, S., Windahl, T., Johansson, R., ... Andersson, G. (2014). Behavioural activation versus mindfulness-based guided self-help treatment administered through a smartphone application: a randomised controlled trial. *BMJ Open, 4*(1), e003440. <https://doi.org/10.1136/bmjopen-2013-003440>
- Maguire, M. (2001). Methods to support human-centred design. *International Journal of Human-Computer Studies, 55*(4), 587–634. <https://doi.org/10.1006/ijhc.2001.0503>
- Maher, C. A., Lewis, L. K., Ferrar, K., Marshall, S., De Bourdeaudhuij, I., Vandelanotte, C., ... I., D. B. (2014). Are health behavior change interventions that use online social networks effective? A systematic review. *Journal of Medical Internet Research, 16*(2), e40. Retrieved from

- <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed16&NEWS=N&AN=373968897>
- Mailey, E. L., Wójcicki, T. R., Motl, R. W., Hu, L., Strauser, D. R., Collins, K. D., & McAuley, E. (2010). Internet-delivered physical activity intervention for college students with mental health disorders: a randomized pilot trial. *Psychology, Health & Medicine, 15*(6), 646–659. <https://doi.org/10.1080/13548506.2010.498894>
- Malhi, G. S., Moore, J., & McGuffin, P. (2000). The genetics of major depressive disorder. *Current Psychiatry Reports, 2*(2), 165–9. <https://doi.org/10.1007/s11920-010-0150-6>.Overview
- Mars, T., Ellard, D., Carnes, D., Homer, K., Underwood, M., & Taylor, S. J. C. (2013). Fidelity in complex behaviour change interventions: a standardised approach to evaluate intervention integrity. *BMJ Open, 3*(11), e003555.
- Marshall, A. L., Leslie, E. R., Bauman, A. E., Marcus, B. H., & Owen, N. (2003). Print versus website physical activity programs: A randomized trial. *American Journal of Preventive Medicine, 25*(2), 88–94. [https://doi.org/10.1016/S0749-3797\(03\)00111-9](https://doi.org/10.1016/S0749-3797(03)00111-9)
- Maynard, B. R., Peters, K. E., Vaughn, M. G., & Sarteschi, C. M. (2013). Fidelity in After-School Program Intervention Research: A Systematic Review. *Research on Social Work Practice, 23*(6), 613–623. <https://doi.org/10.1177/1049731513491150>
- McCarthy, M. M., Dickson, V. V., Katz, S. D., Sciacca, K., & Chyun, D. A. (2015). Process evaluation of an exercise counseling intervention using motivational interviewing. *Applied Nursing Research : ANR, 28*(2), 156–162. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=25448059>
- McHugh, J. E., & Lawlor, B. A. (2012). Exercise and social support are associated with psychological distress outcomes in a population of community-dwelling older adults. *Journal of Health Psychology, 17*(6), 833–844. <https://doi.org/10.1177/1359105311423861>
- McHugh, R., & Whitton, S. (2013). Patient Preference for Psychological vs.

- Pharmacological Treatment of Psychiatric Disorders: A Meta-Analytic Review. ... *of Clinical Psychiatry*, 74(6), 595–602.
<https://doi.org/10.4088/JCP.12r07757.Patient>
- Mead, G. E., Morley, W., Campbell, P., Greig, C. A., McMurdo, M., & Lawlor, D. A. (2009). Exercise for depression. *Cochrane Database Syst Rev*, 3.
- Meeusen, R., & De Meirleir, D. (1995). Exercise and brain neurotransmission. *Sports Medicine*, 20(3), 160–188.
- Michie, S., Ashford, S., Sniehotta, F. F., Dombrowski, S. U., Bishop, A., & French, D. P. (2011). A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychol Health*, 26(11), 1479–1498.
<https://doi.org/938640058> [pii]10.1080/08870446.2010.540664
- Michie, S., Richardson, M., Johnston, M., Abraham, C., Francis, J., Hardeman, W., ... Wood, C. E. (2013). The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals of Behavioral Medicine*, 46(1), 81–95.
- Michie, S., van Stralen, M. M., West, R., Grimshaw, J., Shirran, L., Thomas, R., ... Preston, A. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science*, 6(1), 42. <https://doi.org/10.1186/1748-5908-6-42>
- MIND. (2013). *We still need to talk: A report on access to talking therapies*.
- Moncher, F. J., & Prinz, R. J. (1991). Treatment fidelity in outcome studies. *Clinical Psychology Review*, 11(3), 247–266.
[https://doi.org/http://dx.doi.org/10.1016/0272-7358\(91\)90103-2](https://doi.org/http://dx.doi.org/10.1016/0272-7358(91)90103-2)
- Moore, G., Audrey, S., Barker, M., Bond, L., Bonell, C., Cooper, C., ... Tinati, T. (2014). Process evaluation in complex public health intervention studies: the need for guidance. *Journal of Epidemiology and Community Health*, 68(2), 101–102.
- Moore, G., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., ... Baird, J. (2015). Process evaluation of complex interventions: Medical

- Research Council guidance. *British Medical Journal*, 350(Mar19 6), h1258–h1258. <https://doi.org/10.1136/bmj.h1258>
- Moore, G. F., Raisanen, L., Moore, L., Din, N. U., & Murphy, S. (2013). Mixed-method process evaluation of the Welsh National Exercise Referral Scheme. *Health Education*, 113(Braun, V., Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3, 77–101. <http://dx.doi.org/10.1191/1478088706qp063oa>), 476–501. <https://doi.org/10.1108/HE-08-2012-0046>
- Moret, C., & Briley, M. (2011). The importance of norepinephrine in depression. *Neuropsychiatric Disease and Treatment*, 7(SUPPL.), 9–13. <https://doi.org/10.2147/NDT.S19619>
- Moussavi, S., Chatterji, S., Verdes, E., Tandon, A., Patel, V., & Ustun, B. (2007). Depression, chronic diseases, and decrements in health: results from the World Health Surveys. *Lancet*, 370(9590), 851–858. [https://doi.org/10.1016/S0140-6736\(07\)61415-9](https://doi.org/10.1016/S0140-6736(07)61415-9)
- Moyers, T. B., Martin, T., Manuel, J. K., Hendrickson, S. M. L., & Miller, W. R. (2005). Assessing competence in the use of motivational interviewing. *Journal of Substance Abuse Treatment*, 28(1), 19–26. <https://doi.org/10.1016/j.jsat.2004.11.001>
- Moyers, T. B., & Miller, W. R. (2013). Is Low Therapy Empathy Toxic? *Psycho Addict Behav*, 27(3), 878–884. <https://doi.org/10.1037/a0030274>.Is
- Mueller, T. I., Leon, A. C., Keller, M. B., Solomon, D. A., Endicott, J., Coryell, W., ... Maser, J. D. (1999). Recurrence after recovery from major depressive disorder during 15 years of o ... *Am J Psychiatry*, 156(7), 1000–1006. <https://doi.org/10.1176/ajp.156.7.1000>
- Muller, I., Rowsell, A., Stuart, B., Hayter, V., Little, P., Ganahl, K., ... Yardley, L. (2017). Effects on Engagement and Health Literacy Outcomes of Web-Based Materials Promoting Physical Activity in People With Diabetes: An International Randomized Trial. *Journal of Medical Internet Research*, 19(1).
- Musiat, P., & Tarrrier, N. (2014). Collateral outcomes in e-mental health: a systematic review of the evidence for added benefits of computerized

- cognitive behavior therapy interventions for mental health. *Psychological Medicine*, 44(15), 3137–3150. <https://doi.org/10.1017/S0033291714000245>
- Nestler, E. J., Barrot, M., DiLeone, R. J., Eisch, A. J., Gold, S. J., & Monteggia, L. M. (2002). Neurobiology of depression. *Neuron*, 34(1), 13–25. [https://doi.org/10.1016/S0896-6273\(02\)00653-0](https://doi.org/10.1016/S0896-6273(02)00653-0)
- NHS Digital. (2016a). *Prescriptions Dispensed in the Community, Statistics for England - 2005-2015 [NS]*. Retrieved from <http://content.digital.nhs.uk/catalogue/PUB20664>
- NHS Digital. (2016b). *Psychological Therapies: Annual report on the use of IAPT services England 2015-16*.
- Nice. (2009). Depression in adults, (April 2007), 67. Retrieved from guidance.nice.org.uk/cg90
- NICE. (2009). *Treating depression in adults*.
- NICE. (2014). Behaviour change : individual approaches, (January), 1–14.
- Nutt, D. (2008). Relationship of Neurotransmitters to the Symptoms of Major Depressive Disorder. *Journal of Clinical Psychiatry*, 69.
- Nyström, M. B. T., Neely, G., & Hassmén, P. (2015). Treating Major Depression with Physical Activity : A Systematic Overview with Recommendations, (March), 37–41. <https://doi.org/10.1080/16506073.2015.1015440>
- Nyström, M. B. T., Stenling, A., Sjöström, E., Neely, G., Lindner, P., Hassmén, P., ... Carlbring, P. (2017). Behavioral Activation versus Physical Activity via the Internet: A Randomized Controlled Trial. *Journal of Affective Disorders*. <https://doi.org/10.1016/j.jad.2017.03.018>
- O’Cathain, A., Murphy, E., & Nicholl, J. (2010). Three techniques for integrating data in mixed methods studies. *BMJ*, 341(4587).
- Oliver, M. I., Pearson, N., Coe, N., & Gunnell, D. (2005). Help-seeking behaviour in men and women with common mental health problems, (Table 1), 297–301.
- Onyike, C. U., Crum, R. M., Lee, H. B., Lyketsos, C. G., & Eaton, W. W. (2003). Is obesity associated with major depression? Results from the Third

- National Health and Nutrition Examination Survey. *American Journal of Epidemiology*, 158(12), 1139–1147.
- Opbroek, A., Delgado, P. L., Laukes, C., McGahuey, C., Katsanis, J., Moreno, F. A., & Manber, R. (2002). Emotional blunting associated with SSRI-induced sexual dysfunction. Do SSRIs inhibit emotional responses? *The International Journal of Neuropsychopharmacology*, 5(2), 147–151.
- Orrow, G., Kinmonth, A.-L., Sanderson, S., & Sutton, S. (2012). Effectiveness of physical activity promotion based in primary care: systematic review and meta-analysis of randomised controlled trials. *BMJ*, 344.
- Ottenbreit, N. D., & Dobson, K. S. (2004). Avoidance and depression: The construction of the Cognitive-Behavioral Avoidance Scale. *Behaviour Research and Therapy*, 42(3), 293–313. [https://doi.org/10.1016/S0005-7967\(03\)00140-2](https://doi.org/10.1016/S0005-7967(03)00140-2)
- P., H., M.A., W., C., M., J., Lord, S., D., E., W., ... M., U. (2013). Sarah: Strengthening and stretching for people with rheumatoid arthritis of the hands: A randomised controlled trial. *Annals of the Rheumatic Diseases*. P. Heine, Clinical Trials Unit, University of Warwick, Coventry, United Kingdom: BMJ Publishing Group. Retrieved from http://ard.bmj.com/content/72/Suppl_3/A83.2.abstract?sid=c8b06ab6-9d94-4eb4-8d12-1c40e5d78540
- Park, S., Cho, M. J., Cho, S.-J., Bae, J. N., Lee, J.-Y., Park, J. I., ... Hong, J. P. (2011). Relationship between physical activity and mental health in a nationwide sample of Korean adults. *Psychosomatics*, 52(1), 65–73. <https://doi.org/10.1016/j.psych.2010.11.017>
- Park, S. H., Han, K. S., & Kang, C. B. (2014). Effects of exercise programs on depressive symptoms, quality of life, and self-esteem in older people: A systematic review of randomized controlled trials. *Applied Nursing Research*, 27(4), 219–226. <https://doi.org/10.1016/j.apnr.2014.01.004>
- Pentecost, C., Farrand, P., Greaves, C. J., Taylor, R. S., Warren, F. C., Hillsdon, M., ... Taylor, A. H. (2015). Combining behavioural activation with physical activity promotion for adults with depression: findings of a parallel-group pilot randomised controlled trial (BACPAc). *Trials*, 16(1), 367.

<https://doi.org/10.1186/s13063-015-0881-0>

- Peppone, L. J., Janelins, M. C., Kamen, C., Mohile, S. G., Sprod, L. K., Gewandter, J. S., ... Mustian, K. M. (2015). The effect of YOCAS© yoga for musculoskeletal symptoms among breast cancer survivors on hormonal therapy. *Breast Cancer Research and Treatment*, *150*(3), 597–604. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medc&NEWS=N&AN=25814054>
- Perepletchikova, F., & Kazdin, A. E. (2005). Treatment integrity and therapeutic change: Issues and research recommendations. *Clinical Psychology: Science and Practice*, *12*(4), 365–383. <https://doi.org/10.1093/clipsy/bpi045>
- Perski, O., Blandford, A., West, R., & Michie, S. (2016). Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis. *Translational Behavioral Medicine*, 1–14. <https://doi.org/10.1007/s13142-016-0453-1>
- Pinto, B. M., Goldstein, M. G., DePue, J. D., & Milan, F. B. (1998). Acceptability and feasibility of physician-based activity counseling. The PAL project. *American Journal of Preventive Medicine*, *15*(2), 95–102. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med4&NEWS=N&AN=9713664>
- Podsakoff, P. M., MacKenzie, S. B., Lee, J.-Y., & Podsakoff, N. P. (2003). Common method biases in behavioral research: a critical review of the literature and recommended remedies. *The Journal of Applied Psychology*, *88*(5), 879–903. <https://doi.org/10.1037/0021-9010.88.5.879>
- Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M., ... Duffy, S. (2006). Guidance on the conduct of narrative synthesis in systematic reviews. *A Product from the ESRC Methods Programme. Version, 1.*
- Prochaska, J., & Velicer, W. (1997). The transtheoretical model of health behavior change. *American Journal of Health Promotion*, *12*(1), 38–48.
- Puterman, E., O'Donovan, A., Adler, N., Tomiyama, A., Kemeny, M., Wolkowitz, O., & Epel, E. (2012). Physical activity moderates stressor-induced

- rumination on cortisol reactivity. *Psychosom Med*, 73(7), 604–611.
<https://doi.org/10.1097/PSY.0b013e318229e1e0>.Physical
- Quested, E., Ntoumanis, N., Thøgersen-Ntoumani, C., Hagger, M. S., & Hancox, J. E. (2017). Evaluating quality of implementation in physical activity interventions based on theories of motivation: Current challenges and future directions. *International Review of Sport and Exercise Psychology*, 10(January), 252–269.
<https://doi.org/10.1080/1750984X.2016.1217342>
- Quinn, L., Trubey, R., Gobat, N., Dawes, H., Edwards, R. T., Jones, C., ... Busse, M. (2016). Development and Delivery of a Physical Activity Intervention for People With Huntington Disease: Facilitating Translation to Clinical Practice. *Journal of Neurologic Physical Therapy: JNPT*, 40(2), 71–80. Retrieved from
<http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=26863152>
- Raison, C. L., & Miller, A. H. (2012). NIH Public Access, 13(6), 467–475.
<https://doi.org/10.1007/s11920-011-0232-0>.Is
- Razykov, I., Ziegelstein, R. C., Whooley, M. A., & Thombs, B. D. (2012). The PHQ-9 versus the PHQ-8 - Is item 9 useful for assessing suicide risk in coronary artery disease patients? Data from the Heart and Soul Study. *Journal of Psychosomatic Research*, 73(3), 163–168.
<https://doi.org/10.1016/j.jpsychores.2012.06.001>
- Rebar, A. L., Stanton, R., Geard, D., Short, C., Duncan, M. J., & Vandelanotte, C. (2015). A meta-meta-analysis of the effect of physical activity on depression and anxiety in non-clinical adult populations. *Health Psychology Review*, 9(3), 366–378. <https://doi.org/10.1080/17437199.2015.1022901>
- Renton, T., Tang, H., Ennis, N., Cusimano, M., Bhalerao, S., Schweizer, T., & Topolovec-Vranic. (2014). Web-Based Intervention Programs for Depression: A Scoping Review and Evaluation. *Journal of Medical Internet Research*, 16(9).
- Resnick, B. A. J. B. B. C. R. J. D. L. L. C. D. D. G. S. (2005). Examples of Implementation and Evaluation of Treatment Fidelity in the BCC Studies:

- Where We Are and Where We Need to Go. *Annals of Behavioral Medicine*, 29, 46–54. https://doi.org/10.1207/s15324796abm2902s_8
- Rhodes, S., Richards, D. a, Ekers, D., McMillan, D., Byford, S., Farrand, P. a, ... Wright, K. a. (2014). Cost and outcome of behavioural activation versus cognitive behaviour therapy for depression (COBRA): study protocol for a randomised controlled trial. *Trials*, 15, 29. <https://doi.org/10.1186/1745-6215-15-29>
- Richards, D. (2010). *Behavioural Activation*. (J. Bennett-Levy, D. Richards, P. Farrand, H. Christensen, K. Griffiths, D. Kavanagh, ... C. Williams, Eds.), *Oxford guide to low intensity CBT interventions*. Oxford: Oxford University Press.
- Richards, D. A., Ekers, D., McMillan, D., Taylor, R. S., Byford, S., Warren, F. C., ... Finning, K. (2016). Cost and Outcome of Behavioural Activation versus Cognitive Behavioural Therapy for Depression (COBRA): a randomised, controlled, non-inferiority trial. *The Lancet*, 388(10047), 871–880. [https://doi.org/10.1016/S0140-6736\(16\)31140-0](https://doi.org/10.1016/S0140-6736(16)31140-0)
- Richards, D., & Richardson, T. (2012). Computer-based psychological treatments for depression: A systematic review and meta-analysis. *Clinical Psychology Review*, 32(4), 329–342. <https://doi.org/10.1016/j.cpr.2012.02.004>
- Richards, J., Hillsdon, M., Thorogood, M., & Foster, C. (2013). Face-to-face interventions for promoting physical activity (Review) SUMMARY OF FINDINGS FOR THE MAIN COMPARISON, (9).
- Roiser, J. P., Elliott, R., & Sahakian, B. J. (2012). Cognitive mechanisms of treatment in depression. *Neuropsychopharmacology : Official Publication of the American College of Neuropsychopharmacology*, 37(1), 117–36. <https://doi.org/10.1038/npp.2011.183>
- Rosenbaum, S., Newby, J. M., Steel, Z., Andrews, G., & Ward, P. B. (2015). Online physical activity interventions for mental disorders: A systematic review. *Internet Interventions*, 2(2), 214–220. <https://doi.org/10.1016/j.invent.2015.04.001>
- Rowell, A., Muller, I., Murray, E., Little, P., Byrne, C., Ganahl, K., ... Yardley, L.

- (2015). Views of People With High and Low Levels of Health Literacy About a Digital Intervention to Promote Physical Activity for Diabetes: A Qualitative Study in Five Countries. *Journal of Medical Internet Research*, 17(10).
- Rugulies, R. (2002). Depression as a Predictor for Coronary Heart Disease A Review and Meta-Analysis. *American Journal of Preventive Medicine*, 23(1), 305–311.
- Ryan, C., Bergin, M., & Wells, J. S. (2017). Theoretical Perspectives of Adherence to Web-Based Interventions: a Scoping Review. *International Journal of Behavioral Medicine*. <https://doi.org/10.1007/s12529-017-9678-8>
- Ryan, R. M., & Deci, E. L. (2000). Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American Psychologist*, 55(1), 68.
- Schinckus, L., Van den Broucke, S., & Housiaux, M. (2014). Assessment of implementation fidelity in diabetes self-management education programs: A systematic review. *Patient Education and Counseling*, 96(1), 13–21. <https://doi.org/10.1016/j.pec.2014.04.002>
- Schoenwald, S. K., & Garland, A. F. (2013). A Review of Treatment Adherence Measurement Methods. *Psychological Assessment*, 25(1), 146–156. <https://doi.org/10.1037/a0029715.A>
- Schoenwald, S. K., Garland, A. F., Chapman, J. E., Frazier, S. L., & Sheidow, A. J. (2012). NIH Public Access, 38(1), 32–43. <https://doi.org/10.1007/s10488-010-0321-0.Toward>
- Schuch, F. B., Vancampfort, D., Richards, J., Rosenbaum, S., Ward, P. B., & Stubbs, B. (2016). Exercise as a treatment for depression: A meta-analysis adjusting for publication bias. *Journal of Psychiatric Research*, 77, 42–51. <https://doi.org/10.1016/j.jpsychires.2016.02.023>
- Schulberg, H. C., Raue, P. J., & Rollman, B. L. (2002). The effectiveness of psychotherapy in treating depressive disorders in primary care practice: clinical and cost perspectives. *General Hospital Psychiatry*, 24(4), 203–212. [https://doi.org/10.1016/s0163-8343\(02\)00175-5](https://doi.org/10.1016/s0163-8343(02)00175-5)

- Searle, A., Calnan, M., Lewis, G., Campbell, J., Taylor, A., & Turner, K. (2011). Patients' views of physical activity as treatment for depression: A qualitative study. *British Journal of General Practice*, *61*(585), 149–156. <https://doi.org/10.3399/bjgp11X567054>
- Searle, A., Calnan, M., Turner, K. M., Lawlor, D. A., Campbell, J., Chalder, M., & Lewis, G. (2012). General practitioners' beliefs about physical activity for managing depression in primary care. *Mental Health and Physical Activity*, *5*(1), 13–19. <https://doi.org/10.1016/j.mhpa.2011.11.001>
- Searle, A., Haase, A., Chalder, M., Fox, K. R., Taylor, A., Lewis, G., & Turner, K. (2014). Participants' experiences of facilitated physical activity for the management of depression in primary care. *Journal of Health Psychology*, *19*(11), 1430–1442. <https://doi.org/10.1177/1359105313493648>
- Sharma, T., Guski, L. S., Freund, N., & Gøtzsche, P. C. (2016). Suicidality and aggression during antidepressant treatment: systematic review and meta-analyses based on clinical study reports. *BMJ (Clinical Research Ed.)*, *352*, i65. <https://doi.org/10.1136/bmj.i65>
- Shea, O. O., McCormick, R., Bradley, J. M., Neill, B. O., Shea, O. O., McCormick, R., ... Neill, B. O. (2016). Fidelity review: a scoping review of the methods used to evaluate treatment fidelity in behavioural change interventions. *Physical Therapy Reviews*, *3196*(February 2017), 1–8. <https://doi.org/10.1080/10833196.2016.1261237>
- Sheeran, P. (2002). Intention — Behavior Relations : A Conceptual and Empirical Review Intention-Behavior Relations : A Conceptual and Empirical Review. *European Review of Social Psychology*, *12*(1), 1–36. <https://doi.org/10.1080/14792772143000003>
- Sniehotta, F. F. (2009). Towards a theory of intentional behaviour change: plans, planning, and self-regulation. *British Journal of Health Psychology*, *14*(2), 261–73.
- Soetens, K. C. M., Vandelanotte, C., de Vries, H., & Mummery, K. W. (2014). Using online computer tailoring to promote physical activity: a randomized trial of text, video, and combined intervention delivery modes. *Journal of Health Communication*, *19*(12), 1377–1392. Retrieved from

<http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=24749983>

- Soucy, I., Provencher, M., Fortier, M., & McFadden, T. (2017). Efficacy of guided self-help behavioural activation and physical activity for depression: a randomized controlled trial. *Cognitive Behaviour Therapy*, 6073(July), 1–14. <https://doi.org/10.1080/16506073.2017.1337806>
- Soundy, A., Taylor, A., Faulkner, G., & Rowlands, A. (2007). Psychometric Properties of the 7-Day Physical Activity Recall Questionnaire in Individuals with Severe Mental Illness. *Archives of Psychiatric Nursing*, 21(6), 309–316. <https://doi.org/10.1016/j.apnu.2007.03.001>
- Steele, R. M., Mummery, W. K., & Dwyer, T. (2007). Examination of program exposure across intervention delivery modes: Face-to-face versus internet. (B. Bandura Bauman, Brien, Brown, Brown, Brown, Brug, Cline, Conn, Cox, Dishman, DuCharme, Duncan, Duncan, Dunn, Eastin, Eysenbach, Fotheringham, Glasgow, Gustafson, Harvey-Berino, Harvey-Berino, Kahn, Krishna, LaMonte, Leslie, Lorig, Marcus, Marshall, McKay, Ed.), *International Journal of Behavioral Nutrition and Physical Activity*. R.M. Steele, School of Health and Human Performance, Central Queensland University, Rockhampton, QLD, Australia. E-mail: rebekah.steele@mrc-epid.cam.ac.uk: BioMed Central Limited. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc5&NEWS=N&AN=2014-47848-001>
- Steele, R., & Mummery, K. W. (2007). Development and process evaluation of an Internet-based physical activity behaviour change program. *Patient Education and Counseling*. R. Steele, School of Health and Human Performance, Central Queensland University, Australia. E-mail: rebekah.steele@mrc-epid.cam.ac.uk: Elsevier Ireland Ltd (P.O. Box 85, Limerick, Ireland). Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed11&NEWS=N&AN=46880126>
- Steele, R., Mummery, W. K., & Dwyer, T. (2007). Using the Internet to promote physical activity: a randomized trial of intervention delivery modes. *Journal of Physical Activity & Health*, 4(3), 245–260. Retrieved from

<http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med5&NEWS=N&AN=17846455>

- Ström, M., Uckelstam, C.-J., Andersson, G., Hassmén, P., Umefjord, G., & Carlbring, P. (2013). Internet-delivered therapist-guided physical activity for mild to moderate depression: a randomized controlled trial. *PeerJ*, *1*, e178.
- Stubbs, B., Vancampfort, D., Rosenbaum, S., Ward, P. B., Richards, J., Soundy, A., ... Schuch, F. B. (2016). Dropout from exercise randomized controlled trials among people with depression: A meta-analysis and meta regression. *Journal of Affective Disorders*, *190*, 457–466.
<https://doi.org/10.1016/j.jad.2015.10.019>
- Stubbs, B., Vancampfort, D., Rosenbaum, S., Ward, P. B., Richards, J., Ussher, M., & Schuch, F. B. (2016). Challenges Establishing the Efficacy of Exercise as an Antidepressant Treatment: A Systematic Review and Meta-Analysis of Control Group Responses in Exercise Randomised Controlled Trials. *Sports Medicine*, *46*(5), 699–713. <https://doi.org/10.1007/s40279-015-0441-5>
- Sullivan, L. E., Fiellin, D. A., & O'Connor, P. G. (2005). The prevalence and impact of alcohol problems in major depression: A systematic review. *The American Journal of Medicine*, *118*(4), 330–341.
<https://doi.org/10.1016/j.amjmed.2005.01.007>
- Sullivan, P. F., Neale, M. C., & Kendler, K. S. (2000). Genetic Epidemiology of Major Depression: Review and Meta-Analysis. *American Journal of Psychiatry*, *157*(10), 1552–1562.
<https://doi.org/10.1176/appi.ajp.157.10.1552>
- Suresh, K. (2011). An overview of randomization techniques: An unbiased assessment of outcome in clinical research. *J Hum Reprod Sci*, *4*(1), 8–11.
- Sylvia, L. G. (2015). A Practical Guide to Measuring Physical Activity. *Journal of the Academy of Nutrition and Dietetics*, *114*(2), 199–208.
<https://doi.org/10.1016/j.jand.2013.09.018.A>
- Taylor, A. H., & Faulkner, G. (2014). Evidence and theory into practice in different health care contexts: A call for more translational science. *Mental Health and Physical Activity*, *7*(1), 1–5.

- <https://doi.org/10.1016/j.mhpa.2013.06.007>
- Taylor, A. H., Thompson, T. P., Greaves, C. J., Taylor, R. S., Green, C., Warren, F. C., ... West, R. (2014). A pilot randomised trial to assess the methods and procedures for evaluating the clinical effectiveness and cost-effectiveness of Exercise Assisted Reduction then Stop (EARS) among disadvantaged smokers. *Health Technology Assessment*, *18*(4).
<https://doi.org/10.3310/hta18040>
- Teixeira, P. J., Carraça, E. V, Markland, D., Silva, M. N., & Ryan, R. M. (2012). Exercise, physical activity, and self-determination theory: A systematic review. *Int J Behav Nutr Phys Act*, *9*(1), 78.
- Terwee, C. B., Bot, S. D. M., de Boer, M. R., van der Windt, D. A. W. M., Knol, D. L., Dekker, J., ... de Vet, H. C. W. (2007). Quality criteria were proposed for measurement properties of health status questionnaires. *Journal of Clinical Epidemiology*, *60*(1), 34–42.
- Teychenne, M., Ball, K., & Salmon, J. (2010). Sedentary Behavior and Depression Among Adults: A Review. *International Journal of Behavioral Medicine*, *17*(4), 246–254. <https://doi.org/http://dx.doi.org/10.1007/s12529-010-9075-z>
- Thompson, D., Batterham, A. M., Peacock, O. J., Western, M. J., & Booso, R. (2016). Feedback from physical activity monitors is not compatible with current recommendations: A recalibration study. *Preventive Medicine*, *91*, 389–394. <https://doi.org/10.1016/j.ypmed.2016.06.017>
- Titov, N., Andrews, G., Davies, M., McIntyre, K., Robinson, E., & Solley, K. (2010). Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. *PloS One*, *5*(6), e10939. <https://doi.org/10.1371/journal.pone.0010939>
- Toomey, E., Currie-Murphy, L., Matthews, J., & Hurley, D. A. (2015). Implementation fidelity of physiotherapist-delivered group education and exercise interventions to promote self-management in people with osteoarthritis and chronic low back pain: a rapid review part II. *Manual Therapy*, *20*(2), 287–294. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NE>

WS=N&AN=25466294

- Trick, L., Watkins, E., Windeatt, S., & Dickens, C. (2016). The association of perseverative negative thinking with depression, anxiety and emotional distress in people with long term conditions: A systematic review. *Journal of Psychosomatic Research*, *91*, 89–101.
<https://doi.org/10.1016/j.jpsychores.2016.11.004>
- Trigwell, J., McGee, C. E., Murphy, R. C., Porcellato, L. A., Ussher, M., Garnham-Lee, K., ... Foweather, L. (2015). Process evaluation of a sport-for-health intervention to prevent smoking amongst primary school children: SmokeFree Sports. *BMC Public Health*, *15*(1), 347.
<https://doi.org/10.1186/s12889-015-1645-1>
- Trivedi, M. H. (2004). The link between depression and physical symptoms. *Primary Care Companion to the Journal of Clinical Psychiatry*, *6*(Suppl 1), 12–6. Retrieved from
<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=486942&tool=pmcentrez&rendertype=abstract>
- Tudor Hart, J. (1971). the Inverse Care Law. *The Lancet*, *297*(7696), 405–412.
[https://doi.org/10.1016/S0140-6736\(71\)92410-X](https://doi.org/10.1016/S0140-6736(71)92410-X)
- Ussher, M. H., Taylor, A. H., & Faulkner, G. E. J. (2014). Exercise interventions for smoking cessation. *The Cochrane Database of Systematic Reviews*, *8*, CD002295. <https://doi.org/10.1002/14651858.CD002295.pub5>
- Ussher, M., Lewis, S., Aveyard, P., Manyonda, I., West, R., Lewis, B., ... Coleman, T. (2015). Physical activity for smoking cessation in pregnancy: randomised controlled trial. *BMJ (Clinical Research Ed.)*, *350*, h2145.
<https://doi.org/10.1136/bmj.h2145>
- Ussher, M., Lewis, S., Aveyard, P., Manyonda, I., West, R., Lewis, B., ... Coleman, T. (2015). The London Exercise And Pregnant smokers (LEAP) trial: a randomised controlled trial of physical activity for smoking cessation in pregnancy with an economic evaluation. *Health Technology Assessment (Winchester, England)*, *19*(84), vii-135. Retrieved from
<http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=26491878>

- Ussher, M., Stanbury, L., Cheeseman, V., & Faulkner, G. (2007). Physical activity preferences and perceived barriers to activity among persons with severe mental illness in the United Kingdom. *Psychiatric Services, 58*(3), 405–408. <https://doi.org/10.1176/appi.ps.58.3.405>
- van Gemert-Pijnen, J. E. W. C., Nijland, N., van Limburg, M., Ossebaard, H. C., Kelders, S. M., Eysenbach, G., & Seydel, E. R. (2011). A holistic framework to improve the uptake and impact of eHealth technologies. *Journal of Medical Internet Research, 13*(4), e111. <https://doi.org/10.2196/jmir.1672>
- Varghese, T., Schultz, W. M., McCue, A. A., Lambert, C. T., Sandesara, P. B., Eapen, D. J., ... Sperling, L. S. (2016). Physical activity in the prevention of coronary heart disease: implications for the clinician. *Heart, 102*(12), 904–909. <https://doi.org/10.1136/heartjnl-2015-308773>
- Vickers, K. S., Patten, C. A., Lewis, B. A., Clark, M. M., Ussher, M., Ebbert, J. O., ... Hurt, R. D. (2009). Feasibility of an exercise counseling intervention for depressed women smokers. *Nicotine and Tobacco Research, 11*(8), 985–995. <https://doi.org/10.1093/ntr/ntp101>
- Waller, R., & Gilbody, S. (2009). Barriers to the uptake of computerized cognitive behavioural therapy: a systematic review of the quantitative and qualitative evidence. *Psychological Medicine, 39*(5), 705. <https://doi.org/10.1017/S0033291708004224>
- Watkins, E., Newbold, A., Tester-Jones, M., Javaid, M., Cadman, J., Collins, L. M., ... Mostazir, M. (2016). Implementing multifactorial psychotherapy research in online virtual environments (IMPROVE-2): study protocol for a phase III trial of the MOST randomized component selection method for internet cognitive-behavioural therapy for depression. *BMC Psychiatry, 16*(1), 345. <https://doi.org/10.1186/s12888-016-1054-8>
- Watkins, E. R. (2008). Constructive and unconstructive repetitive thought. *Psychological Bulletin, 134*(2), 163–206. <https://doi.org/10.1037/0033-2909.134.2.163>
- Webb, T., Joseph, J., Yardley, L., & Michie, S. (2010). Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and

- mode of delivery on efficacy. *Journal of Medical Internet Research*, 12(1), e4.
- Webb, T. L., Joseph, J., Yardley, L., & Michie, S. (2010). Using the Internet to promote health behavior change: A systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *Journal of Medical Internet Research*, 12(1). <https://doi.org/10.2196/jmir.1376>
- Westerterp, K. (2009). Assessment of physical activity: a critical appraisal. *European Journal of Applied Physiology*, 105(6), 823–828.
- White, K., Kendrick, T., & Yardley, L. (2009). Change in self-esteem, self-efficacy and the mood dimensions of depression as potential mediators of the physical activity and depression relationship: Exploring the temporal relation of change. *Mental Health and Physical Activity*, 2(1), 44–52. <https://doi.org/10.1016/j.mhpa.2009.03.001>
- Whitehead, A. L., Julious, S. A., Cooper, C. L., & Campbell, M. J. (2015). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, 25(3), 0962280215588241-. <https://doi.org/10.1177/0962280215588241>
- WHO. (2017). Global Health Observatory (GHO) data: Prevalence of insufficient physical activity.
- Whooley, M. A., de Jonge, P., Vittinghoff, E., & et al. (2008). DEpressive symptoms, health behaviors, and risk of cardiovascular events in patients with coronary heart disease. *JAMA*, 300(20), 2379–2388. <https://doi.org/10.1001/jama.2008.711>
- Wight, D., Wimbush, E., Jepson, R., & Doi, L. (2016). Six steps in quality intervention development (6SQulD). *Journal of Epidemiology and Community Health*, 70(5), 520–525. <https://doi.org/10.1136/jech-2015-205952>
- Wilbur, J., Miller, A. M., Fogg, L., McDevitt, J., Castro, C. M., Schoeny, M. E., ... Dancy, B. L. (2016). Randomized Clinical Trial of the Women's Lifestyle Physical Activity Program for African-American Women: 24- and 48-Week

- Outcomes. *American Journal of Health Promotion*, 30(5), 335–345.
<https://doi.org/10.1177/0890117116646342>
- Wilbur, J., Schoeny, M. E., Buchholz, S. W., Fogg, L., Miller, A. M., Braun, L. T., ... Dancy, B. L. (2016). Women's Lifestyle Physical Activity Program for African American Women: Fidelity Plan and Outcomes. *Journal of Physical Activity & Health*, 13(10), 1100–1109. <https://doi.org/10.1123/jpah.2015-0701>
- Wildeboer, G., Kelders, S. M., & van Gemert-Pijnen, J. E. W. C. (2016). The relationship between persuasive technology principles, adherence and effect of web-Based interventions for mental health: A meta-analysis. *International Journal of Medical Informatics*, 96, 71–85.
<https://doi.org/10.1016/j.ijmedinf.2016.04.005>
- Wiles, N., Thomas, L., Abel, A., Barnes, M., Carroll, F., Ridgway, N., ... Lewis, G. (2014). Clinical effectiveness and cost-effectiveness of cognitive behavioural therapy as an adjunct to pharmacotherapy for treatment-resistant depression in primary care: The CoBaIT randomised controlled trial. *Health Technology Assessment*, 18(31), 1–167.
<https://doi.org/10.3310/hta18310>
- Williams, C., Wilson, P., Morrison, J., McMahon, A., Andrew, W., Allan, L., ... Tansey, L. (2013). Guided Self-Help Cognitive Behavioural Therapy for Depression in Primary Care: A Randomised Controlled Trial. *PLoS ONE*, 8(1). <https://doi.org/10.1371/journal.pone.0052735>
- Williams, S. L., Michie, S., Dale, J., Stallard, N., & French, D. P. (2015). The effects of a brief intervention to promote walking on Theory of Planned Behavior constructs: a cluster randomized controlled trial in general practice. *Patient Education and Counseling*, 98(5), 651–659. Retrieved from
<http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medc&NEWS=N&AN=25677127>
- Winder, R., Richards, S. H., Campbell, J. L., Richards, D. A., Dickens, C., Gandhi, M., ... Turner, K. (2017). Development and refinement of a complex intervention within cardiac rehabilitation services: experiences

- from the CADENCE feasibility study. *Pilot and Feasibility Studies*, 3(1), 9.
<https://doi.org/10.1186/s40814-017-0123-1>
- Wongpakaran, N., Wongpakaran, T., Wedding, D., & Gwet, K. L. (2013). A comparison of Cohen ' s Kappa and Gwet ' s AC1 when calculating inter-rater reliability coefficients : a study conducted with personality disorder samples, 1–7.
- World Health Organization [WHO]. (2012). Depression (Fact sheet No. 369). Retrieved from <http://www.who.int/mediacentre/factsheets/fs369/en/>
- World Health Organization [WHO]. (2017). Physical Activity. Retrieved from http://www.who.int/topics/physical_activity/en/
- Yardley, L., & Bishop, F. L. (2007). Mixing qualitative and quantitative methods: a pragmatic approach. In W. Stainton-Rogers & C. Willig (Eds.), *The SAGE Handbook of Qualitative Research in Psychology* (pp. 352–370). SAGE Publications Ltd.
- Yardley, L., Spring, B. J., Riper, H., Morrison, L. G., Crane, D. H., Curtis, K., ... Blandford, A. (2016). Understanding and Promoting Effective Engagement With Digital Behavior Change Interventions. *American Journal of Preventive Medicine*, 51(5), 833–842.
<https://doi.org/10.1016/j.amepre.2016.06.015>
- Zimmerman, F. J., & Katon, W. (2005). Socioeconomic status, depression disparities, and financial strain: What lies behind the income-depression relationship? *Health Economics*, 14(12), 1197–1215.
<https://doi.org/10.1002/hec.1011>