THE UNIVERSITY OF HULL

Use of Wearable Technology in the Treatment of Mental Health Difficulties and Chronic Pain

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by

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Overview

This portfolio thesis has three parts: a Systematic Literature Review followed by an empirical research study and finally, a set of appendices. This thesis explored the potential uses of wearable technology in the treatment of mental health difficulties and in the management of chronic pain.

The systematic literature review explored recent mental health care research that utilised wearable technology. From this body of literature, three potential areas of use for wearable technology in mental health care were synthesised. Consideration is given to the clinical implications and limitations of the research. Potential areas of future research are also discussed.

The empirical section describes a study aimed to investigate the utility of incorporating activity tracking technology into a pain management programme (PMP). This pilot study employed mixed methodology in order to investigate both whether being provided with an activity tracker is beneficial to individuals experiencing chronic pain. No significant improvements on outcome measures for various domains (including sleep, pain levels and mental wellbeing) were found for a group with trackers compared to a group without. However those in the tracker group provided positive feedback about benefits of the trackers. The implications for the findings of this study and avenues for future research are discussed.

The appendices section contains a set of appendices for both the preceding sections. It also contains an epistemological statement and reflective statement in order to provide context about the researcher's experience of conducting the research and the philosophical position from which the design of the research was approached.

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Part One: Systematic Literature Review

Wearable technology in the treatment of mental health difficulties: a systematic review

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Abstract

Wearable technology is capable of recording a number of physiological variables while people go about their daily lives. Increasingly available to consumers, its potential role in healthcare is a growing area of research. Consequently, there is a need for reviews which explore the use of wearable technology in mental health care to guide clinicians and to provide context for future research. A systematic search was conducted, resulting in 13 papers being selected for review. From the literature, three potential areas of use for wearable technology in mental health care were synthesised: early detection of mental health difficulties, monitoring and assessment of problems in individuals already experiencing mental health difficulties, and intervention. The review also explored the acceptability of such devices to service users, finding a contrast between devices being viewed as beneficial and concerns about their accuracy and viability. There remains a need for further research about wearable devices in mental health care.

Keywords: mental health; wearable technology; review

Public Health Statement

This literature review aimed to collect recent research that utilised wearable technology with a focus on mental health and uses it answer the question: How can wearable technology be utilised in the treatment of mental health problems? The findings of the review suggest that wearable technology could have several potential uses in mental health care, including early detection of mental health difficulties in the general population.

Introduction

Innovations in technology have changed the way we live our daily lives and how we deliver care in health services (Stevens, Milne, & Burls, 2003). In the last decade, wearable technology has become increasingly available to consumers (Berglund, Duvall, & Dunne, 2016). Wearable technology can take many forms and can be used for many purposes; ranging from entertainment to health monitoring (Berglund et al., 2016). Such technology varies in its capabilities (Bonato, 2009). Devices have been created which are reported to measure skin temperature, galvanic skin response, heart rate and blood oxygen saturation, gait and body motion (Bonato, 2009). Consumer activity tracking devices are widely reported to be able to record activity levels, step count and sleep duration.

In the last decade, there has been an increasing emphasis on self-management approaches over the more traditional view that the clinician knows what is best for the patient. There has been an acknowledgement that service users bring expertise in their own experiences and that they can be active agents in their recovery (Davidson, 2005). Self-management approaches involve the service user in monitoring their own condition and subsequently taking steps to improve management of their condition (Lawn et al., 2007). Wearable technology has potential utility in being able to measure physiological change and behavioural change at regular intervals. Such information could be utilised by both service users and clinicians to collaboratively aid recovery. The acceptability of such devices to both groups however is yet to be established (Chiauzzi, Rodarte, & DasMahapatra, 2015).

Researchers and clinicians have begun to investigate applications of consumer-grade wearable technology in healthcare, with some of the first uses in weight management programmes (Cheatham, Stull, Fantigrassi, & Motel, 2017).

It has been suggested that a quarter of the population will experience problems with their mental health during their lifetime (Mental Health Taskforce, 2016). While a number of effective treatments for mental health problems exist, there remains a need to investigate new approaches in order to discover potentially more effective treatments, provide more service user choice and create options for when an existing treatment is not appropriate. There has been a recent drive to expand the use of technology in mental healthcare (Mental Health Taskforce, 2016). With continual advances in available wearable technology, there is a need for reviews exploring how wearable technology is being used in mental health care research to guide clinicians and to provide a starting point for future research. With this is mind, this review aimed to address the following question:

How can wearable technology be utilised in the treatment of mental health problems?

Method

A systematic literature search was conducted in December 2019 across several electronic databases: Academic Search Premier, CINAHL Complete, MEDLINE and PsycINFO. This was done in order to capture a greater number of articles from different disciplines that could be exploring the use of wearable technology in the treatment of mental health difficulties. For the purposes of this review treatment is defined as including assessment (at any point), intervention and evaluation of effectiveness.

Broad search terms were implemented, designed to capture different descriptions of wearable technology and of mental health difficulties. The following search terms were used:

Terms relating to wearable technology: wear* N3 (technolog* or device* or electronic* or tracker* or digital*)

Terms relating to mental health difficulties: "mental health" or "mental illness*" or "mental disorder*" or "psychiatric*" or "anxiety" or "depress*"

Inclusion and Exclusion Criteria

Tables 1 and 2 show the inclusion and exclusion criteria applied to papers and the associated rationale. Limiters were used to ensure that only journal articles in English from the last five years were retrieved.

Table 1

Inclusion Criteria and Rationale

Inclusion Criteria	Rationale
The study examined the use of a type of	The review was concerned with how
wearable technology. Devices had to be worn	wearable devices are being used at present.
in order to fulfil their function.	
The study detailed the methodology with	The review is aimed towards literature which
regards to how wearable technology was	would be of use to clinicians and researchers
used with participants.	in future works.
Paper written in English.	Papers needed to be in a language in which
	the researcher was fluent since no resources
	for translation were available.
The paper was published within the last five	The review aimed to gather information
years.	about up-to-date technologies and new

approaches.

Table 2

Exclusion Criteria and Rationale

Exclusion Criteria	Rationale
The study investigates physical health as the	The review is concerned with how wearable
primary outcome	technologies are being used to aid mental
	health.
Participants have chronic physical illnesses	The review is concerned with the use of
	wearable technology with individuals whose
	primary difficulty is with regards to mental
	health.
Participants have a diagnosis of dementia or	The review is concerned with the use of
neurological condition	wearable technology with individuals whose
	primary difficulty is with regards to mental
	health.
Discussion, reflective papers or editorials	To ensure that studies included have
	empirical underpinnings.

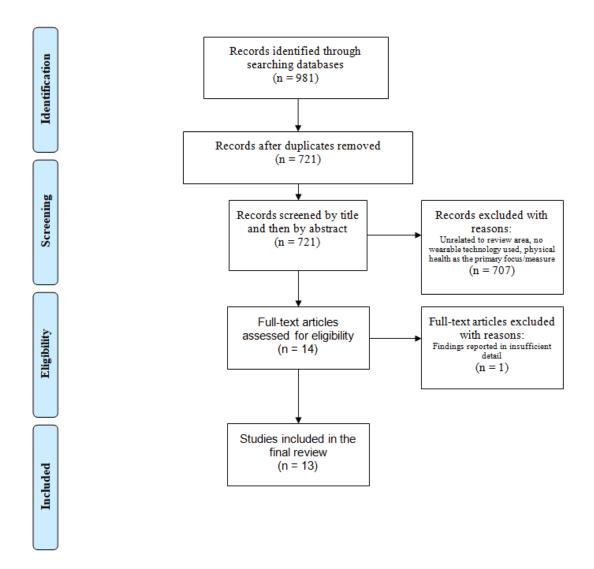


Figure 1 - Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram showing how papers were selected for this review. Adapted from "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement" by D. Moher et al., 2009, *PLoS med*, 6 (7), p.e1000097.

Quality Assessment

The quality of papers was assessed using the Mixed Methods Appraisal Tool (Pluye et al., 2011) which can be used to assess the quality of papers which have Quantitative, Qualitative

or Mixed Methods methodology (see Appendix B). The quality of all the included papers was also assessed independently (blind to the score's given by this paper's author) by a peer researcher to add reliability to the quality assessment; there was 92.3% agreement, it was decided that for the paper where quality was not agreed upon that the lower score would be presented. The scoring system used by the Mixed Methods Appraisal Tool is presented in Table 3 and the outcome of the quality assessment is presented in Table 4.

Table 3

Scoring system for Mixed Methods Appraisal Tool (2011)

Description	Score
All criteria for the given methodology have	****
been met	
75% criteria for the given methodology have	***
been met	
50% of criteria for the given methodology	**
have been met	
25% of criteria for the given methodology	*
have been met	

Table 4

Author and Year Published	Wearable Technology Used	Aims	Method	Number of participants	Participant demographics	Established Measures used	Key findings	Quality Score
Cella et al. (2018)	Wrist-worn autonomic sensor (Empatica E4)	To examine the association between features of schizophrenia and autonomic abnormalities as reported by sensors	Quantitative	55	30 participants with diagnoses of schizophrenia (18M, 10F; mean age = 37.5). 25 control participants (13M, 12F; mean age = 35.9)	Positive and Negative Syndrome Scale (PANSS); Time- Use Survey	Participants with schizophrenia showed lower levels of HRV, movement and functioning. Positive symptoms were associated with "parasympathetic deregulation".	***
Cormack et al. (2019)	Wrist-worn smartwatch (Apple Watch)	To examine the validity and feasibility of wearable, high-frequency cognitive and mood assessment	Quantitative	30	Participants reported to be experiencing mild-to- moderate depression (19F, 11M; mean age = 37.2)	Patient Health Questionnaire (PHQ-9); Perceived Deficits Questionnaire (PQD-D); University of California Los Angeles Loneliness Scale (UCLA-LS)	Daily mood assessments correlated with established depression questionnaires. Daily cognitive assessments correlated with cognitive tests sensitive to depression.	***

Summary of the characteristics and quality of studies included

Dewa et al. (2019)	Wearable technologies used as a broad category	To examine the perspectives of young people experiencing mental health difficulties on the acceptability as well as the feasibility of using wearable technology and social media on deterioration in mental health	Qualitative	16	Participants with diagnoses of severe mental health difficulties (13F, 3M; mean age = 22.0)	N/A	Wearables were considered acceptable and feasible to detect mental health deterioration if they could measure changes in sleep patterns, mood or activity levels as signs of deterioration. Getting help earlier was considered important. Participants identified issues around practicality, safeguarding and patient preference.	****
Jacobson et al. (2019)	Wrist-worn activity tracker (Actiwatch- L)	Explore the relationship between data from a wearable device and self-reports from participants and clinician ratings of depression	Quantitative	15	Participants with diagnosis of Major Depressive Disorder (13F, 2M; mean age = 47.6)	Mini- International Neuropsychiatric Interview (M.I.N.I. 5.0); Beck Depression Inventory-II (BDI-II) and clinician- administered HAM-D.	Model based on activity data significantly predicted depression severity with high precision for self-reported and clinician-rated symptom severity.	***

		severity						
Kim et al. (2019)	Unspecified pedometer- style activity tracker	To evaluate the effectiveness of a walking program on reducing depressive symptoms and acculturative stress levels in Korean- Chinese migrants	Quantitative	132	Participants described as "migrant women workers" (132F; mean age = 54.6)	Center for Epidemiologic Studies Depression Scale; Acculturative Stress Scale for International Students	The walking program led to a reduction in the depressive symptoms and acculturative stress levels among the participants. Activity trackers shown to be a feasible way of measuring compliance.	**
Knight and Bidargaddi. (2018)	Wrist-worn activity trackers (Fitbit and Garmin)	Examine association between activity data from wearable activity trackers and scores on an existing mental health measure	Quantitative	53	Participants reporting psychological distress (41F, 11M, 1T; mean age = 20.7)	The Depression Anxiety Stress Scale - 21 items (DASS-21)	Significant correlation between DASS-21 anxiety subscale scores and movement patterns (of those with over 45 days measurements)	***
Nagano et al. (2019)	Reflective marker sensor (attached to foot)	To investigate if emotional states associated with mental health in older adults can be associated with	Quantitative	126	126 older adults described as "healthy" (96F, 30M; mean age = 66.2)	General Health Questionnaire 12 (GHQ-12)	GHQ-12 scores were highly correlated with left- right gait control, therefore greater gait symmetry was associated with better mental health.	***

		walking mechanics					Mean step width and minimum foot- ground clearance were moderately correlated with GHQ-12.	
Narziev at al. (2020)	Wrist-worn Smartwatch (Gear S3 Frontier)	To develop a framework to classify depression severity using data from sensors	Quantitative	20	20 participants with differing "depression severities" (no information about age or gender provided)	Patient Health Questionnaire (PHQ-9); Beck Depression Inventory-II (BDI-II) and State-Trait Anxiety Inventory (STAI)	Significant correlations between participants' self- reports and sensor data in physical activity, mood, and sleep levels. Framework created from sensor data demonstrated depression severity classification with an accuracy of 96.00%.	***
Ng et al. (2018)	Wrist-worn activity tracker (Fitbit Charge HR)	To investigate patients' motivations whether or not to use wearables devices during a treatment program for post-traumatic stress disorder	Qualitative	13	13 military veterans (11M, 2F; mean age = 41.0)	PTSD checklist for DSM-V (PCL-5)	Three major motivations for veterans to use the Fitbit during their time in the program and three major reasons certain features of the Fitbit were not used.	***

Sano et al. (2018)	Wearable wrist sensors (Q- sensor and Motion Logger)	To investigate using machine learning, how accurately data from wearable sensors could identify self- reported high stress and poor mental health	Mixed methods	201	201 college students (129M, 72F; mean age = 21.5)	Patient Health Questionnaire-9 (PHQ-9); 12- Item Short Form Health Survey; Perceived Stress Scale (PSS)	Wearable sensor features reached 78.3% accuracy for classifying students into high or low stress groups and 87% accuracy for classifying good or poor mental health groups.	***
Smets et al. (2018)	Wearable chest patch and Chillband wrist sensor	To use physiological patterns measured by sensors to create models for stress detection	Quantitative	1002	1002 participants (484M, 451F; mean age = 39.4)	Perceived Stress Scale (PSS); Pittsburgh Sleep Quality Index; Depression Anxiety Stress Scales (DASS- 21); The RAND- 36 Measure of Health-Related Quality of Life	Self-reported poor health indicators and high depression, anxiety and stress scores are associated with "blunted" physiological responses to stress as measured by sensors.	***
Swanson et al. (2018)	Wearable morning light device (Re-timer)	To establish the feasibility and preliminary effects of wearable light therapy for postpartum depression	Quantitative	8	Participants experiencing post-partum depression (8F; mean age = 32.3)	Hamilton Depression Rating Scale; The Edinburgh Postnatal Depression Scale (EPDS); Systematic Assessment for Treatment Emergent Events	Significant improvements in self-report and clinician-rated depression symptoms but little change in circadian measures.	**

						(SAFTEE)		
Zalta et al. (2019)	Wearable morning light device (Re-timer)	To investigate feasibility and acceptability of a wearable light treatment for individuals experiencing probable PTSD	Mixed methods	15	15 participants described as experiencing probable PTSD (9 participants in exp. group: 4F, 5M; mean age = 40.89. 6 allocated to control group: 2M, 4F; mean age = 51.0)	PTSD Checklist for DSM-5 (PCL-5); Patient Health Questionnaire (PHQ-9).	Participants in the experimental group were more likely to achieve a minimal clinically significant change in PTSD and depression symptoms. They also had larger symptom reductions than participants in the control group.	**

Data Synthesis

The studies included varied with regards to which wearable technologies were examined and how they were utilised; as such a meta-analysis was inappropriate. Furthermore, this review was concerned primarily with the ways in which wearable technology can be utilised in the treatment of mental health, not solely comparing the efficacy of different approaches.

Narrative synthesis allows for the compilation of relevant works from which potential themes can be derived (Popay et al., 2006). In line with the suggestions of Popay et al. (2006), a data extraction form (see Appendix C) was used to obtain the relevant information.

The author developed a preliminary synthesis of the finding and methodologies of the studies found by the literature search (Centre for Reviews and Dissemination, 2009). Firstly, relevant characteristics of each study (gathered using the data extraction tool) were tabulated. At this stage, assessment of the quality of the included studies was also conducted. The studies were then grouped into rough groups based on their findings (these initial groups were refined as the synthesis developed).

Subsequently, the relationship between the studies was examined using idea webbing and conceptual mapping (Centre for Reviews and Dissemination, 2009). This process led to the grouping of studies that were conceptually similar in design and findings as well as differentiation between groups based on conceptual differences. This led to the creation of three groups based on how wearable devices could be used and a final group around acceptability of using devices in mental healthcare.

The robustness of the synthesis was explored through assessment of the quality of the studies included and reflection on the process of conducting the synthesis (see reflective statement, Appendix P).

Results

The literature review culminated in several areas of research being identified. The content of the papers was synthesised to establish three main areas whereby wearable devices could be used to aid the treatment of mental health as well as an area of considerations around acceptability.

Table 5

Potential uses of wearable devices and other considerations synthesised from findings

Nagano et al (2019); Sano et al (2018); Smets et al (2018). Cella et al (2018);
Smets et al (2018). Cella et al (2018);
Cella et al (2018);
Cormack et al (2019);
Jacobson et al (2019);
Knight and Bidargaddi (2018);
Narziev at al (2020).
Kim et al (2019);
Swanson et al (2018);
Zalta et al (2019).
Dewa et al. (2019);
Ng et al (2018).

Use of wearable technology in detection of mental health difficulties

Several studies suggested that data from wearable sensors can be correlated with self-reports and existing mental health outcome measures such as the General Health Questionnaire (GHQ-12) and Patient Health Questionnaire (PHQ-9) (Nagano, Sarashina, Sparrow, Mizukami, & Begg, 2019; Sano et al., 2018; Smets et al., 2018).

Methods of included papers.

The studies examined differing populations and devices; however all had reasonably large sample sizes (see Table 4). The studies made use of sensors worn on the wrist (Sano et al., 2018; Smets et al., 2018), feet (Nagano et al., 2019) and on the chest (Smets et al., 2018). Participants were asked to complete outcome measures and self-reports. It is important to note the role of machine learning in these studies - the algorithm building capability becomes increasingly necessary when large quantities of data are gathered (Smets et al., 2018). Machine learning is the utilisation of artificial intelligence to create and improve algorithms using such provided data without the need for explicit programming (Alpaydin, 2020).

Findings.

Studies found that data from wearable devices could be used to classify participants with regards to stress levels (Sano et al., 2018; Smets et al., 2018), with one study reporting that data from wearable devices can categorise individuals with 78.3% accuracy (Sano et al., 2018). One study reported that data from wearable sensors (which measured temperature and skin conductance) could categorise participants into high (good) or low (poor) mental health groups with an accuracy of 87% (Sano et al., 2018). The study suggested that skin responses

between midnight to 3 AM and during sleep were the best predictors for separating high and low self-reported mental health. Sano et al. (2018) explain that skin response is thought to be a biomarker for stress since it has a relationship with sweat gland activity controlled by the sympathetic nervous system. Skin response between 9 AM and 6 PM was one of the best predictors for self-reported stress levels. While examination of the predictive power of skin conductance for stress is not new, the fact that such data can now be gathered outside of a laboratory, wherever an individual may choose to go, opens another avenue for its use in the potential identification of people who may need mental health support. Sano et al's (2018) study was not without limitations. The results of the study did not establish causal links between any of the variables. Additionally, the sample was limited to university students from one university, negatively affecting the generalisability of the results. Participants were from connected groups which may have produced some correlations in the data.

Smets et al. (2018) collected five consecutive days of physiological measurements (skin temperature, skin conductance and electrocardiogram) as well as established psychological measures and self-reports. They then synchronised patterns of physiological response to self-reported stress. They reported that participants' high depression, anxiety and stress scores on established outcome measures were associated with a blunted physiological response to self – reported stress (physiological measures varied less when stress was reported). Smets et al (2018) suggest that predictive models of how physiological response relates to stress levels could be established for different groups, acknowledging that the stress response they observed in their sample of educated participants with sedentary jobs is unlikely to be representative of different demographics.

Nagano et al. (2019) found that step width as measured by a wearable sensor, was significantly positively correlated with elderly participants' scores on a mental health outcome measure (the GHQ-12) (Nagano et al., 2019). It was suggested that discovering low

mental health scores could allow clinicians to intervene, preventing potential future falls (Nagano et al., 2019). There is also the possibility that the sensors used in the study could be used to identify older adults who may be at risk of deteriorating mental health based on their gait patterns. Notably, the researchers excluded any potential participants that had existing physical conditions or cognitive impairments which may have influenced their walking ability. Whilst this controlled for extraneous variables that could have affected the results, the results are only generalizable to healthy older adults.

Collectively, these studies suggest a role for wearable technology in the early detection of mental health difficulties which could facilitate early intervention. A greater awareness of stress levels in the general population could also influence public health initiatives.

Use of wearable technology as part of Assessment and Monitoring

Several studies suggested that data from wearable sensors can be utilised to quantify the severity of mental health difficulties experienced by individuals (Cella et al., 2018; Cormack et al., 2019; Jacobson, Weingarden, & Wilhelm, 2019; Knight & Bidargaddi, 2018; Narziev et al., 2020).

Methods of included papers.

The majority of studies asked patients to complete outcome measures at regular intervals as well as wear activity tracking devices; some studies made use of devices that could record other metrics such as ECG (Cella et al., 2018) or deliver short questions to participants (Cormack et al., 2019). Sample size of these studies varied (see Table 4).

Findings.

A study which correlated activity data from a device worn on the wrist with an existing outcome measure (DASS-21) found a significant positive correlation between volatility in activity as measured by the device and the anxiety subscale of the outcome measure (DASS-21) in a population already considered to be experiencing psychological distress (Knight & Bidargaddi, 2018). Similarly, Jacobson et al. (2019) found a significant positive correlation between predicted depression severity based on activity data as recorded by a wearable device and depression severity as reported by both participants' and clinicians' ratings on the Beck Depression Inventory II. Both of these studies had observational designs, consequently no causal relationship can be established between any of the variables.

Another study suggested that there was a significant negative correlation between activity as recorded by a wearable device and the severity of negative symptoms in individuals with a diagnosis of schizophrenia (Cella et al., 2018). The study also found a significant negative correlation between heart rate patterns and positive symptoms of schizophrenia (e.g. delusions, hallucinatory behaviour and grandiosity). It should be noted however that the researchers did not exclude any participants on the basis of medication; some medications can have an effect on the nervous system such that variables such as heart rate could have been affected. Other lifestyle factors such as smoking and diet may also have affected the findings.

Working with a different clinical population, Narziev et al. (2020) reported how machine learning models were created which classified participants' severity of depression based on activity and sleep data from wearable devices with an accuracy of 96%. Higher levels of sleep and activity were significantly correlated with lower depression severity. It is important to note that the researchers created personalised models for classification for each participant,

with different variables being more important in classification for some participants than others, and therefore the use of such a method in clinical practice may be impractical due to time constraints.

Cormack et al. (2019) demonstrated the potential utility of more sophisticated wearable devices in delivering short assessments of mood and cognition to service users at a greater frequency than using conventional approaches, finding a high level of adherence to responding and correlation between responses to three questions delivered via smart watch and validated depression questionnaires delivered on paper. The study's participants were considered to have mild to moderate depression, whether delivering short assessments through a smart watch would be viable for service users with more severe or different presentations remains to be investigated.

High frequency monitoring of individuals already experiencing mental health difficulties, through the use of activity tracking and delivery of short measures to wearable devices, would potentially allow for more timely intervention if responses indicate that an individual is in need of crisis support.

Use of wearable technology as part of Intervention

Two studies investigated using wearable technology as an active intervention difficulties (Swanson, Burgess, Zollars, & Arnedt, 2018; Zalta, Bravo, Valdespino-Hayden, Pollack, & Burgess, 2019), both demonstrating feasibility and finding promising results. Another study made effective use of wearable activity trackers to check treatment compliance (Kim, Lee, Cho, & Lee, 2019).

Methods of included papers.

Two studies examined how wearable technology can be used as an active intervention for specific mental health difficulties (Swanson, Burgess, Zollars, & Arnedt, 2018; Zalta, Bravo, Valdespino-Hayden, Pollack, & Burgess, 2019), these studies had relatively small sample sizes (see Table 4). These studies both investigated using a device known as The Re-Timer, which emits green-blue light (500 nm dominant wavelength) into the eyes, originally designed to improve users' sleep patterns through phase shifting their circadian rhythm. Both studies involved participants using the device for 60 minutes after waking each morning for a number of weeks (Swanson et al., 2018; Zalta et al., 2019). With regards to methodological quality, it should be noted that Swanson et al's (2018) study did not include a control group, this allows for the possibility that any benefits seen following the use of the Re-Timer could be attributed to other factors.

One study made use of a wearable activity tracker to ensure that participants and researchers could keep track of an exercise treatment (Kim, Lee, Cho, & Lee, 2019). The researchers made use of wearable activity trackers to track the step count of Korean-Chinese migrants who were asked to increase their daily step count by a set amount.

Findings.

Two studies used the same wearable light-emitting device to examine its effects in two different clinical populations: individuals diagnosed with post-partum depression (Swanson et al., 2018) and individuals thought to be experiencing PTSD (Zalta et al., 2019). Both studies suggested that the device could be feasibly used for the treatment of the respective mental health difficulties examined. Clinically significant improvements in responses to

existing outcome measures for depression were found in both populations. Swanson et al. noted that there were no changes in circadian measures (melatonin levels at certain times) for their population of women experiencing post-partum depression (Swanson et al., 2018). This could suggest that the light-emitting properties of the device affect mood without altering circadian patterns.

In a walking intervention study, Kim et al. (2019) found that each time participants' daily step count increased by 1000, their scores on established outcome measures for stress and depression decreased (Kim et al., 2019). Whilst this study does not demonstrate an active role of the activity tracker in the improvement on outcome measures, it would not have been possible for participants to adhere to the proposed treatment or for the researchers to establish a relationship between step count and scores on outcome measures without the wearable trackers. With regards to limitations, the researchers noted that as many participants lived in the same residential area, they could not control for participants from the two groups potentially discussing the study, which could have influenced the results.

The findings of these studies suggest that wearable devices can have a role in intervention for mental health. There remains a need for studies with greater sample sizes and further investigation into treatment adherence before such devices can be considered for widespread use.

Acceptability of wearable technology

Two studies were aimed solely at exploring acceptability of wearable devices with regards to mental health monitoring and treatment (Dewa et al., 2019; Ng, Reddy, Zalta, & Schueller, 2018). The studies found that participants had a consensus that the devices could be beneficial but had concerns about their usage also.

Methods of included papers.

Each study was conducted with different populations: young adults (Dewa et al., 2019) and military veterans (Ng, Reddy, Zalta, & Schueller, 2018). Ng et al. (2018) explored the acceptability of Fitbit activity trackers, whereas Dewa et al. (2019) discussed wearable technology in broad terms rather than focusing on a specific device. The studies were both qualitative in nature.

Findings.

Ng et al. (2018) found three major reasons a wearable device was acceptable to veterans: it was perceived as increasing self-awareness, helping to give back to other veterans and aiding social interactions With regards to increased self-awareness, some of the veterans commented that this led them to make lifestyle changes which they felt had a positive impact on their overall wellbeing Some veterans noted that the ability to compare their activity data with other veterans facilitated social interaction and leverage a sense of competition to improve mood For some veterans, the sharing of their data with healthcare professionals was seen a positive way of shaping future support for other veterans. The study also identified three major barriers to use: lack of clarity around the purpose of the device, lack of meaning in the data from the devices, and challenges in the relationship between veteran and healthcare provider Some veterans said that the device they were using did not meet their expectations with regards to being able to track night-terrors. It was noted by some participants that a lack

of awareness of any relationship between activity and mental health prevented them from using the device, suggesting a need for education on how the devices might be beneficial to service users is needed. The findings of Ng et al's (2018) study may not be generalizable beyond veterans in the United States; veterans in other nations may have different experiences when using activity trackers or may be more or less inclined to use the devices or certain features.

A study reported that young adult participants felt it would be feasible and desirable to have wearable devices, which monitored activity and other measures, that could be used to alert mental health professionals that an individual was in crisis (Dewa et al., 2019). Participants however expressed concerns about the safeguarding (whether artificial intelligence systems would be able to accurately use the data from such devices to alert mental health professionals) and viability of the devices (reliance on the device having what it needs to function, such as sufficient battery and the device being in the possession of the correct person). Whilst there seems to be a general consensus that wearable devices could be beneficial, there does not appear to be total confidence in their ability to accurately and reliably monitor correlates of mental health.

Discussion

Overview of findings and implications

This review has collated and synthesised potential roles for wearable devices in the treatment of mental health, exploring possibilities for early detection, assessment and monitoring as well as in intervention.

Studies suggest that there is a promising role for wearable sensors in the identification of individuals who may be at risk of developing problems with their mental health (Sano et al., 2018; Smets et al., 2018), with devices capable of measuring skin response offering data with remarkable predicative potential (Sano et al., 2018). Wearable devices in combination with algorithms derived from machine learning (Smets et al., 2018) have the potential to allow people to be connected with mental health services at an earlier point. There remain considerations about how potential service users would be made aware that they may need to seek psychological support and how acceptable this would be to the general population.

For individuals who are already experiencing difficulties with their mental health, wearable devices could have a role in determining the severity of mental health problems (Cormack et al., 2019; Jacobson et al., 2019; Narziev et al., 2020) and effectively monitoring individuals' wellbeing such that more timely crisis intervention could be possible (Cormack et al., 2019).

The papers this review considers to have implications for identification and monitoring of mental health difficulties had reasonable quality. All the studies explained their inclusion and exclusion criteria with regards to the population they wished to study. The studies had acceptable response rates to measures. However many of the studies did not comment on the validity of the measures they used, including the measurements that would be gained from the devices being utilised. Due to the established nature of the outcome measures being used, it is understandable why papers may not have gone into detail about their validity due to their expected audience.

Whilst a monitoring approach appears acceptable to young people experiencing mental health problems, concerns remain for this population around the viability of using such devices (Dewa et al., 2019). In addition, such an approach has the potential to create a dynamic of service users relying on clinicians to intervene when changes in behaviour are

detected, potentially affecting their sense of capacity to manage using their own resources or to access support themselves. In a sample of military veterans, benefits from using activity trackers, such as increased self-awareness leading to behaviour change were contrasted against participants having difficulties interpreting the data and participants not using the devices owing to concerns about their accuracy (Ng et al., 2018). The two qualitative papers had reasonable quality, utilising interviewing to collect relevant and detailed data around the acceptability of devices and clearly documented their process of analysis. Both studies gave consideration to how their findings were influenced by their sample and the context they were interviewed in, though more consideration could have been given to how the researchers could have influenced the findings through how they gathered their data.

With regards to wearable devices having an active role in intervention, wearable devices such as morning light-producing devices, have been suggested to be feasible for use with some clinical populations (Swanson et al., 2018; Zalta et al., 2019). There exists however a need for research with greater sample sizes (Swanson et al., 2018). The papers in which an intervention was conducted were generally lower in quality than other papers included. Swanson et al's (2018) study lacked a control group, making it impossible to establish a cause and effect relationship between the use of the Re-Timer and the improvements seen in participants. Zalta et al's (2019) study gave little detail as to how randomisation and blinding were conducted. Consequently, caution should be taken when considering these studies as evidence of the efficacy of such a device with the respective populations.

Future research is implicated since there remains a need to examine the feasibility and efficacy of using various types of wearable devices with different populations for different mental health purposes and to increase confidence in the reliability and accuracy of connected artificial intelligence systems.

Limitations

Some of the studies included have findings which are correlational in nature; one limitation of this is that the relationships between data gathered by trackers and responses mental health outcome measures or self-reports identified could have been the result of unidentified third factors or extraneous variables. Other studies included are attempts to develop predictive models, such that responses to mental health outcome measures or mental health classification could be predicted from data from wearable devices. This should not be confused with casual analysis; predictive modelling studies are not concerned with establishing a causal relationship between the variables.

The majority of papers included in this review reported studies with healthy participants or participants experiencing difficulties with low mood or anxiety and as such the generalisability of findings is limited. Whether the same relationships between measurements from wearable devices, self-reports and outcome measures would be seen in participants experiencing different mental health difficulties (such as responses to trauma or difficulties relating to others) could be found remains to be investigated. These individuals may also have different opinions about and experiences of the use of such devices.

Many of the studies examined the relationship between data gathered from wearable devices and self-reported data from participants. By its nature, self-report data is unavoidably subjective. In contrast, data from wearable devices is often presented as valid and yet the possibility remains that such devices may not accurately record what they intend. It has been proposed that some consumer grade devices show adequate interdevice reliability (Evenson, Goto, & Furberg, 2015). It could be argued however that the produced variable is irrelevant as long as scores on an established measure are accurately and consistently predicted.

While some of the studies within the scope of this review exemplify uses of wearable technology that could benefit those experiencing mental health difficulties, none gave consideration to potential privacy concerns using wearable devices in this way could bring. The data from people experiencing mental health difficulties could be misused by third parties, for example to advertise certain medications towards a specific audience. Dewa et al. (2019) did not report any of the young people interviewed expressing concerns about the privacy of the data gathered by the wearable device; this might highlight the need for clinicians to act as advocates for service users when considering this risk.

Conclusion

There are a number of promising possible uses of wearable technology in the assessment, monitoring and improvement of mental health. The studies included in this review were of varying quality (as determined through use of the MMAT quality assessment tool), with studies focusing on intervention generally of a lower quality than studies focusing on monitoring and assessment. It should be noted that the majority of studies included in this review had participants that were experiencing difficulties with low mood or anxiety and consequently the generalisability of the findings is limited, further research with participants experiencing different mental health difficulties is needed. The findings of correlational studies are arguably insufficient for advocating the use of wearable devices for assessment and monitoring, whereas predictive modelling has more utility. Predicting mental health classification based on data from wearable devices is a developing area, with relatively new tools such as machine learning being utilised. The creation of robust predictive models is necessary step before use of wearable devices in assessment and monitoring of mental health difficulties can become widespread. There is also a need for further work to address the

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concerns of potential service users around the implementation of wearable technology and related systems.

Conflicts of interest

There are no conflicts of interest to report.

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Part Two: Empirical Paper

Activity trackers in the Management of Chronic Pain: a pilot study

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However, in order to improve the accessibility of this thesis, an extended introduction has

been included.

Abstract

Chronic pain has been described as pain that extends beyond the expected point of healing. It is estimated that 43% of the UK population experiences pain which could be considered chronic in nature. The current study aimed to investigate the utility of incorporating activity tracking technology into a pain management programme (PMP). This pilot study employed mixed methodology in order to investigate whether having an activity tracker is beneficial to those in chronic pain. One group of participants were provided Fitbit Charge HRs while undertaking an eight week pain management programme; another group of participants only undertook the programme. Participants' responses to measures (chosen to examine pain levels, sleep quality and well-being), self-reports of activity and hours spent asleep as well as data generated by the Fitbit devices were analysed. Participants in the experimental group were also given a questionnaire asking about their experiences of using a Fitbit. No significant improvements on measures were found for the group with trackers compared to the group without. However those in the tracker group provided positive feedback about the benefits of the trackers. The implications for the findings of this study and avenues for future research are discussed.

Perspective: No treatment consistently and permanently removes chronic pain, thus there is a need for treatments which manage it. The current study aimed to investigate the utility of incorporating activity trackers into PMPs. This study provides a starting point for further research into the use of trackers as part of PMPs.

Keywords: Chronic pain; PMP; activity trackers

Introduction

Defining Chronic Pain

Pain can be defined as an unpleasant sensory and emotional experience in reaction to tissue damage or the potential for tissue damage (Merskey, 1991). Pain is normally expected to dissipate once tissue has healed or an adverse stimulus is removed. Chronic pain has been described as pain that extends beyond the expected point of healing (Turk & Okifuji, 2001). Pain is not considered to be chronic in nature until it has persisted for at least twelve weeks (Geneen et al., 2007). Chronic pain affects a large number of people from various backgrounds; a meta-analysis and systematic review estimated that 43% of the UK population experiences pain which could be considered chronic in nature (Fayaz, Croft, Langford, Donaldson, & Jones, 2016). Chronic pain leads individuals to attempt to find some form of relief (for example use of pain medication). In cases where relief cannot be obtained, this can lead to feelings of hopelessness, helplessness and low mood (Turk & Gatchel, 2013). Chronic pain is not only a negative experience for the individual but for their family members as well (Turk & Gatchel, 2013), with anger (in relation to the pain and perceived level of help received) often directed towards them (Okifuji, Turk, & Curran, 1999). Chronic pain also has an impact at a societal level as individuals with chronic pain may require resources from healthcare and benefits from the state (Turk & Gatchel, 2013). There remains no treatment that consistently and permanently removes chronic pain, thus there is a need for a better understanding of chronic pain to enable treatments which manage it.

Biopsychosocial approach and Fear-Avoidance models

The biopsychosocial approach posits that biological factors may be responsible for the initiation of pain but psychological factors are responsible for the appraisal and perception of the resulting sensation and social factors determine the way that people respond to these perceptions (Turk & Flor, 1999). The strength in such an approach lies in it being applicable to people for whom the level of pain does not appear to match the observable damage to tissue, and where pain continues beyond the expected timeframe (Asmundson, Vlaeyen, & Crombez, 2004).

The importance of avoidance in the maintenance of chronic pain has been suggested in biopsychosocial models, with the concept of operant conditioning being core to such explanations (Asmundson et al., 2004). Following injury, avoidance of activity is negatively reinforced through the short-term reduction in pain that comes from not engaging in activity (Fordyce, 1982). It is suggested that this avoidance of activity allows for damaged tissue to heal and that most individuals reintroduce activity over time, promoting recovery to how an individual was behaving before injury (Fordyce, 1982). However some individuals do not reintroduce activity and also may receive further reinforcement for staying inactive in various social forms. Further negative reinforcement can come from reduced workload and less family responsibilities. Positive reinforcement can come in the form of increased attention and sympathy from others (Asmundson et al., 2004). It is suggested that the result of this reinforcement is the individual learning that avoiding activities associated with the experience of pain will reduce the likelihood of experiencing pain in the future (Asmundson et al., 2004).

It has been suggested that the avoidance of pain is not simply a result of reinforcement but also of expectation. Philips (1987) suggested that an individual's beliefs in their own abilities,

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previous experiences of pain and beliefs about specific situations resulting in pain influence an individual's decision to continue avoidance (Philips, 1987). Vlaeyen and Linton (2000) suggested that when pain is perceived, it is appraised in terms of the meaning of the pain. For some individuals pain is judged to be catastrophic; this results in fear of pain which results in hypervigilance and avoidance which further promotes disability and pain (Vlaeyen & Linton, 2000). Leeuw et al, 2007 suggested that pain-related fear could be a vulnerability factor as well as a maintaining factor for chronic lower back pain, as fearful people may be more likely to misinterpret physical sensations as threatening and consequently be more likely to experience pain.

Fear-anxiety-avoidance model

Asmundson et al. (2004) suggest that individuals with chronic pain experience anxiety (in the form of apprehension) in response to the anticipated threat of pain and this is what leads to avoidance. It is suggested that fear of pain results in defensive behaviours such as sitting down when pain is experienced whereas anxiety around pain results in preventative behaviours such as avoidance and hypervigilance (Asmundson et al., 2004). It is suggested that this fear-escape behaviour and anxiety-avoidance behaviour are mutually reinforcing. The hypervigilance experienced as an element of anxiety is suggested to increase the likelihood of a threatening stimuli being noticed and therefore the individual feeling fear. It is suggested that fear leads to the individual perceiving stimuli as a threat that could be experienced again, reinforcing anxiety (Asmundson et al., 2004).

Rationale for encouraging the majority of individuals with chronic pain to increase activity levels

If those with chronic pain become inactive due to avoidance of pain, their muscles will become deconditioned. This means that they will experience more pain the next time they engage in any activity. This could reinforce the idea that activity leads to pain. Fear-avoidance and Fear-anxiety-avoidance models of chronic pain would suggest reinforcement of this belief exacerbates the problem further. Further weakening will occur due to this avoidance of exercise (Lethem, Slade, Troup, & Bentley, 1983). As such, encouraging appropriate levels activity has been suggested to be vital in preventing further pain and disability (Turk & Gatchel, 2013).

The avoidance of activity also impacts the quality of life of those experiencing chronic pain in other ways. Individuals in pain may no longer attend social activities that they once enjoyed due to the pain travelling to, or engaging in, these activities could cause. This can result in their mood being negatively affected (Turk & Gatchel, 2013). Therefore there is a rationale for asking participants to re-engage with activity to improve their wellbeing.

What is a pain management programme?

Chronic pain is often managed by pain management programmes (PMPs). The content of PMPs vary across services but usually have the same aim. PMPs often contain psychoeducation sessions about what pain is and how certain emotions and behaviours can exacerbate the negative experience of it (Johansson, Dahl, Jannert, Melin, & Andersson, 1998). Individuals with chronic pain are encouraged to build up their activity levels and pace their activity as appropriate (Turk & Gatchel, 2013). Pain management programmes may contain practical sessions where individuals are taught how to exercise safely (Johansson et al., 1998). Studies have found varying degrees of effectiveness of PMPs; a long-term study found that psychological distress reported on outcome measures can be significantly reduced in half of patients by PMPs (Fullen et al., 2014). While some studies have reported improvement in pain symptoms (Dysvik, Kvaloy, & Natvig, 2012), other studies have reported no significant differences (Collins, Carr, & O'Keefe, 1998). The lack of consistency in outcome of pain management programmes could suggest a need for refinement or modification of the content and protocols of PMPs.

What is activity tracking technology?

Activity trackers contain three axis accelerometers (components capable of measuring the rate of change of the velocity of an object in three planar directions) which translate acceleration into data. The data is then analysed to produce further data about intensity, duration and patterns of movement. The devices compare this to normative data using various algorithms in order to give information in the form of steps taken, calories burned, sleep quality and other more understandable categories. Activity trackers are able to detect when an individual is stationary or has been relatively inactive for some time (Mercer, Li, Giangregorio, Burns, & Grindrod, 2016). Many activity trackers are able to be programmed to prompt an individual to move when sedentary behaviour is detected and can be synchronised with other technology to provide the user with information about their progress towards goals such as a walking a certain number of steps per day (Mercer et al., 2016). The devices are commonly worn on the wrist but can also be worn on other parts of the body such as the ankle. In a large scale trial, Finkelstein et al. (2016) provided one group with activity

trackers but not another and demonstrated that activity trackers can motivate increase in activity; even when rewards for increasing activity are not offered.

Previous research utilising activity trackers with individuals experiencing chronic pain

A literature review of mobile health technology in the treatment of chronic pain suggested that there is some preliminary evidence that activity trackers can encourage increased function and improve mood (Sundararaman, Edwards, Ross, & Jamison, 2017). There still remains a general absence of literature around using activity tracking devices with individuals experiencing chronic pain with an aim of aiding recovery. A study compared the effects of providing a popular model of activity tracker (the Fitbit Charge HR) with providing a pedometer to individuals experiencing chronic low back pain (who were undertaking a physical activity programme) on aerobic fitness and disability (Gordon & Bloxham, 2017). The study found that activity trackers were more effective than pedometers at helping to improve the aerobic fitness of participants but only equally effective as pedometers at reducing disability (Gordon & Bloxham, 2017). Gordon and Bloxham (2017) used a revised Oswestry Disability Questionnaire to examine levels of disability; the Obswestry Disability Questionnaire is suggested to have sufficient validity and reliability for this task when compared with similar measures (Roland & Fairbank, 2000).

Another preliminary study investigated the usefulness of activity tracking devices for children (aged between 8 and 12) experiencing chronic pain (Junghans-Rutelonis, Gephardt, Skipper, Timm, & Weiss, 2016). The participants were attending a pain rehabilitation clinic. Participants were asked to wear a Fitbit device for three weeks before attending the pain rehabilitation clinic and for three weeks after. The study found that on average the participants significantly increased the number of steps they took and distance walked daily

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from before they attended the pain rehabilitation clinic to during. The authors did not report how the participants' reported pain levels changed throughout the study so no conclusions as to the activity trackers' effects on pain itself can be made.

Chronic pain negatively affects individuals' sleep (Smith, Perlis, Smith, Giles, & Carmody, 2000) and the activity levels of those with chronic pain are reduced (Asmundson et al., 2004). The advances in consumer-grade tracking technology allow for the gathering of information about an individual's daily life such as their activity level and number of hours spent asleep (Keill, 2016).

Activity monitoring data from devices may allow for clinicians to assess whether individuals are following suggested activity plans or to adjust such plans accordingly based on clients' performance. A recent meta-analysis suggested that wearable activity trackers and their associated systems deliver a number of effective behaviour change strategies, such as giving normative information about others' behaviour, encouraging goal setting and allowing users to become aware of their own behaviour patterns (Mercer et al., 2016). However, it has been suggested that wearable technology can be a facilitator of behaviour change but not the sole driver of change (Patel, Asch, & Volpp, 2015). It remains to be investigated as to whether the use of such devices would motivate behaviour change in individuals living with chronic pain.

Rationale for this study

There is a clear need for the development of treatments that can help manage chronic pain, in order to reduce the distress of those affected and their families and the negative effects on society as a result of having individuals who are unable to work or care for others (Turk & Gatchel, 2013). Fear-Avoidance and Fear-Anxiety-Avoidance models propose that engaging with pain rather than avoiding it is key to recovery (Asmundson et al., 2004) and previous research suggests that using activity trackers can lead to increased activity (Finkelstein et al., 2016). Research into whether activity trackers can be used to prompt and encourage activity in those experiencing chronic pain, and investigating whether this leads to positive outcomes in multiple domains has significant clinical relevance. It could be theorised that if an activity tracker can successfully prompt an individual to engage in activity, this provides them with the opportunity to gather evidence which challenges their beliefs about the nature of pain (for example that it is disabling in nature). It has been suggested that such a confrontation is important in regaining normal function (Vlaeyen & Linton, 2012).

As no other study had integrated activity trackers into a Pain Management Programme before, a pilot study to examine the feasibility of this was necessary. One role of the current study was to identify potential barriers to implementation such as how easy it is to recruit participants and gather data from the devices. The current study also provided preliminary data which could shape the investigations of future studies. The current study aimed to investigate whether providing individuals who are experiencing chronic pain with an activity tracker, which prompts users to engage in activity when sedentary behaviour is detected, can lead to better outcomes during an eight week pain management programme. In addition, it aimed to examine whether there are any differences between what individuals experiencing chronic pain perceive their activity levels and time spent asleep to be and what the activity trackers output. The current study also aimed to explore how acceptable such devices are to individuals experiencing chronic pain.

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Research Questions

The current study had the following research questions:

- Can an activity tracking device assist individuals experiencing chronic pain in improving their pain levels, improving their sleep and improving their sense of wellbeing?
- 2. Is there a discrepancy between individuals with chronic pain's perception of their activity levels and time spent asleep and the findings of tracker technology?
- 3. What is the experience of using activity trackers and how acceptable are activity trackers to individuals with chronic pain?

Hypotheses

Based on the findings of previous research which suggest that the use of activity trackers can lead to an increase in activity levels (Finkelstein et al., 2016) and the concept from Fear-Avoidance models that engagement with pain is core to its improvement and improving quality of life, the following hypotheses were created:

- 1. The group with activity trackers will have a significantly higher self-reported activity than the group without trackers.
- 2. The group with activity trackers will have a significantly different sleep time reported than the group without trackers.
- 3. The group with activity trackers will have a significantly larger decrease in pain symptoms reported on outcome measures than the group without trackers.
- 4. The group with activity trackers will have a significantly different sleep quality reported on outcome measures than the group without trackers.

- 5. The group with activity trackers will have a significantly higher increase in well-being reported on outcome measures than the group without trackers.
- 6. The group with activity trackers will have significantly greater decrease in depression and anxiety on an outcome measure than the group without trackers.
- 7. There will be significant differences between the group with trackers' self-reported activity levels and the data from their activity trackers.
- 8. There will be significant differences between the group with trackers' self-reported time spent asleep and the data from their activity trackers.

Methods

Design

This study employed a mixed methods design; data was collected across an eight week pain management programme. Participants completed measures throughout the programme as well as one group wearing activity tracking devices. Participants' responses to outcome measures and self-reports of activity and hours spent asleep as well as activity data generated by the activity tracker devices themselves (steps an individual takes, the distance an individual walks or runs, the number of minutes an individual spends active, and number of hours of sleep) were gathered. At the end of the eight week programme, participants in the activity tracker group were asked to complete a questionnaire about their experience of using the activity trackers. The study received a favourable opinion following a proportionate ethical review by a REC committee and HRA approval (see Appendix G)

Sample

The participants for this research were recruited from individuals eligible for a pain management programme at a hospital in the north of England (there were 23 eligible potential participants during the period of recruitment). Twenty two participants volunteered to take part in the study. It was considered important from both an ethical and practical perspective that participants in the activity tracker group were happy to wear the devices for the whole eight week programme and so participants were asked if they were willing to do so, seven participants agreed to wear an activity tracking device for the duration of the study. None of the participants had undertaken a pain management programme before. Twenty participants were female, two participants were male. There was one male participant in each group. One participant (from the group without trackers) stopped attending the pain management programme (for reasons unrelated to the study) and so there was insufficient data to include them in the analysis.

Sample Characteristics

The characteristics of the sample are outlined in Table 1.

Table 1

Characteristics of the sample

Group without trackers	Group with activity trackers
14	7
49.85	47.42
100	85.71
0	14.29
21.43	14.29
14.29	14.29
28.57	42.86
35.71	28.57
	14 49.85 100 0 21.43 14.29 28.57

Materials - Activity monitoring devices

The model of activity monitoring devices used was the Fitbit Charge HR (Fitbit Inc, San Francisco, CA, USA). This model of activity tracker is capable of measuring steps an individual takes, the distance an individual walks (or runs), the number of minutes an individual spends active, continuous heart rate, number of hours of sleep and provides an estimate of sleep quality. The device is worn on the dominant wrist of the user. Unlike some other consumer-grade devices, the device is not waterproof so participants were informed to take it off before showering or swimming. Participants were required to return the activity trackers after the eight week programme.

Materials – Pain Management Programme

The Pain Management Programme (PMP) had multidisciplinary input, including from psychologists, physiotherapists, occupational therapists and nurses. Sessions took place weekly for eight weeks, with each session lasting three and a half hours. Sessions included discussion of readiness to change, introduction to the concept of activity management and models of chronic pain, goal setting, discussion of the barriers to and benefits of exercise, as well as education about anatomy, medication use and sleep (see Appendix H for order). Each session also included 30 minutes guided exercise in a physiotherapy gym.

Materials - Measures

In order to examine pain levels, well-being, activity levels and sleep quality, self-report measures were used weekly (see Appendix I to Appendix M):

- Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) (Tennant et al., 2007) A short self-report measure where positively worded statements are rated from "none of the time" to "all of the time". This scale is widely used throughout various services. The SWEMWBS is suggested to have sufficient construct validity, including better than that of the longer WEMWBS (Stewart-Brown et al., 2009). The measure is scored by summing the scores for the seven items (each item is scored one to five). Higher scores indicate higher well-being.
- Pain and Sleep Questionnaire (Ayearst, Harsanyi, & Michalko, 2012) A self-report measure designed to investigate how an individual feels pain affects their sleep. This measure was selected due to its focus on the degree to which pain affects individual's sleep, its ease of use for participants and its brief nature. Refined to a three item

measure, the PSQ-3 is suggested to have sufficient construct and criterion validity. Participants mark three lines based on responses to questions about their pain's effect on their sleep. These lines are a standardised length; a participant's score can be derived for each question by measuring how far along the line they marked (in mm). A total score is created by summing the score for each question. Higher scores indicate that pain is having a greater effect on sleep.

- Short-form McGill Pain Questionnaire (Melzack, 1987) A questionnaire designed to measure intensity and type of pain. This questionnaire was selected as it is one of the most widely used pain questionnaire in both research and clinical settings, being considered a gold-standard measure. It has been suggested to be both valid and reliable in different populations (Melzack & Katz, 2001). The short-form McGill has different sections. An individual is asked to rate fifteen adjectives around pain (11 sensory, 4 emotional). Each adjective is rate from None (scored 0) to Severe (scored 3). The total score for each section (e.g. sensory) is calculated by summing the scores for that section's adjectives. The final part of the McGill is a visual scale (from No Pain to Worst Possible Pain), which an individual marks based on their current pain level. The score for the visual scale is derived by measuring where on the line the mark is (in cm). Higher scores indicate higher levels of pain being experienced.
- Participant self-reports of number hours they spend active weekly (including activity type, e.g. running).
- Weekly participant self-reports of number of hours of sleep they are getting each night on average.

This measure was gathered before and after the intervention:

Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) – A self-report measure intended to measure anxiety and depression used widely in hospital services. This measure was selected as it has been has been suggested to be valid for individuals experiencing chronic pain (Castro et al., 2006; Williams, 1988) and commonly used by Pain Management Programmes. This measure was only used before and after the intervention due to the time required to complete it. The measure presents an individual with 14 statements (7 statements pertaining to anxiety and 7 to depression), for example: "I feel cheerful". A participant is asked to choose one of four responses indicating to what degree the statement is accurate for them, each response has an associated score (of 0 to 4). A total score for depression or anxiety is calculated by summing the scores for the responses to the respective statements. Higher scores indicate higher levels of depression and anxiety. The measure also provides classifications of Normal, Borderline and Abnormal (case) dependent on score.

Participants in the group that were given activity trackers also completed a questionnaire about their experience of using the tracker (see Appendix N).

Procedure

Potential participants were provided with full information sheets (see Appendix E) regarding the study by clinicians prior to them beginning the pain management programme. The information sheets contained contact information of the researcher for potential participants to ask any questions they had about the research. If an individual wished to take part, they signed and returned a consent form (see Appendix F) to the principal researcher via the clinical team conducting the Pain Management Programme. Participants completed the HADS before and after the PMP as well as shorter measures throughout the programme (detailed above), with the first use of these measures being at week one of the programme. Participants in the activity tracker group were given activity trackers at their first session of the PMP as well as information on how to operate their activity trackers, how to view the data they generate and how to care for them. Participants were asked to wear their devices as much as possible over the eight weeks. At the end of the eight week programme, participants in the activity tracker group were asked to complete a questionnaire about their experience of using the activity trackers.

Sample Size Analysed

Data from 21 participants was included in the analysis (14 from the non-activity tracker group and 7 from the activity tracker group). A power analysis was conducted with the assumptions of an effect size of 0.25 (considered moderate), an equal likelihood of type 1 and type 2 errors, specificity maximally violated and with 8 measurement points. The power analysis estimated a power of 83.8%. In reality, observed power for the interaction between time and group type on mean SWEMWBS score (considered the main analysis) was higher at 99.4%.

Statistical Analysis

In order to examine the effect of any interaction between whether or not participants were given an activity tracker and time on responses to each of the measures, a series of mixed ANOVAs were conducted. Additionally, to investigate whether any differences between the group with trackers' self-reported activity and sleep levels and the data from their activity trackers was statistically significant, repeated measures ANOVAs were conducted.

Content Analysis

A content analysis of the responses to the open questions (that followed the Likert scales) in the questionnaire was conducted (informed by Hsieh & Shannon, 2005) in order to investigate participants' experience of using the devices throughout the study. Each questionnaire was read through and different responses were extracted. These responses were then described to establish conceptual codes and then grouped based on what they were referring to. These groups were then named as major themes. The data was then re-examined to ensure that all responses fit their respective theme. Finally, the number of pieces of content in each theme was counted.

Results

Hypothesis: The group with activity trackers will have a significantly higher selfreported activity than the group without trackers

The findings did not support this hypothesis:

The self-report of activity data was analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Mauchly's test indicated that the assumption of sphericity had been violated,

W(27) =.004, p < .001. Therefore the Greenhouse-Geisser correction was used. Whilst on average the group with activity trackers had greater mean self-reported weekly activity than the group without trackers, the interaction between time and group was not significant, F (2.96, 56.1) = .203, p = .984, $\eta_p^2 = .011$. Additionally, there was no significant effect of group, F(1, 19) = .053, p = .821, $\eta_p^2 = .003$.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean weekly self-reported activity reduced by an average (mean) of 10.98 hours when week one and week eight were compared; however this difference was not statistically significant, p = .109.

Within the group with activity trackers, post hoc tests (LSD pairwise comparison) revealed that mean weekly self-reported activity reduced by an average (mean) of 6.57 hours when week one and week eight were compared; however this difference was not statistically significant, p = .293.

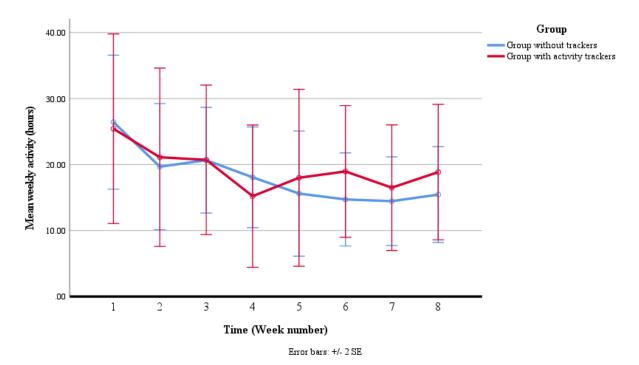


Figure 1

Effect of interaction between time and group type on mean weekly activity reported by participants

Hypothesis: The group with activity trackers will have a significantly different sleep time reported than the group without trackers

The findings did not support this hypothesis:

The self-report of sleep data was analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Mauchly's test indicated that the assumption of sphericity had been violated, W(27) = .075, p = .033. Therefore the Greenhouse-Geisser correction was used. Whilst on average the group with activity trackers had greater mean self-reported sleep per night than the group without trackers, the interaction between time and group was not significant, F (4.39, 72.9) = .247, p = .924, $\eta_p^2 = .013$. Additionally, there was no significant effect of group, F(1, 19) = 2.44, p = .135, $\eta_p^2 = .114$.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean weekly self-reported average sleep per night increased by an average (mean) of 0.96 hours when week one and week eight were compared; this difference was statistically significant, p = .006.

Within the group with activity trackers, post hoc tests (LSD pairwise comparison) revealed that mean weekly self-reported average sleep per night increased by an average (mean) of 1.00 hours when week one and week eight were compared; this difference was statistically significant, p = .044.

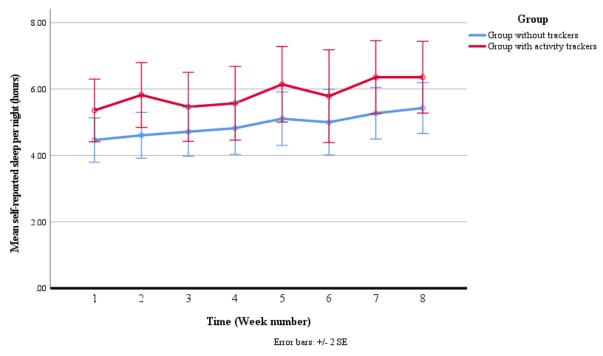


Figure 2

Effect of interaction between time and group type on mean sleep per night reported by participants

Hypothesis: The group with activity trackers will have a significantly different sleep quality reported on outcome measures than the group without trackers

The findings did not support this hypothesis:

The total scores for the Pain and Sleep Questionnaire (PSQ-3) were analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Mauchly's test indicated that the assumption of sphericity had been violated, W(27) = .010, p < .001. Therefore the Greenhouse-Geisser correction was used. Whilst on average the group with activity trackers had lower mean total score on the PSQ-3 than the group without trackers, the interaction between time and group was not significant, F(2.39, 45.5) = .454, p = .672, $\eta_p^2 = .023$. Additionally, there was no

significant effect of group, F(1, 19) = 2.81, p = .110, $\eta_p^2 = .129$. There are no established clinical cut-offs for this measure, so no comments on clinically significant differences can be made.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean weekly total score on the PSQ-3 reduced by an average (mean) of 27.14 when week one and week eight were compared; however this difference was not statistically significant, p = .223.

Within the group with activity trackers, post hoc tests (LSD pairwise comparison) revealed that mean weekly total score on the PSQ-3 reduced by an average (mean) of 28.43 when week one and week eight were compared; however this difference was not statistically significant, p = .051.

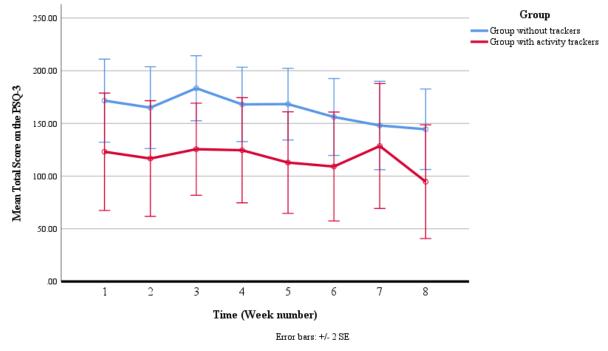


Figure 3

Effect of Interaction between time and group type on mean total score on the PSQ-3

Hypothesis: The group with activity trackers will have a significantly higher increase in well-being reported on outcome measures than the group without trackers.

The findings did not support this hypothesis:

Lower Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS) scores suggest lower levels of wellbeing. The SWEMWBS data was analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Mauchly's test indicated that the assumption of sphericity had not been violated, W(27) = .098, p = .082. The interaction between time and group was significant, F(7, 133) = 4.74, p < .001, $\eta_p^2 = .200$. Participants who were given an activity tracker had lower mean SWEMWBS scores over time. Additionally, there was a significant effect of group, F(1, 19) = 5.96, p = .025, $\eta_p^2 = .239$. There are no established clinical cutoffs for this measure, so no comments on clinically significant differences can be made. However both groups at the end of the PMP would be considered to have lower scores than the general population (Fat et al., 2016).

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean SWEMWBS score increased by an average (mean) of 4.50 when week one and week eight were compared; this difference was statistically significant, p < .001.

Within the group with activity trackers, post hoc tests (LSD pairwise comparison) revealed that mean SWEMWBS score increased by an average (mean) of 0 when week one and week eight were compared; however this difference was not statistically significant, p = 1.00.

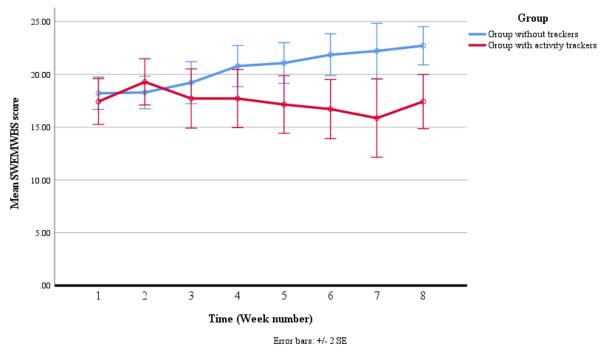


Figure 4

Effect of Interaction between time and group type on mean SWEMWBS score

Hypothesis: The group with activity trackers will have a significantly larger decrease in pain symptoms reported on outcome measures than the group without trackers.

The findings did not support this hypothesis:

The McGill Pain Questionnaire Short-Form can be broken down into several elements: sensory descriptors of pain, affective descriptors of pain and the visual analogue scale (VAS).

The responses to McGill Pain Questionnaire sensory section were analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Mauchly's test indicated that the assumption of sphericity had been violated, W(27) = .014, p < .001. Therefore the Greenhouse-Geisser correction was used. Whilst on average the group with activity trackers had lower mean scores on the sensory section of the McGill Pain Questionnaire than the group without

trackers, the interaction between time and group was not significant, F(2.27, 51.7) = 1.73, p = .177, $\eta_p^2 = .083$. Additionally, there was no significant effect of group, F(1, 19) = .937, p = .345, $\eta_p^2 = .047$. There are no established clinical cut-offs for this measure, so no comments on clinically significant differences can be made.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean McGill Sensory score reduced by an average (mean) of 3.93 when week one and week eight were compared; this difference was statistically significant, p = .026.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean McGill Sensory score increased by an average (mean) of 1.00 when week one and week eight were compared; however this difference was not statistically significant, p = .687.

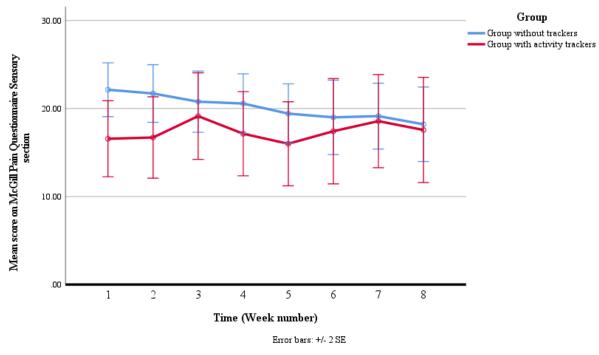


Figure 5

Effect of Interaction between time and group type on mean score on McGill Pain

Questionnaire Sensory section

The responses to McGill pain questionnaire affective section were analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Mauchly's test indicated that the assumption of sphericity had been violated, W(27) = .031, p = .001. Therefore the Greenhouse-Geisser correction was used. Whilst on average the group with activity trackers had lower mean scores on the affective section of the McGill Pain Questionnaire than the group without trackers, the interaction between time and group was not significant, F (3.04, 57.8) = .691, p = .563, η_p^2 = .035. Additionally, there was no significant effect of group, F (1, 19) = .399, p = .535, η_p^2 = .021. There are no established clinical cut-offs for this measure, so no comments on clinically significant differences can be made.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean McGill Affective score reduced by an average (mean) of 1.00 when week one and week eight were compared; however this difference was not statistically significant, p = .240.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean McGill Affective score reduced by an average (mean) of 0.57 when week one and week eight were compared; however this difference was not statistically significant, p = .611.

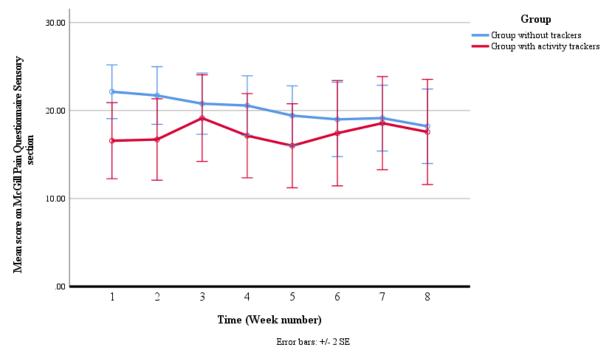


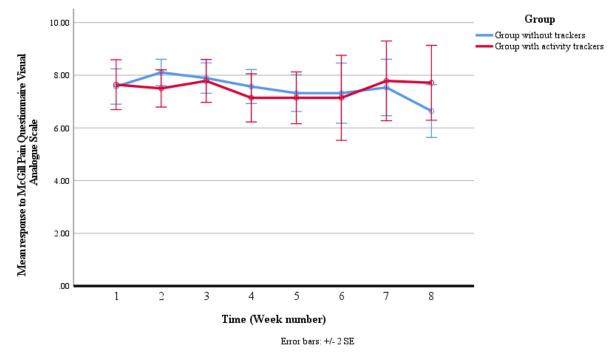
Figure 6

Effect of Interaction between time and group type on mean score on McGill Pain Questionnaire Affective section

The responses to McGill pain questionnaire visual analogue scale were analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Mauchly's test indicated that the assumption of sphericity had been violated, W(27) = .021, p < .001. Therefore the Greenhouse-Geisser correction was used. Whilst on average the group with activity trackers had lower mean responses on the visual analogue scale section of the McGill Pain Questionnaire than the group without trackers, the interaction between time and group was not significant, F (2.88, 54.7) = .950, p = .420, $\eta_p^2 = .048$. Additionally, there was no significant effect of group, F (1, 19) = .001, p = .979, $\eta_p^2 < .001$. There are no established clinical cut-offs for this measure, so no comments on clinically significant differences can be made.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean McGill Visual Analogue Scale score decreased by an average (mean) of 0.93 when week one and week eight were compared; however this difference was not statistically significant, p = .161.

Within the group without trackers, post hoc tests (LSD pairwise comparison) revealed that mean McGill Visual Analogue score increased by an average (mean) of 0.071 when week one and week eight were compared; however this difference was not statistically significant, p = .805.



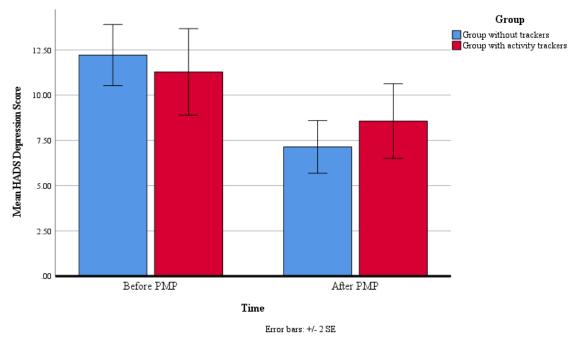


Effect of Interaction between time and group type on mean response to McGill Pain Questionnaire Visual Analogue Scale

Hypothesis: The group with activity trackers will have significantly greater decrease in depression and anxiety on an outcome measure than the group without trackers.

The findings did not support this hypothesis:

The Hospital Anxiety and Depression Scale Depression scores were analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Following the PMP, the group with activity trackers had higher mean depression scores on the HADS than the group without trackers. However the interaction between time and group was not significant, F(1, 19) = 2.56, p = .126, $\eta_p^2 = .119$. Additionally, there was no significant effect of group, F(1, 19) = .047, p = .830, $\eta_p^2 = .002$. Mean depression scores for the group without trackers would be considered to have gone from clinically significant (case) to being considered within the "normal" range by the end of the PMP (7.14). Mean depression scores for the group with trackers would be considered to have gone from clinically significant (case) to being considered within the "normal" range by the end of the PMP (8.57).





Effect of Interaction between time and group type on HADS Depression scores

The HADS Anxiety scores were analysed using a mixed ANOVA with a within-subjects factor of time and a between-subject factor of group (whether the participants had an activity tracker or not). Following the PMP, the group with activity trackers had higher mean anxiety scores on the HADS than the group without trackers. However the interaction between time and group was not significant, F(1, 19) = 1.70, p = .207, $\eta_p^2 = .082$. Additionally, there was no significant effect of group, F(1, 19) = .013, p = .910, $\eta_p^2 = .013$. Mean anxiety scores for the group without trackers would be considered to have gone from clinically significant (case) to being considered within the "borderline" range by the end of the PMP (9.64). Mean anxiety scores for the group with trackers would be considered to still be clinically significant (case) by the end of the PMP (10.86).

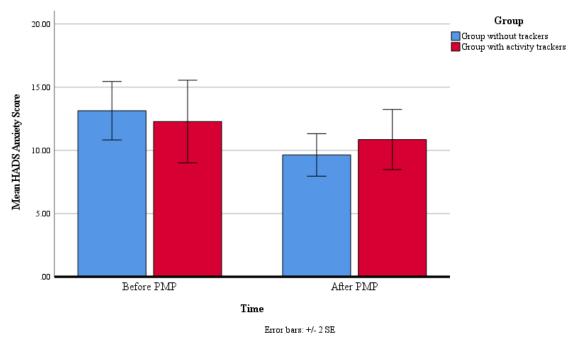


Figure 9

Effect of Interaction between time and group type on HADS Anxiety scores

Hypothesis: There will be significant differences between the group with trackers' selfreported activity levels and the data from their activity trackers.

The findings supported this hypothesis:

The discrepancy between sleep as recorded by the activity trackers and self-reported by participants was calculated by subtracting the self-report data from the data from the activity trackers. Mauchly's test indicated that the assumption of sphericity had not been violated, W(20) = .002, p = .415. There were significant differences in the size of the discrepancy over time, F(1, 6) = 1.36, p = .256, $\eta_p^2 = .185$. On average, participants gave lower estimates of their time spent asleep than recorded by the trackers.

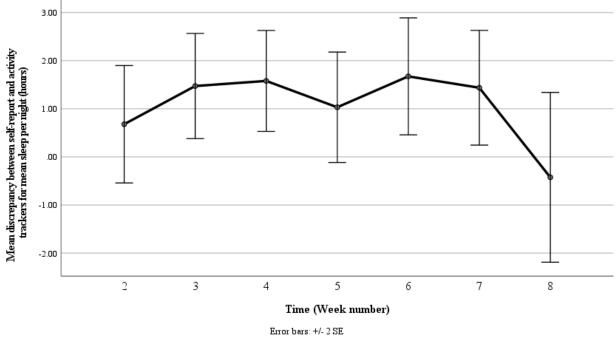


Figure 10

Discrepancy between self-reports and activity trackers for sleep

Hypothesis: There will be significant differences between the group with trackers' selfreported time spent asleep and the data from their activity trackers.

The findings supported this hypothesis:

The discrepancy between activity as recorded by the activity trackers and self-reported by participants was calculated by subtracting the self-report data from the data from the activity trackers. Mauchly's test indicated that the assumption of sphericity had been violated, W(20) = .001, p = .040. Therefore the Greenhouse-Geisser correction was used. There were significant differences in the size of the discrepancy over time, *F* (2.43, 14.6) = 6.07, *p* = .009, η_p^2 = .503. On average, participants gave lower estimates of their activity time than recorded by the trackers.

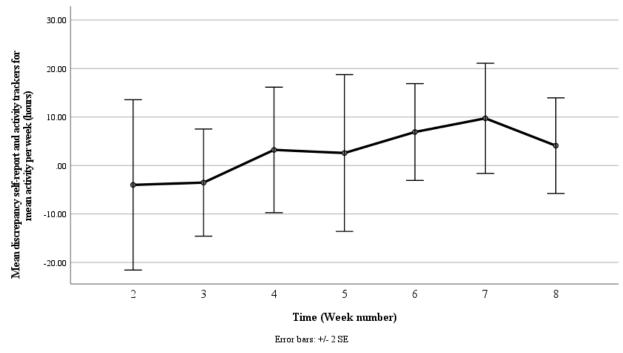


Figure 11

Discrepancy between self-reports and activity trackers for activity

Observed Power (Post-Hoc Power Analyses)

In order to establish whether power may have influenced the results observed and to aid the development of any future research, post-hoc power analyses were conducted. The results are summarised in Table 2:

Table 2

Summary of Observed Power

Measure	Observed power for effect of interaction of time and group (%)	Observed power for effect of group (%)
Self-reported activity	10.6	5.5
Self-reported sleep	12.0	31.7
PSQ-3	19.4	35.6
McGill Sensory	68.7	15.1
McGill Affective	28.9	9.2
McGill VAS	39.7	5.0
SWEMWBS	99.4	63.9
HADS Depression	33.0	5.5
HADS Anxiety	23.6	5.1
Discrepancy between self- reports and activity trackers	46.3 (Effect of Time only)	N/A

Discrepancy between self-	99.5 (Effect of Time only)	N/A
reports and activity trackers		
for sleep		

Reported Adherence

Participants were asked each week if they had been wearing the devices as requested (i.e. at all times when not showering or bathing, doing a water-based activity or charging the device). All participants reported adhering to these instructions at each week of the PMP. It is possible participants may have reported wearing them at all times due to perceived social pressure. The devices themselves were not capable of corroborating their self-reports.

Qualitative responses to questionnaire about experience of using an activity tracker

A content analysis of the responses to the questionnaire about participants in the activity tracker group's experience of using the activity trackers was conducted. The findings are summarised in Table 4:

Table 4

Content analysis of responses to questionnaire about experiences of using an activity tracker

Theme	Description	Examples	Frequency (number of participants giving similar responses)
Activity monitoring	Comments about the	"Useful to know how	7
	utility of being able	many steps taken and	
	to track activity.	also heart-rate"	
Sleep monitoring	Comments about the	"Was able to look at	4
	utility of being able	my sleep patterns"	
	to track sleep.		
Frequent usage	Comments about	"Wore it every day"	7
	frequent use of the	"Always on except	
	device.	for charging"	
Mental health	Comments about	"Gave me a mental	2
benefits	benefits to mental	boost"	
	health.		
Physical health	Comments about	"Helped with weight-	1
benefits	benefits to physical	loss"	
	health.		
Positive behaviour	Comments about the	"Made me do more"	4
change	device facilitating	"Looking at it pushed	

	behaviour change.	me more"	
	-	"Wanted to achieve	
		10,000 steps a day"	
Improved social	Comments about	"Got me active with	3
engagement	how having the	the kids"	
	device change	"Went to the gym	
	approach to social	and met new people"	
	life		
Increased reflection	Comments about the	"Having a Fitbit	3
	device facilitating	made me realise I	
	reflection on own	was not doing as	
	activity.	much as I could or	
		should do"	
Desire for	Comments about	"I have now bought	2
continuation	acquiring own	one [activity tracker]	
	devices following the	so I can continue	
	study.	with this"	
Reliability issues	Comments about the	"Did not get many	2
	reliability of the	prompts"	
	devices.	"First Fitbit did not	
		work properly - kept	
		dying"	

Discussion

Summary of findings and implications

This study aimed to explore whether the addition of activity trackers to a pain management programme was feasible and beneficial to participants experiencing chronic pain. Participants in the activity tracker group's responses to outcome measures were not significantly different to those that did not receive activity trackers, except for their responses to a measure of wellbeing (SWEMWBS) where their responses suggested lower wellbeing over time. This finding is contrary to what was hypothesised; a potential explanation is that the devices made those in the activity tracker group aware of their levels of inactivity (as participants commented on the questionnaire) and that this awareness impacted their wellbeing. Whether such a decrease in wellbeing would continue long-term as participants increase their activity remains to be investigated. The fear-anxiety-avoidance model would posit that if an individual continues to engage with their pain rather than avoiding it, they should achieve some level of recovery (Asmundson et al., 2004).

With regards to clinical significance, the group without trackers had larger improvements than the group with trackers on the HADS for both anxiety and depression scores. The findings of the post-hoc tests suggest that with regards to outcomes on established measures, including activity trackers in an eight week PMP is as effective or ineffective as conducting a PMP as usual.

Another possibility is that whilst participants find the devices helpful to some degree, the underlying cause of their distress is not being acted on. Psychodynamic theories of chronic pain suggest that family dynamics, past traumatic experiences and personality characteristics are all factors in an individual's experience of their pain (Adams, Ravey, & Taylor, 1996). Activity trackers may not facilitate significant change in these areas and so levels of wellbeing and subjective pain levels may be subsequently unaffected.

Finkelstein et al. (2016) suggested that activity trackers were sufficient motivators to increase activity levels in healthy volunteers, the findings of this study could suggest that this is not the case for individuals experiencing chronic pain. Philips (1987) suggested that individuals' own beliefs in their abilities and beliefs about specific situations resulting in pain can influence their decision to continue avoidance. Whilst activity trackers prompt activity, it may be that users' beliefs in their abilities to engage in activity without further injury prevent them from engaging in increased levels of activity; which would provide evidence against these beliefs. It could also be possible that use of activity trackers does not provide positive reinforcement which is sufficient to compete with the negative reinforcement that individuals experiencing chronic pain may get from sedentary behaviour (Asmundson et al, 2004). Vlaeyen and Linton (2012) suggest the extinction of pain-related fear can be achieved through the creation of new nonthreat associations via three pathways: direct experience, observation and verbal instruction. Activity trackers arguably could be able to help individuals experiencing chronic pain acquire direct experience, through prompting activity, but potential barriers to engagement remain.

Participants in the activity tracker group provided mostly positive feedback about the devices, with individuals noting benefits to their mental health, behaviour and social life. This finding could suggest that outcome measures do not capture the benefits that activity trackers can provide but equally could be a demonstration of demand characteristics from participants who do not wish to appear ungrateful for being loaned a device. However, contrary to such a potential explanation, some participants bought their own activity tracking devices following the study; suggesting that they have a genuine feeling that the devices are beneficial.

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Discrepancies between the data from the activity tracking devices and the self-reports from participants

There were significant differences between the activity and sleep self-reports provided by participants and the activity and sleep data gathered by the activity trackers. These differences could suggest that the devices do not accurately record the activity and sleep of the wearer; this would be a considerable limitation of the devices and would suggest a need for refinement of their design before they could be used for clinical purposes. However it remains possible that individuals in chronic pain have difficulties accurately reporting their sleep and activity. If this is the reason discrepancies are present, there would be significant value to clinicians in using such devices with this population. Further research is required in order to provide evidence for either of these hypotheses.

Strengths and Limitations

The findings of the post-hoc power analyses could suggest that some of the differences seen between the groups may have been significant if the study had a larger sample. Whilst this project was always intended to be a pilot study, sample size remains a significant limitation of this study. There was a limited pool of potential participants as there were limited places on the Pain Management Programme and a higher number of people who dropped out of the PMP or opted-out before it began than usual. Recruitment of participants to the activity tracker condition proved challenging. Many participants wanted to take part in the research but were not willing to wear activity tracking devices (so took part in the group that did not wear devices). This experience is somewhat contrary to the findings of previous research about the acceptability of such devices (Janevic, Shute, Murphy, & Piette, 2020). It may have been beneficial to gather formal feedback on why participants did not want to be part of the tracker condition, this was an oversight of this study and future studies may wish to incorporate this.

This study was constrained by the limits of its budget, the devices that the researchers had access to were four years old. Some participants commented that the devices were too outdated to be desirable for use. More advanced activity trackers have been produced since and it remains possible that such devices would have provided more accurate measurements of activity and sleep.

There were large standard errors around the mean for most measures; it is possible that outliers in the activity tracker group affected the analyses such that non-significant differences were more likely. There were a number of factors which were not measured that could have influenced the findings. The medications used by participants were not recorded; it is possible that some participants may have been benefiting from pain medications or sleep medications and that this affected the means for the PSQ-3 and McGill Pain Questionnaire for their respective groups. It is also possible that some participants engaged with the content of the PMP more than others and consequently improved more on measures than participants that did not engage as well. This may have been influenced by participants' readiness to change, which was not controlled for. Some participants may also have undertaken more treatments than others before coming onto the programme (for example some may have had individual psychological therapy where as others may not have) and this may have influenced how much benefit they got from the PMP.

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As discussed above, the study only examined the effect of the devices in the short term (eight weeks); a longitudinal study over a longer time period may have found different results as participants became more acquainted with devices and how they can be used.

A further limitation was that participant compliance with wearing the devices was hard to interpret. With no way to ensure that participants were wearing the devices at all times beyond their own reports, there remains the possibility that participants undertook activity without wearing their devices and so some data was potentially lost.

Conducting research in a clinical setting has the advantage of ecological validity and the potential to yield results which can directly influence clinical practice but this is contrasted against a lack of control of extraneous variables and a need to conduct the research in a way that is unobtrusive as possible to working professionals. For this study, the need for the completion of measures to be reasonably brief as not to disrupt the delivery of the PMP was a factor which influenced the selection of the measures. Clinical research has to take place in a way and on a timescale which is compatible with the clinical setting, in the case of this study there were limited people who were eligible for the pain management programme (as well as an increased number of people who opted out of attending a PMP) and set times of the year when the PMP took place.

Clinical considerations and implications for clinical practice

Conducting this study raised a number of issues to consider in the event that the activity tracking devices are incorporated into Pain Management Programmes in the future. Two devices had to be swapped for replacement activity trackers (of the same type) as they had poorly performing batteries. Maintaining and replacing devices could become costly for pain

clinics long term. In addition, during the study, two of the activity trackers malfunctioned and had to be reprogrammed. Whilst the principal researcher had the technical expertise to rectify the problem, it cannot reasonably be expected that all members of an MDT would have the knowledge needed to do so. Similarly, an understanding of how activity tracking devices work was necessary in order to answer the questions of participants throughout the PMP and so MDT members would need to familiarise themselves with this information if this technology was to be utilised routinely.

With regards to the clinical utility of activity tracking devices, the findings of this study suggest that there may be limited benefit from the use of such devices, with no significant improvement in outcome measures over delivering a normal pain management programme being seen. However, as participants reported finding the devices beneficial and for the most part the devices appear non-maleficent, a role for activity trackers may remain. Further research on a larger scale may demonstrate significant differences on outcome measures or that there are additional factors which influence who may benefit from using an activity tracker.

Conclusion

The findings of the current study provide mixed evidence for the use of activity trackers in the management of chronic pain. Whilst participants provided positive feedback about the benefits of using the devices, data from outcome measures and self-report data suggest that the devices provide no significant benefit over only attending a pain management programme. In addition, there remains ambiguity as to the accuracy of measurements provided by the devices. This study has demonstrated that activity trackers can be incorporated into a pain management programme unobtrusively, but further large scale, longterm research into efficacy with up to date activity trackers is needed before such devices can be considered for widespread use as part of the management of chronic pain.

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Part Three: Appendices

Appendix A: Guidance for submission to Clinical Psychology: Science and Practice

Author Guidelines

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Mixed Methods Appraisal Tool (MMAT) - Version 2011

For dissemination, application, and feedback: Please contact pierre.pluye@mcgill.ca, Department of Family Medicine, McGill University, Canada.

The MMAT is comprised of two parts (see below): criteria (Part I) and tutorial (Part II). While the content validity and the reliability of the pilot version of the MMAT have been examined, this critical appraisal tool is still in development. Thus, the MMAT must be used with caution, and users' feedback is appreciated. Cite the present version as follows.

Pluye, P., Robert, E., Cargo, M., Bartlett, G., O'Cathain, A., Griffiths, F., Boardman, F., Gagnon, M.P., & Rousseau, M.C. (2011). *Proposal: A mixed methods appraisal tool for systematic mixed studies reviews.* Retrieved on [date] from http://mixedmethodsappraisaltoolpublic.pbworks.com. Archived by WebCite[®] at http://www.webcitation.org/5tTRTc9yJ

Purpose: The MMAT has been designed for the appraisal stage of complex systematic literature reviews that include qualitative, quantitative and mixed methods studies (mixed studies reviews). The MMAT permits to concomitantly appraise and describe the methodological quality for three methodological domains: mixed, qualitative and quantitative (subdivided into three sub-domains: randomized controlled, non-randomized, and descriptive). Therefore, using the MMAT requires experience or training in these domains. E.g., MMAT users may be helped by a colleague with specific expertise when needed. The MMAT allows the appraisal of most common types of study methodology and design. For appraising a qualitative study, use section 1 of the MMAT. For a quantitative study, use section 2 or 3 or 4, for randomized controlled, non-randomized, and descriptive studies, respectively. For a mixed methods study, use section 1 for appraising the qualitative component, the appropriate section for the quantitative component (2 or 3 or 4), and section 5 for the mixed methods component. For each relevant study selected for a systematic mixed studies review, the methodological quality can then be described using the corresponding criteria. This may lead to exclude studies with lowest quality from the synthesis, or to consider the quality of studies for contrasting their results (e.g., low quality vs. high).

Scoring metrics: For each retained study, an overall quality score may be not informative (in comparison to a descriptive summary using MMAT criteria), but might be calculated using the MMAT. Since there are only a few criteria for each domain, the score can be presented using descriptors such as *, **, ***, and ****. For qualitative and quantitative studies, this score can be the number of criteria met divided by four (scores varying from 25% (*) -one criterion met- to 100% (****) -all criteria met-). For mixed methods research studies, the premise is that the overall quality of a combination cannot exceed the quality of its weakest component. Thus, the overall quality score is the lowest score of the study components. The score is 25% (*) when QUAL=1 or QUAN=1 or MM=0; it is 50% (**) when QUAL=2 or QUAN=2 or MM=1; it is 75% (***) when QUAL=3 or QUAN=3 or MM=2; and it is 100% (****) when QUAL=4 and QUAN=4 and MM=3 (QUAL being the score of the qualitative component; QUAN the score of the quantitative component).

Rationale: There are general criteria for planning, designing and reporting mixed methods research (Creswell and Plano Clark, 2010), but there is no consensus on key specific criteria for appraising the methodological quality of mixed methods studies (O'Cathain, Murphy and Nicholl, 2008). Based on a critical examination of 17 health-related systematic mixed studies reviews, an initial 15-criteria version of MMAT was proposed (Pluye, Gagnon, Griffiths and Johnson-Lafleur, 2009). This was pilot tested in 2009. Two raters assessed 29 studies using the pilot MMAT criteria and tutorial (Pace, Pluye, Bartlett, Macaulay et al., 2010). Based on this pilot exercise, it is anticipated that applying MMAT may take on average 15 minutes per study (hence efficient), and that the Intra-Class Correlation might be around 0.8 (hence reliable). The present 2011 revision is based on feedback from four workshops, and a comprehensive framework for assessing the quality of mixed methods research (O'Cathain, 2010).

Conclusion: The MMAT has been designed to appraise the *methodological quality* of the studies retained for a systematic mixed studies review, not the quality of their *reporting* (writing). This distinction is important, as good research may not be 'well' reported. If reviewers want to genuinely assess the former, companion papers and research reports should be collected when some criteria are not met, and authors of the corresponding publications should be contacted for additional information. Collecting additional data is usually necessary to appraise *qualitative research and mixed methods studies*, as there are no uniform

standards for reporting study characteristics in these domains (<u>www.equator-network.org</u>), in contrast, e.g., to the CONSORT statement for reporting randomized controlled trials (<u>www.consort-statement.org</u>).

Authors and contributors: Pierre Pluye¹, Marie-Pierre Gagnon², Frances Griffiths³ and Janique Johnson-Lafleur¹ proposed an initial version of MMAT criteria (Pluye et al., 2009). Romina Pace¹ and Pierre Pluye¹ led the pilot test. Gillian Bartlett¹, Belinda Nicolau⁴, Robbyn Seller¹, Justin Jagosh¹, Jon Salsberg¹ and Ann Macaulay¹ contributed to the pilot work (Pace et al., 2010). Pierre Pluye¹, Émilie Robert⁵, Margaret Cargo⁶, Alicia O'Cathain⁷, Frances Griffiths³, Felicity Boardman³, Marie-Pierre Gagnon², Gillian Bartlett¹, and Marie-Claude Rousseau⁸ contributed to the present 2011 version.

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PART I. MMAT criteria & one-page template (to be included in appraisal forms)

Types of mixed methods	Methodological quality criteria (see tutorial for definitions and examples)		Responses	
study components or primary studies		Yes	No Can't tell	Comments
Screening questions	• Are there clear qualitative and quantitative research questions (or objectives*), or a clear mixed methods question (or objective*)?			
(for all types)	• Do the collected data allow address the research question (objective)? E.g., consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components).			
	Further appraisal may be not feasible or appropriate when the answer is 'No' or 'Can't tell' to one or both scree	ning qı	uestions.	
1. Qualitative	1.1. Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)?			
	1.2. Is the process for analyzing qualitative data relevant to address the research question (objective)?			
	1.3. Is appropriate consideration given to how findings relate to the context, e.g., the setting, in which the data were collected?			
	1.4. Is appropriate consideration given to how findings relate to researchers' influence, e.g., through their interactions with participants?			
2. Quantitative	2.1. Is there a clear description of the randomization (or an appropriate sequence generation)?			
randomized controlled (trials)	2.2. Is there a clear description of the allocation concealment (or blinding when applicable)?			
	2.3. Are there complete outcome data (80% or above)?			
	2.4. Is there low withdrawal/drop-out (below 20%)?			
3. Quantitative non-	3.1. Are participants (organizations) recruited in a way that minimizes selection bias?			
randomized	3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?			
	3.3. In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups?			
	3.4. Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?			
4. Quantitative	4.1. Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?			
descriptive	4.2. Is the sample representative of the population understudy?			
-	4.3. Are measurements appropriate (clear origin, or validity known, or standard instrument)?			

	4.4. Is there an acceptable response rate (60% or above)?			
5. Mixed methods	5.1. Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)?			
	5.2. Is the integration of qualitative and quantitative data (or results*) relevant to address the research question (objective)?			
	5.3. Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative			
	data (or results*) in a triangulation design?			
	Criteria for the qualitative component (1.1 to 1.4), and appropriate criteria for the quantitative component (2.1 to 2.4, or 3.1 t	to 3.4, or 4.1	to 4.4), m	ust be also applied.

*These two items are not considered as double-barreled items since in mixed methods research, (1) there may be research questions (quantitative research) or research objectives (qualitative research), and (2) data may be integrated, and/or qualitative findings and quantitative results can be integrated.

PART II. MMAT tutorial

Types of mixed methods study components or primary studies	Methodological quality criteria
1. Qualitative	1.1. Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question
Common types of qualitative research methodology include:	(objective)?
A. Ethnography The aim of the study is to describe and interpret the shared cultural	E.g., consider whether (a) the selection of the participants is clear, and appropriate to collect relevant and rich data; and (b) reasons why certain potential participants chose not to participate are explained.
behaviour of a group of individuals.	1.2. Is the process for analyzing qualitative data relevant to address the research question (objective)?
 B. Phenomenology The study focuses on the subjective experiences and interpretations of a phenomenon encountered by individuals. 	E.g., consider whether (a) the method of data collection is clear (in depth interviews and/or group interviews, and/or observations and/or documentary sources); (b) the form of the data is clear (tape recording, video material, and/or field notes for instance); (c) changes are explained when methods are altered during the study; and (d) the qualitative data analysis addresses the question.
C. Narrative The study analyzes life experiences of an individual or a group.	1.3. Is appropriate consideration given to how findings relate to the context, e.g., the setting, in which the data were collected? *
 D. Grounded theory Generation of theory from data in the process of conducting research (data collection occurs first). 	E.g., consider whether the study context and how findings relate to the context or characteristics of the context are explained (how findings are influenced by or influence the context). "For example, a researcher wishing to observe care in an acute hospital around the clock may not be able to study more than one hospital. () Here, it is essential to take care to describe the context and particulars of the case [the hospital] and to flag up for the reader the similarities and differences between the case and other settings of the same type" (Mays & Pope, 1995).
E. Case study In-depth exploration and/or explanation of issues intrinsic to a particular case. A case can be anything from a decision-making	The notion of context may be conceived in different ways depending on the approach (methodology) tradition.

process, to a person, an organization, or a country.	1.4. Is appropriate consideration given to how findings relate to researchers' influence, e.g., through their interactions with participants? *
F. Qualitative description	
There is no specific methodology, but a qualitative data collection	E.g., consider whether (a) researchers critically explain how findings relate to their perspective, role, and interactions with participants
and analysis, e.g., in-depth interviews or focus groups, and hybrid	(how the research process is influenced by or influences the researcher); (b) researcher's role is influential at all stages (formulation of a
thematic analysis (inductive and deductive).	research question, data collection, data analysis and interpretation of findings); and (c) researchers explain their reaction to critical events that occurred during the study.
Key references: Creswell, 1998; Schwandt, 2001; Sandelowski, 2010.	
	The notion of reflexivity may be conceived in different ways depending on the approach (methodology) tradition. E.g., "at a minimum,
	researchers employing a generic approach [qualitative description] must explicitly identify their disciplinary affiliation, what brought
	them to the question, and the assumptions they make about the topic of interest" (Caelli, Ray & Mill, 2003, p. 5).

*See suggestion on the MMAT wiki homepage (under '2011 version'): Independent reviewers can establish a common understanding of these two items prior to beginning the critical appraisal.

Types of mixed methods study components or primary studies	Methodological quality criteria
2. Quantitative randomized controlled (trials)	2.1. Is there a clear description of the randomization (or an appropriate sequence generation)?
Randomized controlled clinical trial: A clinical study in which individual participants are allocated to intervention or control groups by randomization (intervention assigned by researchers).	In a randomized controlled trial, the allocation of a participant (or a data collection unit, e.g., a school) into the intervention or control group is based solely on chance, and researchers describe how the randomization schedule is generated. "A simple statement such as 'we randomly allocated' or 'using a randomized design' is insufficient".
	<i>Simple randomization:</i> Allocation of participants to groups by chance by following a predetermined plan/sequence. "Usually it is achieved by referring to a published list of random numbers, or to a list of random assignments generated by a computer".
Key references: Higgins & Green, 2008; Porta,	
2008; Oxford Center for Evidence based medicine, 2009.	<i>Sequence generation:</i> "The rule for allocating interventions to participants must be specified, based on some chance (random) process". Researchers provide sufficient detail to allow a readers' appraisal of whether it produces comparable groups. E.g., blocked randomization (to ensure particular allocation ratios to the intervention groups), or stratified randomization (randomization performed separately within strata), or minimization (to make small groups closely similar with respect to several characteristics).
	2.2. Is there a clear description of the allocation concealment (or blinding when applicable)?
	The allocation concealment protects assignment sequence until allocation. E.g., researchers and participants are unaware of the assignment sequence up to the point of allocation. E.g., group assignment is concealed in opaque envelops until allocation.
	The blinding protects assignment sequence after allocation. E.g., researchers and/or participants are unaware of the group a participant is allocated to during the course of the study.

2.3. Are there complete outcome da	ta (80% or above)?		
E.g., almost all the participants contri	E.g., almost all the participants contributed to almost all measures.		
2.4. Is there low withdrawal/drop-o	out (below 20%)?		
E.g., almost all the participants comp	leted the study.		
Types of mixed methods study components or primary studies	Methodological quality criteria		
3. Quantitative non-randomized	3.1. Are participants (organizations) recruited in a way that minimizes selection bias?		
 Common types of design include (A) non-randomized controlled trials, and (B-C-D) observational analytic study or component where the intervention/exposure is defined/assessed, but not assigned by researchers. A. Non-randomized controlled trials The intervention is assigned by researchers, but there is no randomization, e.g., a pseudo-randomization. A non-random method of allocation is not reliable in producing alone similar groups. 	At recruitment stage: For cohort studies, e.g., consider whether the exposed (or with intervention) and non-exposed (or without intervention) groups are recruited from the same population. For case-control studies, e.g., consider whether same inclusion and exclusion criteria were applied to cases and controls, and whether recruitment was done independently of the intervention or exposure status. For cross-sectional analytic studies, e.g., consider whether the sample is representative of the population.		
 B. Cohort study Subsets of a defined population are assessed as exposed, not exposed, or exposed at different degrees to factors of interest. Participants are followed over time to determine if an outcome occurs (prospective longitudinal). 	3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?At data collection stage:		
 C. Case-control study Cases, e.g., patients, associated with a certain outcome are selected, alongside a corresponding group of controls. Data is collected on whether cases and controls were exposed to the factor under study (retrospective). 			
D. Cross-sectional analytic study At one particular time, the relationship between health-related characteristics	For non-randomized controlled trials, the intervention is assigned by researchers, and so consider whether there was absence/presence of a contamination. E.g., the control group may be indirectly exposed to the intervention through family or community relationships.		

(outcome) and other factors (intervention/exposure) is examined. E.g., the frequency of outcomes is compared in different population sub-groups according to the presence/absence (or level) of the intervention/exposure.Key references for observational analytic studies: Higgins & Green, 2008; Wells, Shea, O'Connell, Peterson, et al., 2009.	 3.3. In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups? At data analysis stage: For cohort, case-control and cross-sectional, e.g., consider whether (a) the most important factors are taken into account in the analysis; (b) a table lists key demographic information comparing both groups, and there are no obvious dissimilarities between groups that may account for any differences in outcomes, or dissimilarities are taken into account in the analysis. 3.4. Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?
Types of mixed methods study components or primary studies	Methodological quality criteria
4. Quantitative descriptive studies	4.1. Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?
Common types of design include single-group studies:A. Incidence or prevalence study without comparison group In a defined population at one particular time, what is happening in a population, e.g.,	E.g., consider whether (a) the source of sample is relevant to the population under study; (b) when appropriate, there is a standard procedure for sampling, and the sample size is justified (using power calculation for instance).
frequencies of factors (importance of problems), is described (portrayed).	4.2. Is the sample representative of the population understudy?
 B. Case series A collection of individuals with similar characteristics are used to describe an outcome. 	E.g., consider whether (a) inclusion and exclusion criteria are explained; and (b) reasons why certain eligible individuals chose not to participate are explained.
 C. Case report An individual or a group with a unique/unusual outcome is described in details. Key references: Critical Appraisal Skills Programme, 2009; Draugalis, Coons & Plaza, 	 4.3. Are measurements appropriate (clear origin, or validity known, or standard instrument)? E.g., consider whether (a) the variables are clearly defined and accurately measured; (b) measurements are justified and appropriate for answering the research question; and (c) the measurements reflect what they are supposed to measure.
2008.	4.4. Is there an acceptable response rate (60% or above)?
	The response rate is not pertinent for case series and case report. E.g., there is no expectation that a case series would include all patients in a similar situation.

Types of mixed methods study components or primary studies	Methodological quality criteria
5. Mixed methods Common types of design include:	5.1. Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)?
 A. Sequential explanatory design The quantitative component is followed by the qualitative. The purpose is to explain quantitative results using qualitative findings. E.g., the quantitative results guide the selection of qualitative data sources and data collection, and the qualitative findings contribute to the 	 E.g., the rationale for integrating qualitative and quantitative methods to answer the research question is explained. 5.2. Is the integration of qualitative and quantitative data (or results) relevant to address the research
 interpretation of quantitative results. B. Sequential exploratory design The qualitative component is followed by the quantitative. The purpose is to explore, develop and test an instrument (or taxonomy), or a conceptual framework (or theoretical model). E.g., the qualitative findings inform the quantitative data collection, and the quantitative results allow a generalization of the qualitative findings.	question (objective)? E.g., there is evidence that data gathered by both research methods was brought together to form a complete picture, and answer the research question; authors explain when integration occurred (during the data collection-analysis or/and during the interpretation of qualitative and quantitative results); they explain how integration occurred and who participated in this integration.
 C. Triangulation design The qualitative and quantitative components are concomitant. The purpose is to examine the same phenomenon by interpreting qualitative and quantitative results (bringing data analysis together at the interpretation stage), or by integrating qualitative and quantitative datasets (e.g., data on same cases), or by transforming data (e.g., quantization of qualitative data). 	5.3. Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results)?
 D. Embedded design The qualitative and quantitative components are concomitant. The purpose is to support a qualitative study with a quantitative sub-study (measures), or to better understand a specific issue of a quantitative study using a qualitative sub-study, e.g., the efficacy or the implementation of an intervention based on the views of participants. 	
Key references: Creswell & Plano Clark, 2007; O'Cathain, 2010.	

Appendix C: Data Extraction Tool (Based on Popay et al, 2006)

Participants?	
Any mental health difficulties described?	
What technology was used?	
Qualitative/Quantitative/Mixed?	
Design of study (RCT, Non-RCT, etc)?	
What was the aim of the study?	
What outcome measures were used?	
Any other measurements?	
Main findings?	
Strengths and Limitations?	

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Use nonproprietary names for drugs, and descriptions for devices. Brand name may be mentioned only once within the text (upon first reference), unless essential to the study. For presentation of brand or trade names, include manufacturer's name, city, state and country within parentheses. Upon subsequent reference, use generic drug names or device descriptions only.

AFTER ACCEPTANCE

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Appendix E: Participant Information Sheet

Date: 24/10/19 Version Number: 3.0 IRAS ID: 260287 ♥◎★� UNIVERSITY OF HULL



INFORMATION SHEETS FOR PARTICIPANTS

<u>Title of study: Use of Activity Tracking Technology in Chronic Pain</u> Intervention

I would like to invite you to participate in a research project which forms part of my doctorate research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact me if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The aim of this study is to investigate both whether or not having an activity tracker (Fitbit) is beneficial to people experiencing chronic pain and potential reasons why or why not this is the case.

Why have I been invited to take part?

You are being invited to participate in this study because you have been offered a place on a pain management programme. Staff members at the Department of Psychological Medicine send this information sheet to people who may fulfil the criteria to take part in the study as they may be interested in participating.

What will happen if I take part?

If you agree to take part you will be asked to fill in some additional self-report measures about your sleep and physical activity each week while you undertake the pain management programme along with outcome measures that you would normally be asked to fill in while you undertake the programme, including measures about how much pain you are experiencing and your wellbeing. You may also be are asked to wear an activity monitoring device (a Fitbit) on your wrist while you undertake the pain management programme, from which the researchers will gather data about your levels of physical activity, steps taken and time spent asleep. Not all participants will be asked to wear a Fitbit. If you are asked to wear a Fitbit, you will be asked to link it with an internet enabled device such as a smartphone or a laptop and you will be asked to fill in a questionnaire about your experience of wearing one. Your Lead Professional will be informed that you are taking part in the study. A lead professional is a named NHS worker who will make sure that you, your family, carers and supporters have access to information, and ensures there is appropriate care and support for you. We will ask you to return the Fitbit so that other participants may use it.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. Once you have read the information sheet, please feel free to contact me if you have any questions that will help you make a decision about taking part. If you decide to take part you are asked to sign a consent form and return it to the Department of Psychological Medicine and you will be given a copy of this consent form to keep. Staff from the department of Psychological Medicine will pass consent forms on to me so that they can be stored securely at the University of Hull.

What are the possible risks of taking part?

Participating in the study will require you to fill in some additional self-report measures while you undertake the pain management programme and if you are asked to wear an activity monitoring device, you will be asked to fill in a questionnaire about your experience. The time taken to fill in the measures and questionnaire may be inconvenient to you. Some people may experience emotional distress filling in measures because it may bring to mind difficult issues about your pain. If this happens to you can seek support from your clinical care team, if needed.

What are the possible benefits of taking part?

We cannot promise that you will have any direct benefits from taking part in the study. However, it is hoped that participants may find having a Fitbit helpful in changing their activity levels in a way that may improve wellbeing.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2018 (GDPR). Information about how health researchers use information from patients in line with GDPR can be found at the end of this information sheet.

All of the personal information that you provide will be kept strictly confidential. Any information that could be used to identify you will not be used in the research. To protect your anonymity you will be assigned a numeric code. This will ensure it will not be possible to identify you from the information you provide. Anonymous research data will be stored securely in an on-line storage repository at the University of Hull for a period of ten years.

Anonymous activity data collected by the Fitbit devices will be stored on secure servers belonging to the Fitbit Corporation in line with their privacy policy (which can be accessed at https://www.fitbit.com/uk/legal/privacy-policy). This is a requirement for the Fitbit devices to function. We will request that this data is deleted from the Fitbit servers following the end of the research. This data will also be downloaded to

encrypted NHS devices for analysis with the purposes of answering the research questions. We cannot be responsible for any activity data you choose to download onto your own devices.

Any physical measures and self-reports you fill in will be stored in locked areas at the Department of Psychological Medicine. Anonymised digital copies of these documents will be stored on encrypted NHS devices.

Your contact details will be held securely by the Department of Psychological Medicine. Your consent form will be held securely at the University of Hull.

Who has reviewed this study?

Research studies are reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and been given a favourable opinion by South Central - Oxford C Research Ethics Committee.

Data Protection Statement

The data controller for this project will be the University of Hull. The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest' You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the University of Hull Information Compliance Manager, Mr Luke Thompson (<u>l.thompson3@hull.ac.uk</u>). If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. Any data you have provided up to the point you withdraw will be kept in line with General Data Protection Regulation (2018). No further data will be gathered from you once you have withdrawn.

What will happen to the results of the study?

The results of the study will be summarised in a written thesis as part of a Doctorate in Clinical Psychology. The thesis will be available on the University of Hull's on-line repository https://hydra.hull.ac.uk/ The research may also be published in academic journals or presented at conferences.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact me using the following contact details:

Joel Dalton

Clinical Psychology Aire Building The University of Hull Cottingham Road Hull HU6 7RX E-mail: j.dalton@2017.hull.ac.uk

What if I have further questions, or if something goes wrong?

If you wish to make a complaint about the conduct of the study, you can contact the University of Hull using the research supervisor's details below for further advice and information:

Dr Emma Lewis

Clinical Psychologist/Academic Tutor Aire Building The University of Hull Cottingham Road Hull HU6 7RX Telephone: 01482 464617 Email address: E.Lewis@hull.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.

This section explains how health researchers use information from patients. If you are asked to take part in research, you can ask what will happen in the study.

What is patient data?

When you go to your GP or hospital, the doctors and others looking after you will record information about your health. This will include your health problems, and the tests and treatment you have had. They might want to know about family history, if you smoke or what work you do. All this information that is recorded about you is called patient data or patient information.

When information about your health care joins together with information that can show who you are (like your name or NHS number) it is called identifiable patient information. It's important to all of us that this identifiable patient information is kept confidential to the patient and the people who need to know relevant bits of that information to look after the patient. There are special rules to keep confidential patient information safe and secure.

What sort of patient data does health and care research use?

There are lots of different types of health and care research.

If you take part in a clinical trial, researchers will be testing a medicine or other treatment. Or you may take part in a research study where you have some health tests or answer some questions. When you have agreed to take part in the study, the research team may look at your medical history and ask you questions to see if you are suitable for the study. During the study you may have blood tests or other health checks, and you may complete questionnaires. The research team will record this data in special forms and combine it with the information from everyone else in the study. This recorded information is research data.

In other types of research, you won't need to do anything different, but the research team will be looking at some of your health records. This sort of research may use some data from your GP, hospital or central NHS records. Some research will combine these records with information from other places, like schools or social care. The information that the researcher collects from the health records is research data.

Why does health and care research use information from patients?

In clinical trials, the researchers are collecting data that will tell them whether one treatment is better or worse than other. The information they collect will show how safe a treatment is, or whether it is making a difference to your health. Different people can respond differently to a treatment. By collecting information from lots of people, researchers can use statistics to work out what effect a treatment is having.

Other types of research will collect data from lots of health records to look for patterns. It might be looking to see if any problems happen more in patients taking a medicine. Or to see if people who have screening tests are more likely to stay healthier.

Some research will use blood tests or samples along with information about the patient's health. Researchers may be looking at changes in cells or chemicals due to a disease.

All research should only use the patient data that it really needs to do the research. You can ask what parts of your health records will be looked at.

How does research use patient data?

If you take part in some types of research, like clinical trials, some of the research team will need to know your name and contact details so they can contact you about your research appointments, or to send you questionnaires. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are.

In lots of research, most of the research team will not need to know your name. In these cases, someone will remove your name from the research data and replace it with a code number. This is called coded data, or the technical term is pseudonymised data. For example, your blood test might be labelled with your code number instead of your name. It can be matched up with the rest of the data relating to you by the code number.

In other research, only the doctor copying the data from your health records will know your name. They will replace your name with a code number. They will also make sure that any other information that could show who you are is removed. For example, instead of using your date of birth they will give the research team your age. When there is no information that could show who you are, this is called anonymous data.

Where will my data go?

Sometimes your own doctor or care team will be involved in doing a research study. Often, they will be part of a bigger research team. This may involve other hospitals, or universities or companies developing new treatments. Sometimes parts of the research team will be in other countries. You can ask about where your data will go. You can also check whether the data they get will include information that could show who you are. Research teams in other countries must stick to the rules that the UK uses.

All the computers storing patient data must meet special security arrangements.

If you want to find out more about how companies develop and sell new medicines, the Association of the British Pharmaceutical Industry has information on its <u>website</u> (http://www.abpi.org.uk/).

What are my choices about my patient data?

- You can stop being part of a research study at any time, without giving a reason, but the research team will keep the research data about you that they already have. You can find out what would happen with your data before you agree to take part in a study.
- In some studies, once you have finished treatment the research team will continue to collect some information from your doctor or from central NHS records over a few months or years so the research team can track your health. If you do not want this to happen, you can say you want to stop any more information being collected.

• Researchers need to manage your records in specific ways for the research to be reliable. This means that they won't be able to let you see or change the data they hold about you. Research could go wrong if data is removed or changed.

What happens to my research data after the study?

Researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. You can ask about who will keep it, whether it includes your name, and how long they will keep it.

Usually your hospital or GP where you are taking part in the study will keep a copy of the research data along with your name. The organisation running the research will usually only keep a coded copy of your research data, without your name included. This is kept so the results can be checked.

If you agree to take part in a research study, you may get the choice to give your research data from this study for future research. Sometimes this future research may use research data that has had your name and NHS number removed. Or it may use research data that could show who you are. You will be told what options there are. You will get details if your research data will be joined up with other information about you or your health, such as from your GP or social services.

Once your details like your name or NHS number have been removed, other researchers won't be able to contact you to ask you about future research.

Any information that could show who you are will be held safely with strict limits on who can access it.

You may also have the choice for the hospital or researchers to keep your contact details and some of your health information, so they can invite you to take part in future clinical trials or other studies. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data. Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

What if I don't want my patient data used for research?

You will have a choice about taking part in a clinical trial testing a treatment. If you choose not to take part, that is fine.

In most cases you will also have a choice about your patient data being used for other types of research. There are two cases where this might not happen:

- 1. When the research is using anonymous information. Because it's anonymous, the research team don't know whose data it is and can't ask you.
- 2. When it would not be possible for the research team to ask everyone. This would usually be because of the number of people who would have to be contacted. Sometimes it will be because the research could be biased if some people chose not to agree. In this case a special NHS group will check that the reasons are valid. You can opt-out of your data being used for this sort of research. You can ask your GP about opting-out, or you can <u>find out more</u> (https://www.hra.nhs.uk/information-about-patients/).

Who can I contact if I have a complaint?

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Appendix F: Participant Consent Form

Version number and date: Version 1.1 (24/10/2019)

[IRAS ID: 260287]

CONSENT FORM

Title of study: Use of Activity Tracking Technology in Chronic Pain Intervention

Name of Researcher: Joel Dalton

Please initial box

- 1. I confirm that I have read the information sheet dated 24/10/19 (version 3.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- 3. I understand that relevant sections of my medical notes and data collected during the study may be accessed by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 4. I understand that if I am given an activity tracker as part of the study, it is required that anonymous activity data is stored on servers belonging to Fitbit Corporation in line with their privacy policy.
- 5. I agree to professionals involved in my care being informed of my participation in the study.
- 6. I understand that the information held and maintained by the NHS Foundation Trust may be used to help contact me or provide information about my health status.



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- 7. I give permission for the collection and use of my data to answer the research question in this study.
- 8. I agree to take part in the above study.
- 9. Are you taking part in any other research at this time? Yes/No

If so, please state:

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix G: Ethical Approval

Appendix H: Outline of content of the Pain Management Programme

- Session 1: Introductions Recap on Holistic Model/readiness to change Introduction to Acceptance of Chronic Pain Hopes and Concerns Activity Management (part one) Introduction to Goal Setting Recap/Homework
- Session 2: Feedback (on last session and homework) Psychology of Pain Management (part one) Goal Setting Exercise in gym Introduction to Relaxation Recap/Homework

Session 3: Feedback Barriers and Benefits to Exercise Pain Pathways (part one) Exercise in gym Relaxation Recap/Homework

Session 4: Feedback

Psychology of Pain Management (part two) Anatomy, posture and positions of ease Exercise in gym

	Relaxation Recap/Homework
Session 5:	Feedback
	Activity Management (part two)
	Sleep
	Exercise in gym
	Relaxation
	Recap/Homework
Session 6:	Feedback
	Use of Medication
	Activity Management (part three)
	Exercise in gym
	Relaxation
	Recap

Session 7: Feedback

Psychology of Pain Management (part three)

Pain Pathways (part two)

Exercise in gym

Relaxation

Recap

Session 8: Feedback

Coping with set backs Individual review of progress Exercise in gym Relaxation

Recap

Appendix I: Weekly Self-Report Sheet

Sleep and Activity

Version: 2 (24/04/2019) IRAS: 260287

Please fill in the number of hours spent for the following:

Sleep this week (best estimate)

Average number of hours of sleep each night (e.g. 7 hours):

Activity this week:

Activity/Exercise Type (e.g. walking, swimming, cleaning)	Number of hours spent

Appendix J: Short Warwick-Edinburgh Mental Wellbeing Scale

Appendix K: Pain and Sleep Questionnaire (PSQ-3)

Appendix L: Short-form McGill Pain Questionnaire

[Removed for digital archiving]

Appendix M: Hospital Anxiety and Depression Scale

[Removed for digital archiving]

Appendix N: Experience of using an activity tracker questionnaire and responses

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Experience of using a Fitbit questionnaire

Version: 1 (23/04/2019)

IRAS: 260287

Instructions: Please circle the number of the item that best describes how you feel about each statement.

How many times per week did you look at the data from your Fitbit?

I found looking at the data from my Fitbit helpful.

- 1. Strongly disagree
- 2. Disagree
- 3. Neither agree nor disagree
- 4. Agree
- 5. Strongly agree

Please give reasons as to your answer:

I remembered to wear my Fitbit.

- 1. Strongly disagree
- 2. Disagree
- 3. Neither agree nor disagree
- 4. Agree
- 5. Strongly agree

Please give reasons as to your answer:

Having a Fitbit did not motivate me to increase my activity.

- 1. Strongly disagree
- 2. Disagree
- 3. Neither agree nor disagree
- 4. Agree

5. Strongly agree

Please give reasons as to your answer:

The prompts from the Fitbit made me want to exercise or move more.

- 1. Strongly disagree
- 2. Disagree
- 3. Neither agree nor disagree
- 4. Agree
- 5. Strongly agree

Please give reasons as to your answer:

The Fitbit made me feel more in control of my pain.

- 1. Strongly disagree
- 2. Disagree
- 3. Neither agree nor disagree
- 4. Agree
- 5. Strongly agree

Please give reasons as to your answer:

Having a Fitbit helped me achieve my own goals.

- 1. Strongly disagree
- 2. Disagree
- 3. Neither agree nor disagree
- 4. Agree
- 5. Strongly agree

Please give reasons as to your answer:

Having a Fitbit was not helpful.

- 1. Strongly disagree
- 2. Disagree
- 3. Neither agree nor disagree

4. Agree

5. Strongly agree

Please give reasons as to your answer:

Any other comments:

Responses (Quantitative)

Mean self-reported number of times activity tracker looked at per week: 7.67

Statement			Response (%)		
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I found looking at the data from my Fitbit helpful.	0	0	0	0	100
I remembered to wear my Fitbit.	0	0	0	0	100
Having a Fitbit did not motivate me to increase my activity.	14.29	85.71	0	0	0
The prompts from the Fitbit made me want to exercise or move more.	0	0	0	100	0
The Fitbit made me feel more in control of my pain.	0	0	100	0	0
Having a Fitbit helped me achieve my own goals.	0	0	0	71.42	28.57
Having a Fitbit was not helpful.	100	0	0	0	0

Appendix O: Epistemological Statement

Pragmatism

Epistemology entails the nature of knowledge and how we go about gaining it (Ritchie, Lewis, Nicholls, & Ormston, 2013). One epistemological position is pragmatism.

With regards to the nature of knowledge, pragmatists value truth over the method of which one arrives at knowledge. Pragmatists take the position of that which is useful is true (Peirce & Moore, 1986). Belief becomes knowledge through experimentation and practice in the world (Peirce & Moore, 1986), known as inquiry (Peirce & Moore, 1986). Inquiry is not just about knowledge construction, it is also required to maintain said knowledge by affirming its truth (through rigorous testing, experimentation and corroboration) (Misak, 2004). As such, pragmatism views knowledge as both the goal and product of inquiry. Effectively, if knowledge is useful (and remains useful), it can be considered truth.

Pragmatism holds that the methods of inquiry used should be the ones best suited to the area being investigated (Kaushik & Walsh, 2019). Positivists traditionally use quantitative methods and deductive reasoning in contrast to those with a constructivism stance who use qualitative approaches and inductive reasoning (Kaushik & Walsh, 2019). Pragmatists instead make use of a more a flexible approach, seeing the different research methods as tools to be used to varying degrees in service of the research question (Kaushik & Walsh, 2019).

A phenomenological problem with pain

The lack of tangibility of pain presents a unique problem: an individual may report a level of pain higher than would be expected from the observable tissue damage (Asmundson, Norton,

& Vlaeyen, 2004). The biopsychosocial approach to chronic pain essentially holds that pain is not an objective reality but subjective to the individual (Asmundson et al., 2004). Whilst the level of pain an individual is experiencing may be subjective, the need for this pain to be managed remains. Pragmatism concerns itself with the consequences of research (Kaushik & Walsh, 2019); in this case the research was conducted with the hopes of establishing the basis for a new approach to managing chronic pain; something the researchers would consider potential knowledge on the basis that what could be found could be useful.

Mixed Methods

From a pragmatist stance, it was important that any findings would be useful in the context of existing approaches to pain management. In order to investigate the potential utility of activity trackers in the treatment of chronic pain, the principal researcher designed a study which could investigate what differences in outcome using activity trackers would lead to compared to an established approach.

However, the principal researcher wanted to ensure that all benefits of and issues with the devices were captured as well as gathering data which might suggest why the devices were or were not helpful. As such, the principal researcher also designed a questionnaire for participants in the group using the devices. The data from the responses questionnaire presented a contrasting picture to the findings of the statistical analyses of the outcome and self-report data. Without the mixed methods approach, less flexible conclusions may have been suggested. Thus the potential knowledge drawn from the work is arguably more likely to survive future experimentation.

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Empirical

The Beginning

Technology has always been something I have had an interest in, some of my earliest memories are sitting in my family's spare room trying to get some piece of hardware or software to work as intended. Chronic pain was the topic I found most interesting during the third year of my undergraduate degree. Unlike the majority of my peers, I even chose to write about it in one of our final exams. When I heard that the clinician that taught me at undergraduate had acquired a set of activity trackers for potential use with individuals experiencing chronic pain but had never got around to exploring this approach, I was intrigued. I expressed my interest in conducting a piece of research and met with the clinicians to pitch how I could conduct the research. Luckily, the clinicians liked my ideas and even provided me with an activity tracker to better acquaint myself with. Knowing that I was setting out on an ambitious piece of research, I began the task of formally writing up a research proposal and preparing to undertake the research. I was aware that there would be significant setup needed in order to gather the data I wanted from the devices as well as directly from the participants.

The Middle

After finally receiving ethical approval, the time came to recruit participants and prepare the activity trackers to be used. Recruitment to the activity tracker group proved challenging, with the appeal of the activity trackers not being as high as expected. The fact that the devices

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were not recent and were basic models was commented on. I reflected on the pace of adoption of technology. Technology once considered cutting edge and desirable is now considered not worth bothering with by some. Getting the activity trackers to work as intended also proved challenging at times, with many factory resets and troubleshooting needed before they were ready to be handed out to participants. The laborious nature of this gave me a greater appreciation for the work of researchers in this field.

Once set up however, the groups ran reasonably well. Participants were seen to be wearing their devices and were quick to raise any technical problems they were having. Collecting the data went as intended for the most part. The emergence of COVID-19 toward the end of data collection was an unexpected complication, which resulted in participants not returning post-PMP measures I had intended to include in the analysis (the Pain Stages of Change Questionnaire and Self-Experience Questionnaire). This was disappointing but understandable given the circumstances.

The next challenge was collating that data such that it could be analysed. I have to admit that I had underestimated just how much time this task would take. From this I took further appreciation of the efforts of researchers in this field and recognised why adoption of artificial intelligence and machine learning is a growing area.

Analysing the data was not without its challenges, but refreshing my knowledge of statistics allowed me to conduct the analyses as I had intended. I reflected on how this is a reminder not to forget the skills I have acquired on my journey to getting to this level of education.

The End

This research was always considered a starting point; I knew that I did not have the resources to conduct a large scale piece of research. While I had expected to find more significant results, I have reflected that it is equally important to demonstrate when something does not improve an intervention as when it does. I hope that this work provides some small benefit to the field, even if it simply leads to more research being conducted. The challenges I faced have given me an appreciation for the complexity of conducting research with a clinical population. I believe at heart I have always been a pragmatist, concerned more with finding something which can help people than what investigative tools I use to achieve this, I feel that this research has cemented my position of flexibility and going forward I will use whatever approach I feel is best in service of discovering useful information. That said, I believe that my experience of conducting this research has made me more open to using mixed methods and qualitative methods in future research.

I was glad that the participants found the devices helpful and that some chose to continue experimenting independently by buying their own devices. I hope that they continue to find them helpful to manage their pain, perhaps one day they will be able to say they were "early adopters" of such an approach.

Systematic Literature Review

The Beginning

I have to be honest in saying that I always found myself drawn to working on my empirical research more than my SLR. I understood the importance of systematic literature reviews in

collating knowledge and had benefitted from SLRs throughout my studies. Reflecting on this, I believe that writing the SLR was something of a daunting prospect for me.

The Middle

Once I established what I wanted to write my SLR, gathering papers and reading about the field was actually engaging. I started to see patterns in what was being written about and had thoughts as to what I might draw from each paper. However writing for the SLR up was still something I avoided, choosing to focus on my empirical section. Eventually, I recognised my own avoidance and challenged myself to begin writing longer sections of my SLR. Once I got writing, it became a lot easier. I reflected that I often guide service users to not engage in avoidance, I will remember that I too must gather the same courage sometimes.

The End

I am glad to be able to say that I finished my SLR. It may not be my favourite part of my thesis but it has value in how it informed my final thoughts about my empirical work. Conducting the SLR was a valuable reminder of how new innovations are constantly being tested, and how we live in an ever changing world with regards to technology. Use of wearable technology continues to expand, with some nations' healthcare services deploying it to help with the fight against COVID-19. I have been known to joke that one day mental health care will be automated, but perhaps that will not be so far from the truth.