

EXPLORATION OF SELF-MONITORING AS A THEORY-DRIVEN
MANAGEMENT APPROACH FOR CHRONIC PAIN

by

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Submitted in partial fulfilment of the requirements
for the degree of Master of Science

at

Dalhousie University
Halifax, Nova Scotia
August 2014

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DEDICATION

For my mother: who has been a continuous source of love, support, encouragement, and gentle (yet persistent) reminders to take my vitamins and get enough sleep throughout this grueling process. Without her, I could not have succeeded to such a level of satisfying accomplishment. Our often used mantra has applied to many situations over the years and became a daily theme of this journey: *“Breathe deep, seek peace.”*

This thesis is for you, Mom.

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ABSTRACT

Theory is often recommended as a framework for guiding hypothesized mechanisms of effect. There is limited guidance about how to use theory in intervention development.

We used two novel approaches to explore theory as a framework to guide intervention development: 1) systematic review to evaluate use of theory in existing interventions, 2) pilot study to test support for theory from reported experiences. We used the social cognitive theory of self-regulation to explore self-monitoring as a potential chronic pain management strategy.

We used systematic review to identify theory use within interventions that reported being developed using theory. We propose using review to identify whether theory is a feasible intervention framework. Our pilot study found participant reports were a feasible source to identify theory support. We propose methods to identify theoretical mechanisms for consideration of intervention development. This work provides preliminary investigation into exploring use of theory to guide development of interventions.

LIST OF ABBREVIATIONS USED

QUIPS	Quality in Prognosis Studies
PMR	Progressive muscle relaxation
CBT	Cognitive behavioral therapy
BFB	Biofeedback
AT	Autogenic training
VAS	Visual analog scale

ACKNOWLEDGEMENTS

I extend my appreciation to my family and friends for enduring this thesis alongside me, with patience and love ready at a moment's notice. Thank you, Mom, for believing in me and for your excellent advice for improving the thesis and defense presentations. Thank you, Anthony, for standing by me as I put my head down and focused, and for your comfort whenever it was needed. Thank you, Robynne, for reminding me that there will be life after my thesis, and for always being confident that I will finish and excel. You have all made me feel inspired, special, and incredibly loved.

I thank my thesis committee, including my supervisors Dr. Jill Hayden and Dr. Patrick McGrath, and committee member Dr. Anna Huguet for their support and guidance. Although we explored many paths, the final destination of this thesis is a great one.

I would also like to thank the Centre for Research in Family Health of the IWK Health Centre for provision of data for analysis. I thank Sharlene Rozario for her assistance as a second reviewer for both of the thesis studies. I appreciate the extensive help from Dalhousie's library and Document Delivery that provided me with access to thousands of journal articles for my systematic review.

I am very grateful for the funding support of the Nova Scotia Cochrane Resource Centre, and the Department of Community Health and Epidemiology.

CHAPTER 1: Introduction

1.1 Chronic Pain Epidemiology

Chronic pain is highly prevalent in the general population, with 7-25% adults and 8-49% of youth estimated, at any given time, to have continuous or recurring pain that has lasted for least three months.(1-4) In adults, the most prevalent chronic pain conditions are back pain (14-44%)(2,3), musculoskeletal pain other than back pain (7-19%) (3,5,6), and headache (9-16%).(5-7) In children the most prevalent chronic pain conditions are headache (8-49%), musculoskeletal pain (9-49%), and abdominal pain (10-41%).(4)

1.1.1 Chronic Pain Incidence

The estimated annual incidence for chronic pain onset is 8.3%, as reported by a 4-year community-based study.(8) Many factors may be related to the onset of chronic pain. Systematic reviews have identified older age, mental health problems, work dissatisfaction, female sex, and poor social support as potential risk factors for chronic pain incidence.(9-12) In children, female sex has also been identified in population-based studies as a risk factor for chronic pain onset.(13,14)

1.1.2 Chronic Pain Prognosis

Chronic pain often has poor prognosis. In a sample of children with chronic pain, 20% reported experiencing chronic pain as young adults.(15) Canadian and European population-based studies have reported chronic pain in adults to last an average of 8-11 years.(1,3,6,16) High quality evidence from a synthesis of systematic reviews identified older age, female sex, high initial pain intensity, low social support, and fear avoidance behaviours to be associated with chronic pain persistence.(10)

1.2 Chronic Pain Impact

1.2.1 Social Impact of Chronic Pain

Chronic pain may interfere with participation in social engagements, family commitments, and leisure activities.(17,18) In a population-based survey of 16 countries,

22% of individuals with chronic pain reported being less able to maintain relationships with family and friends because of pain, while 14% reported no longer being able to attend social activities at all because of pain.(5) Almost half of Canadians with chronic pain (49%) have reported being unable to attend social and family events because of their pain.(6)

1.2.2 Physical and Psychological Associations with Chronic Pain

Physical and psychological conditions including anxiety, depression, and sleep problems have been found to be associated with chronic pain.(5,9,19,20) A European population-based study found the presence of chronic pain was associated with major depression diagnosis.(20) Of individuals with chronic pain surveyed from 16 countries, 56% reported being less able to sleep because of pain, and 9% reported an inability to sleep at all due to pain.(5) A survey of Canadian chronic pain patients found that those who reported high pain severity were more likely than patients who reported lower severity to also report sleep problems.(21) In a European survey, respondents with severe daily pain reported physical functioning reduced by 40% compared to their pain-free counterparts.(22)

1.2.3 Economic Impact of Chronic Pain

Almost 70% of individuals with chronic pain are of working age, and the majority of costs associated with chronic pain are because of absences from work and reduced productivity.(18) Indirect healthcare costs have the largest economic impact, associated not only with time off work and lost productivity, but also with medication fees, travel to and from healthcare visits, and personal care services.(23) Estimated societal health care costs of physician visits, medication fees, and disability pensions range from 1884-4144 Canadian dollars per chronic pain patient each year, with similar figures in the United States of America and Europe.(1,3,24,25)

1.3 Need to Improve Chronic Pain Management

With its high prevalence, long-lasting impact, associated burden, and economic costs, the management of chronic pain is an important concern. In the developed world, the

majority of chronic pain patients are treated by general practitioners (69%), with 2-14% of individuals with chronic pain seen by pain specialists.(1,5,17,26) Current treatment methods appear to adhere to general guidelines recommending medication as the first-line treatment option (1,17,26), with approximately half (46-47%) of chronic pain patients being prescribed pain medication.(1,6,17) Despite its frequent use, medication intake for chronic pain is often associated with the risk of side effects.(27-29) 26% of chronic pain patients receive non-pharmacological therapies including psychological, physical, and behavioural management.(26) Cochrane Reviews synthesizing the effectiveness of psychological therapies consistently show small, significant effects across reviews ranging from low to moderate quality of evidence.(30-33) Although both pharmacological and non-pharmacological therapies show some benefit in treating chronic pain, almost half of individuals with chronic pain (46%) report being dissatisfied with their pain management.(1,17,26) There is a need to explore alternative methods for developing and evaluating chronic pain interventions, in order to identify specific management strategies that may contribute to improving chronic pain treatment.

1.4 Self-monitoring as a Chronic Pain Assessment Strategy

Self-monitoring of chronic pain is often implemented as an assessment tool within chronic pain management, using pain diaries to track clinically relevant variables, including changes in pain intensity, frequency, duration, medication effectiveness, side effects, coping strategies, and treatment adherence.(34,35) Most chronic pain pharmacological and non-pharmacological clinical guidelines recommend self-monitoring alongside treatment, in order to evaluate, measure, and monitor pain and pain control strategies.(36-39) In the clinical setting, self-monitoring is typically used for at least one month to identify a pain diagnosis and to establish a baseline of typical symptoms.(35) Self-monitoring is implemented alongside chronic pain treatments to help monitor changes associated with treatment, and to guide pain management decisions.(35,40,41) Patients are usually advised to self-monitor either regularly throughout the day or at the end of the day, in each case recording their daily pain and related experiences in their natural environments.(42,43) Pain diaries are used in intervention research as an assessment tool to test the efficacy of psychological

treatments, often using change in pain intensity retrieved from pain diaries as the primary outcome.(30,31,44) Individuals with chronic pain have traditionally used self-monitoring through paper-based diaries.(45,46) With the expanding functionality and popularity of smartphone and web-based technology, electronic-based diaries are rapidly replacing their paper-based predecessors. Studies testing electronic chronic pain self-monitoring have found high rates of self-monitoring compliance, adherence, accuracy, efficiency, and acceptability, and have identified low rates of error.(43,44,47) Whether paper-based or electronic, self-monitoring has potential as a treatment modality that is accessible to a large proportion of the chronic pain population.(48)

1.5 Self-monitoring as a Management Strategy

Even though self-monitoring as an assessment tool for chronic pain is acceptable, efficient to use, with high compliance rates, it is rarely presented to patients or explored in research as a management strategy for chronic pain.

1.5.1 Preliminary Review of Self-monitoring as a Chronic Pain Management Strategy

A preliminary review of the literature was conducted to explore how self-monitoring is reported as a chronic pain management strategy. Appendix A provides a complete description of the methods and results of the review. To summarize, six randomized controlled trials comparing self-monitoring of chronic pain to psychological treatment or no-treatment were identified in a systematic search of PubMed.

The four studies comparing self-monitoring to psychological treatment used self-monitoring as a control condition, with the expectation that self-monitoring would not produce any effects on pain intensity. Three studies reported small significant effects for psychological treatment as more effective in reducing pain intensity than self-monitoring (49-51); the fourth study reported no significant difference between conditions (Table 1).(52)

The two studies comparing self-monitoring to no-treatment were designed to test whether self-monitoring was an appropriate clinical tool that did not influence pain outcomes.

Neither of these studies found any significant difference between conditions for reducing pain intensity (Table 1).(53,54)

Table 1 Characteristics of studies comparing self-monitoring to active psychological treatment or control conditions for managing chronic pain identified by a systematic search of PubMed.

Author	Type	Self-monitoring condition	Control	Duration	Outcome	Mean difference (0-5 VAS)
Appelbaum (52)	Paper	Pain intensity, 4 times daily, medication intake	PMR + Cognitive stress coping	8 weeks	Pain index	1.90 (-0.28-4.08)
Kashikar-Zuck (49)	Paper	Average daily pain level, medication intake, sleep	CBT coping-skills training	8 weeks	Pain intensity	1.52 (0.03-3.01)
Larsson (51)	Paper	Pain intensity, 4 times daily, medication intake	Relaxation	5 weeks	Pain intensity	2.15 (0.86-3.44)
Labbe (50)	Paper	Pain intensity, 4 times daily, medication intake	BFB + AT	7 weeks	Pain intensity	1.60 (0.48-2.72)
Stone (53)	Electronic	Pain intensity, location, characteristics, disability	No daily diary	2 weeks	Pain intensity	Not significant
Von Baeyer (54)	Paper	Pain intensity, 4 times daily, pain duration	Daily food checklist	8 days	Pain intensity	Not significant

PMR= Progressive muscle relaxation, CBT = Cognitive behavioral therapy, BFB= biofeedback, AT = Autogenic training, VAS=visual analog scale

The six studies included in this review used self-monitoring diaries with minimal functionality (i.e., tracking only pain intensity and medication intake), and reflected typical designs used in clinical self-monitoring assessment tools.(49-54) This review showed that when self-monitoring is approached as an assessment tool, it is not sufficient as a management strategy to improve chronic pain outcomes. There is a need to identify whether self-monitoring is applicable only as a chronic pain assessment tool, or whether there are mechanisms and self-monitoring characteristics that support self-monitoring as a potential chronic pain management strategy.

1.5.2 Self-monitoring for Managing Chronic Health Conditions

Although we found that self-monitoring has rarely been explored in the literature as a method for managing chronic pain, it is used extensively as an effective management strategy for several other chronic health conditions, including arthritis (55), asthma (56), diabetes (57), heart disease (58), and weight management.(59) These conditions have characteristics similar to those of chronic pain, being non-communicable and long-lasting, with a constant non- or slowly-progressive course, and with associated health

episodes or behaviour suitable for monitoring. Identifying the self-monitoring intervention characteristics used in chronic health conditions may provide guidance for understanding how self-monitoring can be applied as a chronic pain management strategy, rather than being used only as an assessment tool.

1.5.2.1 Self-monitoring Arthritis: Self-monitoring is used in arthritis management to monitor progress, encourage goal directed behaviour, and guide treatment adaptation.(55,60) A systematic review of arthritis management found the main arthritis self-regulation intervention components included: 1) goal setting, 2) planning, 3) self-monitoring, 4) feedback, and 5) relapse prevention.(55)

1.5.2.2 Self-monitoring Asthma: Monitoring asthma symptoms and airflow is an essential component of asthma self-management, as these factors vary in frequency and severity on a daily basis.(61) A Cochrane Review of asthma self-management randomized controlled trials found optimal self-management to include: 1) self-monitoring peak airflow and/or asthma symptoms, 2) an individualized written action plan to self-manage asthma exacerbations, and 3) regular medical reviews with a healthcare professional to discuss asthma status and medications.(56)

1.5.2.3 Self-monitoring Diabetes: Self-monitoring blood glucose in diabetes management is necessary to control glycemic levels.(62) A systematic review of Type II diabetic patients who were not using insulin found the common components of self-monitoring interventions to include 1) self-monitoring of blood glucose levels, 2) education on self-monitoring, 3) interpretation of feedback, and 3) recommended action.(57)

1.5.2.4 Self-monitoring Heart Disease: Cardiovascular patients are often asked to self-monitor blood pressure, heart rate, weight, and medication use as a self-management treatment option.(58) A systematic review of randomized controlled trials for self-monitoring heart disease reported that the most frequent self-monitoring components used were: 1) education on the topics of self-monitoring, disease management, and lifestyle, 2) self-measurement 3) self-adjustment, and 4) healthcare professional contact.(58)

1.5.2.5 Self-monitoring Weight: Self-monitoring has a key role in weight management interventions.(59) A systematic review exploring self-monitoring for behavioural weight loss found the main self-monitoring components across studies to be self-monitoring of diet, physical activity, and weight.(59).

1.5.3 Understanding Self-monitoring as a Chronic Pain Management Strategy

The self-monitoring intervention characteristics used for chronic health conditions are varied, ranging from self-monitoring important behaviours related to the conditions, to interventions with several interacting strategies, including goal setting, planning, self-monitoring, feedback and relapse prevention.(55-59) Interventions with a focus on self-monitoring for chronic health conditions similar to pain monitor not only symptoms, but also behaviours that influence the condition, as well as incorporate education about the condition, and providing active strategies for managing the condition and associated behaviour. In comparison to existing self-monitoring intervention characteristics, self-monitoring of chronic pain may need to involve management strategies in addition to the monitoring of pain symptoms, in order to be used as a chronic pain management strategy. To understand whether these self-monitoring characteristics may be applicable to chronic pain, the self-monitoring mechanisms and relationships involved that may be associated with chronic pain outcomes need to be identified and explored. Theory may provide a useful framework to guide the exploration of self-monitoring as an a management strategy for chronic pain.

1.6 Theory-driven Intervention Research

Theory is “*a set of interrelated concepts, definitions, and propositions that present a systematic view of events or situations by specifying relationships among variables in order to explain and predict the events or situations.*”(63) A substantial number of behaviour change theories exist, with the purpose of organizing concepts to suggest specific mechanisms and relationships that may influence behaviour. Behaviour change theory is used to specify what determinants and factors are most important for predicting behaviour and influencing behaviour modification.(64) This knowledge provides a foundation upon which behaviour change interventions can be developed to target

potential mechanisms, relationships, and interactions hypothesized to be associated with behaviour change.(65-67) The use of theory is often recommended in the development of interventions as an initial phase with which to identify the mechanisms and relationships that intervention characteristics should target.(68)

Recommendations from the UK Medical Research Council suggest several phases for researchers to consider in the development of theory-driven interventions.(68,69) The recommendations suggest first identifying existing evidence about similar interventions and the methods used, through a systematic review if recent synthesis is unavailable. A recommended second step for using theory to guide intervention development is to perform initial testing to identify relevant theoretical mechanisms and potential barriers to outcomes, and to test key uncertainties of the design by using qualitative research, surveys or case studies.(69)

Together the information from these identifying and testing stages may allow a comprehensive evaluation of relevant theoretical mechanisms, and ultimately lead to the development of a more constructive intervention that is guided by the chosen theoretical framework.(68) Despite available recommendations for using theory in the process of developing interventions, only 22-36% of interventions in health behaviour literature explicitly report using theoretical frameworks to guide development.(70,71) The recommendations to use theory for intervention development fail to provide guidance outlining specifically how to appropriately identify and review available theory and associated evidence.(72)

Guidelines are needed to assist researchers in exploring theory as a framework to inform the development of interventions. This thesis presents a preliminary exploration of methods that can be used to identify theory to be used to inform intervention development. We tested these methods by exploring whether behaviour change theory is useful as a conceptual framework for self-monitoring of chronic pain as a management strategy.

1.7 The Social Cognitive Theory of Self-regulation

Many behaviour change theories are used in health behaviour literature to describe the mechanisms and processes that may be associated with behavioural modification. The social cognitive theory is one of the most widely accepted theories hypothesizing factors that influence human learning and behaviour.(70,73) One of the main concepts of the social cognitive theory focuses on the importance of self-regulation as a source of behaviour change.(74,75) The social cognitive theory of self-regulation provides a comprehensive explanation of the potential effects that self-monitoring may contribute to successful behaviour change and proposes that three main components contribute to self-regulation and influence behaviour change: 1) self-monitoring, 2) self-judgement, and 3) self-evaluation.(74,75) The theory suggests that several specific mechanisms may directly influence each of the three main self-regulation theory components.

1.7.1 Self-monitoring Theory Component

The social cognitive theory of self-regulation identifies self-monitoring as the first and possibly most important step to initiating and informing self-judgement and self-evaluation, leading to appropriate self-regulation and behaviour change. The theory defines self-monitoring as systematic attention to, noticing, and tracking personal behaviour, subsequently informing both self-judgement and self-evaluation (Figure 1).(74,75) The theory proposes that eight influential mechanisms are associated with successful self-monitoring (Figure 1).(74,75)

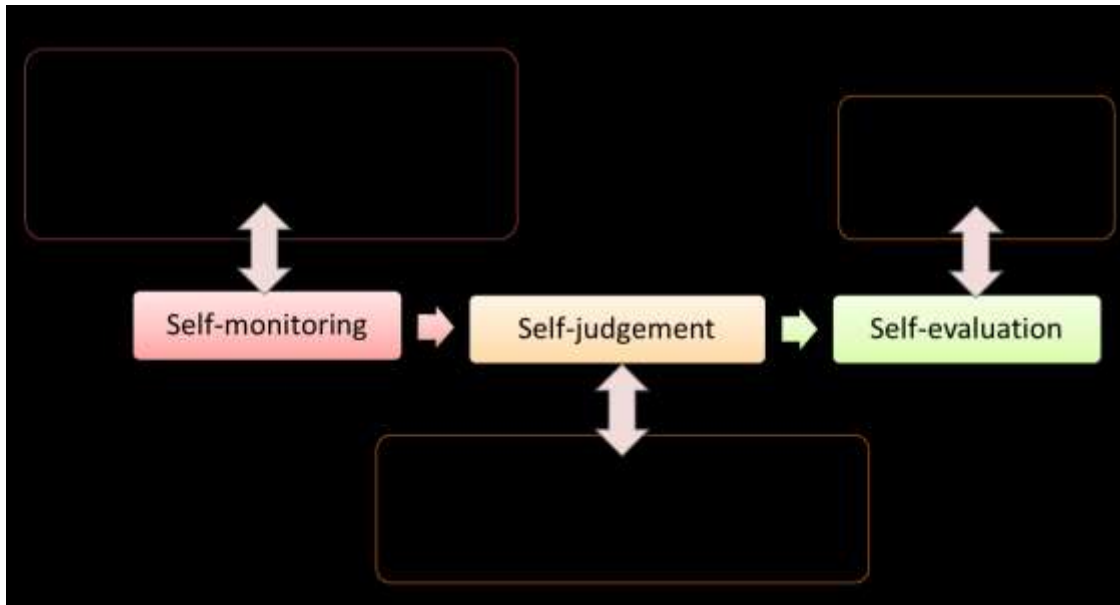


Figure 1 Framework of the three main components and mechanisms associated with self-regulation using the terminology specified in the social cognitive theory of self-regulation.(74,75)

According to the social cognitive theory of self-regulation, the eight mechanisms proposed to influence successful self-monitoring include: 1) ‘Feedback,’ 2) ‘Temporal proximity,’ 3) ‘Consistency,’ 4) ‘Focus on success,’ 5) ‘Value of behaviour,’ 6) ‘Control,’ 7) ‘Motivation,’ and 8) ‘Self-diagnosis.’(74,75) ‘Feedback’ consists of receiving information about the monitored behaviour, which provides a clear idea of progress. This information can be used to inform judgements and evaluation about behaviour. ‘Temporal proximity’ refers to monitoring behaviour in real-time, close to when it occurs. This immediacy provides information both about the behaviour and about factors that may directly influence the behaviour as it happens. Judgement and evaluation of behaviour that occurred in the past is less likely to influence behaviour change. ‘Consistency’ is the regular monitoring of behaviour, providing continuous information needed to guide judgement and evaluation of the behaviour. Intermittent monitoring is not as informative. ‘Focus on success’ refers to attending to achievements of the monitored behaviour that are encouraging and more likely to lead to positive judgement and self-evaluation. Focusing on failures is discouraging and is not as likely to influence behaviour change. ‘Value of behaviour’ focuses on monitoring behaviour that is of importance, which is more likely to produce self-satisfaction and influence behaviour

change. Monitoring negative or neutral behaviours is unlikely to influence a change in behavioural performance. ‘Control’ consists of monitoring behaviours that are easily modified, and are therefore more likely to produce lasting effects in behaviour change, rather than monitoring behaviours that are resistant to change. ‘Motivation’ refers to a person desiring to change the behaviour that is monitored, which influences their positive self-evaluation; low motivation is unlikely to influence self-evaluation or behaviour change. ‘Self-diagnosis’ is gaining self-insight from noticing recurrent trends or patterns of the behaviour from self-monitoring, and provides information needed to evaluate progress and alter behaviour.(74,75)

1.7.2 Self-judgement Theory Component

The social cognitive theory of self-regulation proposes self-judgement as the process of applying personal standards and values to assess the behaviour that is monitored.(74,75) Self-judgement is an intermediate component between observing behaviour (self-monitoring) and reacting to it (self-evaluation). The theory proposes five influential mechanisms are associated with development of personal standards that guide self-judgement (Figure 1).(74,75)

1.7.3 Self-evaluation Theory Component

The social cognitive theory of self-regulation proposes that self-evaluation occurs as a result of responding to judgements of the monitored behaviour based on whether or not personal standards are met.(74,75) Self-evaluation directly influences subsequent action, which leads all three of the theory components to contribute to self-regulation and behaviour change. The theory proposes three influential mechanisms associated with positive self-evaluation (Figure 1).(74,75)

The social cognitive theory of self-regulation meets the needs of a theory to potentially guide the understanding of how self-monitoring may be associated with behaviour change for chronic pain. The theory proposes specific mechanisms and relationships that contribute to the behaviour change process.

1.8 Thesis Objectives

This thesis uses two novel approaches to explore methods that can be used to identify applicability of theory as a framework for the development and testing of theory-driven interventions. As an example, we explored the social cognitive theory of self-regulation in order to understand self-monitoring as a theory-driven management strategy for chronic pain. These findings will guide recommendations for the use of theory in the early stages of intervention development.

Study 1: A systematic review of the literature. We explored how the social cognitive theory of self-regulation has been used as a conceptual framework to inform the development of self-monitoring interventions for chronic health conditions, including arthritis, asthma, chronic pain, diabetes, heart disease, and weight management. The review explored which of the theory components and associated mechanisms were implemented most often within interventions, and identified intervention characteristics addressing each of the theoretical mechanisms.

Study 2: A pilot investigation to explore feasibility of identifying support of theory from participant reported experiences. We evaluated the experiences of individuals with recurrent headache using self-monitoring, in order to explore support for the self-monitoring mechanisms of the social cognitive theory of self-regulation.

CHAPTER 2: A Systematic Review Exploring the Social Cognitive Theory of Self-regulation as a Framework for Chronic Health Condition Interventions

2.1 Introduction

Theory provides a framework for guiding the development and implementation of health interventions. Theory may be particularly useful for interventions that encompass several interacting active management strategies, and that are often difficult to evaluate and reproduce.(69) Theory can provide hypotheses of specific mechanisms and interactions to inform the development of interventions, which may lead to improved intervention outcomes.(64,66,67,76)

The use of theory is recommended by the UK Medical Research Council as the first phase in the development of interventions.(68) Recommendations to use theory early in the design of interventions fail to give guidance outlining specifically how to incorporate theory in the development process. In health behaviour literature, only 22-36% of interventions describe using any theoretical framework or theory components to guide their development.(70,71)

The importance of managing chronic health conditions is evident by their increasing prevalence and leading role in worldwide mortality.(77) Many of these conditions are prevented, treated, and managed through behaviour change interventions, which provide individuals with the capability to have control over and improve their health.(70,77)

The social cognitive theory proposed by Bandura (1986) (75), is one of the most common behaviour change theories applied in the management of chronic health conditions.(70) One concept of the theory focuses on the importance of self-regulation as a source of behaviour change.(74,75) Evidence from randomized controlled trials based on the social cognitive theory of self-regulation supports the clinical benefits of interventions based on this theory for health outcomes in asthma (78), arthritis (79), weight loss (80), and cardiac rehabilitation (81). These findings suggest that interventions based on the social cognitive theory of self-regulation can be useful for improving outcomes in some chronic health conditions. Nonetheless, the selection of the specific theory components and

associated mechanisms researchers have chosen to address with particular intervention characteristics remains unclear.

The objective of this systematic review of the literature to explore how theory has been used in the development of existing interventions. We explored how researchers use the social cognitive theory of self-regulation to inform the management of chronic health conditions. We assessed which theory components and mechanisms were implemented most often, and identified how the interventions addressed each of the theory mechanisms.

2.2 Methods

2.2.1 Literature Search and Data Sources

We used multiple search strategies to identify relevant studies. First we searched electronic databases PubMed, PsychINFO, and EMBASE from inception to May 2014, using a search strategy of MeSH terms, keywords reflecting the health conditions of interest, and terms associated with the social cognitive theory of self-regulation (see Appendix B for full PubMed search strategy); we searched the Cochrane Central Register of Controlled Trials for completed controlled trials, and the trial registry clinicaltrials.gov for relevant protocols, which were followed up for published studies. Second, we conducted a citation search in Web of Science to identify studies citing either Bandura's first report of the social cognitive theory of self-regulation (75), or Bandura's first paper (74) that comprehensively described the theory components and mechanisms. Third, we examined the reference lists of all included studies, and the reference lists of studies included in systematic reviews of self-monitoring interventions identified through a scoping literature search.(55-57,59) We searched PubMed for available published studies of identified protocols that met our inclusion criteria by searching for publications by the first author of protocols, and by keyword searching for publications using the intervention's name, when available. All of the retrieved citations were imported into an EndNote database, where duplicate citations across data sources were identified and removed.

2.2.2 Inclusion and Exclusion Criteria

We included peer-reviewed publications of interventions for chronic health conditions based on the social cognitive theory of self-regulation.

We selected a range of chronic health conditions with similar characteristics, which were non-communicable, long-lasting, with a constant non- or slowly-progressive course, and with associated health episodes or behaviour suitable for monitoring. We included the chronic health conditions arthritis, asthma, chronic pain, diabetes, heart disease, and weight management.

We included interventions that used self-monitoring as an intervention characteristic, reported being designed using the social cognitive theory of self-regulation as the theoretical basis for the intervention, and cited one of the main theory publications.(74,75) We included peer-reviewed publications that reported the evaluation of interventions, for example evaluation of the usability, feasibility, or efficacy of the interventions using observational or experimental designs.

The social cognitive theory of self-regulation proposes that three main components of the theory, self-monitoring, self-judgement, and self-evaluation, contribute to self-regulation, and influence successful behaviour change. The theory suggests that specific mechanisms related to each of these three main components may be directly associated with successful self-monitoring, self-judgement, and self-evaluation, and influence subsequent behaviour change. The theory identifies self-monitoring as the first and most important step to initiating and informing appropriate self-regulation and behaviour change. We included in this systematic review only interventions that explicitly recommended and expected participants to self-monitor by observing, tracking, and/or recording their own behaviour as a core component of the interventions.

We excluded studies that: 1) cited the social cognitive theory of self-regulation but did not report evaluation of an intervention, 2) were study protocols without published data, conference proceedings, abstracts, case studies, theses, reviews, summaries, commentaries, editorials, or letters to the editor, 3) were proxies of the population of

interest (e.g., parental administration of an intervention designed to change child behaviour), or were non-human subjects, 4) were non-English.

2.2.3 Selection Process

We used two phases to screen the titles and abstracts identified from the search strategy. First, one reviewer (MT) conducted an initial title and abstract screening to eliminate readily identifiable ineligible types of publications, and studies conducted in clearly irrelevant health conditions. Second, two reviewers (MT, SR) independently screened the remaining titles and abstracts to determine study design eligibility for full text review.

We also used two screening phases at the full text level. In the first phase one reviewer (MT) screened the full-text articles to identify those citing the social cognitive theory of self-regulation.(74,75) In the second phase, both reviewers independently screened the remaining full text articles using the inclusion criteria to determine interventions eligible for inclusion in the review. We report the final number of interventions identified; duplicate publications (i.e., studies reporting the same intervention) were reviewed for any additional information and used to complete data extraction. We calculated interrater reliability for title/abstract and full text screening levels using Cohen's Kappa (82), and considered Kappa between 0.41-0.60 an indication of moderate and acceptable level of agreement.(83) Discrepancies were discussed and resolved, using consultation with a third reviewer (JH) when necessary.

To supplement information extracted about the content of included interventions, we searched for related publications, protocols, guidelines, and web-based resources. We contacted first authors of included studies, for access to either an intervention manual describing the intervention content, or an intervention guide or outline if a manual was not available. When our searches identified information from multiple sources about the same intervention, we combined this information during extraction. We considered interventions that were published by the same research team across multiple publications distinct from one another only when at least one of the main theory components was added or removed.

2.2.4 Data Extraction

We extracted two types of data from included studies: 1) study characteristics, and 2) theory-related intervention characteristics.

One reviewer (MT) extracted data on study characteristics, including: study authorship, health condition, inclusion/exclusion criteria, age group, study design, intervention objectives, intervention duration, intervention delivery format, general intervention content, and any additional theories guiding intervention development. A second reviewer (SR) checked the extracted data for accuracy. Appendix C provides the full, final data extraction form.

We extracted data on the intervention characteristics related to the social cognitive theory of self-regulation. We initially followed a consensus procedure to define the extraction process. We created an outline based on Bandura's two publications that describe the three main components of the theory that are related to successful self-regulation and behaviour change: self-monitoring, self-judgement, and self-evaluation.(74,75) Self-monitoring involves attention to, noticing, and tracking personal behaviour, which may inform self-judgement. Self-judgement is the process of applying personal standards and values to judge monitored behaviour. Finally, the theory proposes that self-evaluation of monitored behaviour may occur as a result of judgement and directly inform subsequent action, leading all three components to contribute to self-regulation and behaviour change. Within each of the three components, the theory proposes specific mechanisms that may directly influence self-monitoring, self-judgement and self-evaluation (Table 2).

Table 2 Description of self-regulatory mechanisms that influence self-monitoring, self-judgement, and self-evaluation, as proposed by the social cognitive theory of self-regulation.(74,75)

	Mechanism	Descriptions
Monitoring	Feedback	Providing clear evidence of behaviour change progress
	Temporal proximity	Monitoring behaviour close in time to when the behaviour actually occurs
	Consistency	Regular rather than intermittent self-monitoring
	Focus on success	Attending to achievement rather than failure
	Value of behaviour	Self-monitoring behaviours with perceived importance, rather than behaviours of no importance

	Mechanism	Descriptions
	Control	Self-monitoring behaviours that are relatively easy to modify by deliberate effort
	Motivation	Desiring to change the monitored behaviour
	Self-diagnosis	Gaining new insight through identifying and noticing patterns of behaviour
Judgement	Social comparison	Relating self-progress with peers in similar situations, in particular to those with similar capabilities
	Self-comparison	Contrasting ongoing progress with previous behaviour
	Statistical comparison	Evaluating progress with standards through normative information
	Modeling	Using examples of others who are successful in changing behaviour to judge ongoing progress
	Education/reaction	Using other's opinions about progress or responses to behaviour to inform judgement
Evaluation	Self-satisfaction	Gaining self-respect for noticed goal completion or behaviour progress
	Self-incentives	Setting personal rewards for achieving progress to enhance motivation
	External rewards	Setting tangible benefits contingent upon completion of a task or goal

We used the theory definitions to identify intervention characteristics that addressed each of the specific mechanisms proposed to be associated with the three theory components. Three reviewers (MT, JH, AH) independently reviewed four selected interventions that comprehensively described included intervention characteristics. The reviewers used the mechanism definitions to independently code the intervention characteristics that addressed each theory mechanism. We explored agreements and disagreements across the reviewers and reached consensus through discussion about the types of intervention characteristics that were applicable to each of the theory mechanisms. We revised the extraction guide with descriptions to specify the type of intervention characteristics that addressed each theoretical mechanism (Appendix D). We used the extraction guide to develop the final extraction form (Appendix C). Subsequently, two reviewers (MT, SR) extracted the intervention characteristics using the extraction form.

2.2.5 Risk of Bias Assessment

Two reviewers (MT, SR) independently assessed the risk of bias of the extracted studies. We assessed randomized controlled trials for internal validity, using the Cochrane

Collaboration's Risk of Bias tool to assess the selection bias, performance bias, detection bias, attrition bias, and reporting bias (Appendix E).(84) Following recommendations by Higgins (85), we judged studies to have an overall 'high risk of bias' when at least one of the key domains had a high risk of bias, 'unclear' risk of bias when any of the key domains were rated as unclear risk, and 'low' risk of bias when all domains were rated as low risk.(85) We used the Quality in Prognosis Studies (QUIPS) tool (86) to assess risk of bias for observational studies, while considering the following domains: participant selection, attrition, outcome measurement, confounding, and analysis/reporting (see reference for the full published tool). We rated each domain as high, moderate, or low risk of bias, and judged the overall internal validity across domains by judging studies as low risk only when all of the domains were rated as low, and as high risk of bias when any of the domains were rated as moderate or high. We calculated interrater reliability for risk of bias assessment using Cohen's Kappa (82) and considered Kappa between 0.41-0.60 an indication of a moderate and acceptable level of agreement.(83) A third reviewer was available for consultation about any unresolved discrepancies, however such consultation was not necessary.

2.2.6 Data Synthesis

We report frequency of how often the social cognitive theory of self-regulation was used in the development of each intervention, including how often: 1) interventions addressed all three theory components together, two theory components, or only self-monitoring, 2) interventions had characteristics belonging to each specific theory component, and 3) interventions included characteristics belonging to each specific theory mechanism. We considered interventions to address a specific mechanism when at least one intervention characteristic included the theory element proposed to be associated with that mechanism (Table 2). We rated interventions as addressing a specific theory component when at least one mechanism related to that component was judged to be present. Interventions addressed all three theory components when at least one intervention characteristic was judged to be present for at least one mechanism related to each of the self-monitoring, self-judgement, and self-evaluation theory components. Interventions addressed only two theory components when at least one intervention characteristic related to at least one

mechanism was present for self-monitoring, along with one other theory component (either self-judgement or self-evaluation). When reporting our results, we did not separate our findings according to intervention characteristics (e.g., health condition, age group, design), since the main purpose of this study was to explore use of theory from existing interventions. To illustrate the types of intervention characteristics that we judged as addressing the theory mechanisms, we provide some examples of characteristics from the included interventions that clearly represented the descriptions in our extraction guide.

We explored whether the risk of bias impacted how often the main theory components were addressed across the interventions. We present subgroup information about how many theory components were addressed by interventions for each assessed risk of bias.

2.3 Results

2.3.1 Description of Included Studies

We identified and screened 16,188 independent titles and abstracts (see Figure 2 for details). We excluded the majority of citations because of ineligible designs. We assessed full text publications for 202 potentially relevant articles that reported interventions for the health conditions of interest, and cited the social cognitive theory of self-regulation.(74,75) The most common reason for exclusion of full text publications was because self-monitoring was not a core intervention component (105 of 202 publications). Our interrater reliability for study selection was acceptable for title and abstract, as well as for full-text screening, with a Kappa of 0.60 and 0.55, respectively.



Figure 2 Flow diagram of title/abstract and full-text screening process to identify interventions included in the review.

Table 3 Summary of intervention characteristics for each of the 35 interventions included in the review.

First author	Population	Intervention duration	Intervention delivery	Instructor qualification
		Weight		
Annesi (87)	Severely obese adults	26 weeks	Group-based	Wellness specialist
Burke (88)	Overweight adults	18 months	Group-based	Physiotherapist
Collins (89)	Overweight adults	12 weeks	Web-based	None
Gallagher (90)	Overweight adults	16 weeks	Group-based	Multidisciplinary
Gray (80)	Overweight men	12 weeks	Group-based	Community coach
Hollis (91)	Overweight adults	24 weeks	Group-based	Nutritionist, counselor
Kiernan (92)	Overweight women	20 weeks	Group-based	Intervention staff
Ma (93)	Overweight adults	12 weeks	Group-based	Dietitian, fitness instructor
Mockus (94)	Overweight children	20 weeks	Face-to-face	Counselor
Morgan (95)	Overweight men	12 weeks	Web-based	None
Morgan (96)	Overweight fathers	12 weeks	Group-based	Study investigator
Patrick (97)	Overweight adults	12 months	Web-based	None
Short (98)	Overweight men	9 months	Web-based	None
Shuger (99)	Overweight adults	14 weeks	Group-based	Intervention staff

First author	Population	Intervention duration	Intervention delivery	Instructor qualification
Diabetes				
Lawler (100)	Type II diabetic overweight adults	18 months	Telephone	Counselor
Liebreich (101)	Type II diabetic adults	12 weeks	Web-based	None
Miller (102)	Type II diabetic adults	10 weeks	Group-based	Dietitian
Nansel (103)	Type I diabetic youth	8 weeks	Face-to-face	Intervention staff
Tan (104)	Type I or Type II diabetic adults	12 weeks	Face-to-face	Study investigator
Tudor-Locke (105)	Type II diabetic sedentary adults	16 weeks	Group-based	Physical activity experts
Van Dyck (106)	Type II diabetic overweight adults	24 weeks	Telephone	Psychologist
Heart disease				
Furber (81)	Cardiac patients, adults	6 weeks	Telephone	Not reported
Moore (107)	Recent cardiac event, adults	12 weeks	Group-based	Nurse
Padula (108)	Heart failure, adults	12 weeks	Face-to-face	Nurse
Peterson (109)	Coronary artery disease, adults	12 months	Telephone	Intervention staff
Pinto (110)	Cardiac rehabilitation, adults	14 weeks	Telephone	Intervention staff
Shao (111)	Heart failure, older adults	12 weeks	Face-to-face, telephone	Not reported
Arthritis				
Hughes (112)	Lower extremity osteoarthritis, adults	8 weeks	Group-based	Physical therapists
Kovar (79)	Knee osteoarthritis, adults	8 weeks	Group-based	Intervention staff
Manning (113)	Upper extremity rheumatoid arthritis, adults	12 weeks	Group-based	Physiotherapist
Shigaki (114)	Rheumatoid arthritis, adults	10 weeks	Web-based	None
Asthma				
Baptist (78)	Asthma, adults	6 weeks	Group-based, Telephone	Health educator
Burkhart (115)	Asthma, children	16 weeks	Face-to-face	Nurse
Clark (116)	Asthma, adult women	24 weeks	Telephone	Nurse
McGhan (117)	Asthma, children	6 weeks	Group-based	Nursing students

We included 35 unique interventions (published in 60 studies) developed using the social cognitive theory of self-regulation as a conceptual framework (Table 3). Appendix F provides an in depth description of the characteristics of the included interventions. Weight management as the most common type of intervention addressed (14/35) (Table 4). In the included studies, interventions lasted from four weeks up to twelve months, and

were delivered through individual-based (17 interventions), group-based (16 interventions), or mixed settings (2 interventions). Most interventions were evaluated using a randomized controlled trial study design (33/35), with an equal distribution of studies assessed as low, high, and unclear risk of bias. The risks of bias domain most commonly rated as ‘high’ risk of bias was due to incomplete outcome data due to unbalanced attrition rates between intervention and control groups, and selective outcome reporting. Our interrater reliability for risk of bias assessment was acceptable with a Kappa of 0.59. Of the thirty-four intervention authors contacted (regarding thirty-five interventions), eleven provided additional information: five provided access to an intervention manual, two provided intervention outlines, and four referred to previous publications.

Table 4 Summary of intervention design and characteristics in included interventions (n=35).

Intervention design and study characteristics		Number of interventions (% ¹)
Health condition	Weight	14 (40%)
	Diabetes	7 (20%)
	Heart disease	6 (17%)
	Arthritis	4 (11%)
	Asthma	4 (11%)
	Pain	0 (0%)
Study age group	Adults	31 (89%)
	Children or adolescents	4 (11%)
Method(s) of intervention delivery	Group-based	16 (46%)
	Individual telephone contact	6 (17%)
	Internet-based	6 (17%)
	Individual face-to-face	5 (14%)
	Individual face-to-face + telephone contact	1 (3%)
Study design	Group-based + telephone contact	1 (3%)
	Experimental (randomized controlled trials)	33 (94%)
Study overall risk of bias rating	Observational	2 (6%)
	Low	13 (37%)
	Unclear	11 (31%)
Use of theory	High	11 (31%)
	All three theory components	21 (60%)
	Two theory components	14 (40%)
	Only self-monitoring theory component	0 (0%)

¹All percentages are rounded to the nearest whole number

2.3.2 Overview of Theory Component Use

Twenty-one of thirty-five interventions incorporated all three of the main theory components by including at least one intervention characteristic that addressed one or more mechanism for self-monitoring, self-judgement, and self-evaluation. Based on information available in peer-reviewed publications, only seventeen interventions were initially identified that used characteristics addressing mechanisms related to self-evaluation. Additional information from four of five intervention manuals provided by authors, were found to incorporate self-evaluation characteristics that were not previously identified and that addressed self-evaluation, resulting in 21 interventions identified to address all three of the main theory components.

2.3.2.1 Self-monitoring: Each intervention addressed an average of 6.17 of the 8 self-monitoring mechanisms. Table 5 describes the intervention characteristics that addressed each of the self-monitoring theory mechanisms. Appendix G provides a summary of the interventions that addressed each of the self-monitoring mechanisms.

Table 5 Characteristics of interventions included in the review (n=35) addressing self-monitoring mechanisms as proposed by the social cognitive theory of self-regulation.

Mechanism	Number of interventions	Description
Feedback	35	Participants were provided with information about their behaviour by actively using any type of self-monitoring
	26	Participants were provided with information about their behaviour from instructors who reviewed participants' monitored data, or from data summaries or graphs
Temporal proximity	16	Participants monitored all behaviour in real-time, using automatic monitoring devices including pedometers, peak air flow, heart rate, and blood glucose monitors
Consistency	35	Participants were requested to routinely observe and record their behaviour
Focus on success	16	Participants were instructed about the importance of attending to achievements or positive changes, rather than failures, through positive thinking, recognizing successes, and outcome expectations
Value of behaviour	28	Participants were informed of the importance of the monitored behaviour and its influence on health outcomes, and/or the importance of self-monitoring the behaviour

Mechanism	Number of interventions	Description
	5	Participants were given the option to choose to monitor behaviour they selected as important
Control	24	Participants were actively taught skills needed to modify behaviour through personalized problem-solving, development of action plans, and relapse prevention plans, to overcome barriers to change
Motivation	24	Participants were engaged in actively identifying and setting their own goals, developing behavioural contracts, setting personalized rewards for behaviour attainment, or receiving personalized motivational interviewing
	8	Participants were given pre-set goals selected by the intervention
Self-diagnosis	14	Participants were educated about common barriers or facilitators to their behaviour
	11	Participants were guided to explore their own environment and identify their personal triggers, barriers or facilitators to behaviour

As outlined in our extraction guide, the mechanisms ‘Feedback’ and ‘Consistency’ were addressed by all interventions. We specified a priori that when information was not provided, we would assume that participants were expected to consistently, rather than intermittently, self-monitor the behaviour of interest, since interventions were unlikely to suggest that participants monitor their behaviour irregularly. We also specified a priori that any type of self-monitoring completed by an individual would provide information about the monitored behaviour, because observing and tracking behaviour may provide new information that would not have otherwise been obtained. We therefore judged that all self-monitoring conditions provided informative feedback to participants, regardless of whether that feedback was explicitly reported or not. Twenty-six interventions provided direct and personalized feedback to participants, most often through professionals associated with the intervention delivery.

The self-monitoring mechanisms ‘Value of behaviour’ and ‘Motivation’ were addressed by 33 and 32 interventions, respectively. The mechanism ‘Value of behaviour’ was addressed by 28 interventions in which participants were passively engaged by receiving education about the importance of their monitored behaviour in relation to health

outcome. Only 5 of interventions actively engaged participants and encouraged them to choose which behaviour they wanted to monitor.

In an individualized diabetes management training program for adolescents with Type 1 diabetes, an instructor helped the participants select which behaviours to monitor and plan how to assess progress of behaviour throughout the program.(103)

Intervention characteristics that addressed the mechanism ‘Motivation,’ either actively engaged participants (24/35 interventions), usually through guiding them to personally set their own goals, or passively engaged participants (8/35 interventions), through giving pre-set goals for participants to work toward.

In a rheumatoid arthritis exercise intervention (113), participants were directed to complete daily upper extremity exercise at home, and to use a daily exercise diary to monitor exercise occurrence and perceived intensity. A physiotherapist advised participants to set and record weekly goals and action plans to identify ‘when,’ ‘where,’ and ‘how’ to achieve the weekly goals.

Sixteen interventions with characteristics addressing the ‘Temporal proximity’ mechanism had participants monitoring in real-time with the assistance of an automatic tracking device, usually a pedometer.

The First Step Program, an intervention for sedentary individuals with diabetes, requested that participants wear a pedometer during waking hours while engaging in usual activities, and record the number of steps taken each day in a daily calendar. This information was used to guide goal setting and to monitor physical activity progress throughout the intervention.(105)

The 25 interventions addressing the mechanism ‘Self-diagnosis’ either provided participants with passive education (14/35 interventions), or actively guided participants (11/35 interventions) to identify personal triggers, barriers or facilitators linked with their health behaviour.

An asthma intervention for adults older than age 65, focusing on increasing self-management of asthma symptoms, had participants monitor their daily peak airflow values, asthma symptoms, and barriers to asthma control. Participants were advised to observe potential associations between environmental factors and asthma symptoms, with special attention focused on how barriers interfered with asthma control.(78)

The mechanism ‘Focus on success’ was the least common self-monitoring mechanism, addressed by 16 of the 35 interventions.

In a lifestyle intervention for weight loss, as a method for dealing with setbacks in healthy eating and activity, participants were advised to focus on all of the positive changes that had been made, and recognize that setbacks were part of the process to behaviour change.(118)(Participant Handout, Session 9)

Appendix H provides more examples of intervention characteristics that addressed each of the self-monitoring mechanisms.

2.3.2.2 *Self-judgement*: All of the included interventions incorporated characteristics addressing at least one of the mechanisms related to self-judgement. Each intervention addressed an average of 2.37 of the 5 self-judgement mechanisms. Table 6 describes the intervention characteristics that addressed each of the self-judgement theory mechanisms. Appendix I provides a summary of the interventions that addressed each of the self-judgement mechanisms.

Table 6 Characteristics of interventions included in the review (n=35) addressing the self-judgement theory component as proposed by the social cognitive theory of self-regulation.

Mechanism	Number of interventions	Description
Social comparison	11	Participants were encouraged or provided with the opportunity to interact with peers and judge their ongoing progress through group discussion of progress, group discussion of problems and solutions, or web-based tracking of selected peers’ progress

Mechanism	Number of interventions	Description
Self-comparison	20	Participants were encouraged to review the progress of their monitored behaviour and goals, or reflect on previous behaviour to assess any progress made
Statistical comparison	7	Participants were either guided in comparing their monitored data with national nutritional or physical activity guidelines to identify differences, or provided with evidence-based data from existing studies
Modeling	18	Participants received examples of behaviour through demonstrations from instructors, scenario examples from intervention materials, or identifying or engaging with a role model with proven behaviour change success
Education/reaction	27	Participants received encouragement, praise, support, and/or engaged feedback on progress from instructors

The ‘Education/reaction,’ self-judgement mechanism was most common, addressed by 28 interventions, and was facilitated by instructors informing participants of their progress or giving participants praise for progress.

In a weight loss intervention delivered by a dietician and physiotherapist, participants were guided in changing their physical activity and nutritional intake. Participants were encouraged by the instructors that they had the ability to lost weight, and were informed of their biological and physical changes and progress.(88)

The mechanism ‘Self-comparison’ was addressed by 19 interventions, which guided participants in identifying either general progress made since beginning the interventions, or progress made toward specific goals.

In a behaviour intervention for individuals with recent cardiac events, CHANGE (Change Habits by Applying New Goals and Experiences), participants were instructed to track exercise and associated heart rate (assessed through a wrist-worn heart rate monitor). Weekly, participants were instructed to review their monitored data to identify personal patterns of exercise.(107)

Ten interventions included characteristics addressing the ‘Social comparison’ mechanism, providing the opportunity for participants to engage with peers and identify the progress that others have made.

In a weight management group-based intervention for men delivered by a local coach in a community football club, peer engagement was a significant component of the intervention. Friendly competition was encouraged through quizzes, engagement through walking groups was recommended, regular group-based discussion of progress was facilitated by the coach, and weekly group-based coach led exercise sessions were used.(80)

Only six interventions had characteristics addressing the ‘Statistical comparison’ mechanism, with interventions comparing participant data to national recommendations or evidence-based research.

In the Living Well With Diabetes program, a physical activity and dietary behaviour change program for adults with Type II diabetes, participants’ self-monitored their daily physical activity (measured through a pedometer) and dietary intake. Over 12 months and 18 telephone sessions, the monitored physical activity level and dietary behaviours were graphically presented to participants and compared to national recommendations. Updated graphs and comparisons were mailed to participants after each assessment throughout the intervention.(100)

Appendix H provides more examples of intervention characteristics that addressed each of the self-judgement mechanisms.

2.3.2.3 Self-evaluation: We found a total of twenty-one interventions that included characteristics related to self-evaluation. Each of these interventions addressed an average of 0.74 of the 3 self-evaluation mechanisms. Table 7 describes the intervention characteristics that addressed each of the theory mechanisms. Appendix J provides a summary of the interventions that addressed each of the self-evaluation mechanisms.

Table 7 Characteristics of interventions included in the review (n=21) addressing the self-evaluation theory component as proposed by the social cognitive theory of self-regulation.

Mechanism	Number of interventions	Description
Self-satisfaction	16	Participants were guided in self-approval or respect for their behaviour through promoting confidence, self-efficacy, acceptance, and positive thoughts associated with behaviour change
Self-incentives	6	Participants were guided in personally setting self-administered rewards for achieving progress or attaining goals
External rewards	4	Interventions offered participants rewards for achieving progress, such as certificates, stickers, t-shirts, bags

The ‘Self-satisfaction’ self-evaluation mechanism was most common, addressed by 17 interventions, and used to guide participants in reacting positively to behaviour change.

A weight loss intervention for women guided behaviour change of food intake and physical activity by focusing on intervention characteristics addressing problem solving and setting goals. Participants were taught skills to be satisfied with maintaining their weight, plan for regular weight fluctuations, and not let setbacks interfere with the weight loss plan.(92)

Six interventions addressed the ‘Self-incentive’ mechanism, by guided participants to set personal rewards to recognize achievement.

In the Women Breathe Free asthma intervention for adult women, participants were guided in setting personal rewards to celebrate when asthma management goals or desired progress was achieved.(116)

The mechanism ‘External rewards’ was addressed by only four interventions, which provided participants with achievement awards such as gifts or certificates, to recognize reaching goals and maintaining engagement in the interventions.

In a hospital based walking program for adults with chronic osteoarthritis in the knee, participants were given achievement awards at different stages throughout the program, including walking suits, exercise socks, or key chains. Participants were also given gift certificates for good class attendance.(79)

Appendix H provides more examples of intervention characteristics that addressed each of the self-judgement mechanisms.

2.3.3 Exploring Differences in Use of the Theory Components

Of the interventions that we evaluated as having a low risk of bias, most (9/13 interventions) used all three of the main theory components. Just over half of the interventions that we evaluated as having high risk of bias (6/11 interventions) and unclear risk of bias (6/11 interventions) used all of the three main theory components.

2.4 Discussion

This review provides an example of how literature can be explored to identify the extent to which a selected theory has been used as a framework for existing interventions. Our review process was a useful method of identifying the theoretical mechanisms that are addressed within existing interventions. To illustrate how researchers can explore theory use in existing literature, we provide an overview of the specific mechanisms and theory components that were incorporated into interventions developed using the social cognitive theory of self-regulation as a conceptual framework. From a comprehensive search of multiple sources we identified only thirty-five interventions that used the social cognitive theory of self-regulation to develop interventions for the management of arthritis, asthma, diabetes, heart disease, and weight conditions. All of the interventions addressed at least two of the main theory components, and 21 of the interventions incorporated characteristics that addressed mechanisms related to all three of the main theory components. We identified that some of the theory mechanisms were rarely addressed, including the self-judgement mechanisms ‘Social comparison’, and ‘Statistical comparison’, and the self-evaluation mechanisms ‘Self-incentives’, and ‘External rewards’.

Our review provides a novel example of how to explore the application of theory within existing interventions. Recommendations for the development of theory-driven interventions begin with the suggestion of exploring existing interventions, and conducting a systematic review exploring interventions for closely related conditions if relevant synthesized evidence is unavailable for the health condition of interest.(68,119) Reviews exploring theory usually do so by identifying which theories are commonly used (70,71), or by testing theoretical mechanisms associated with change (120,121), rather than identifying intervention characteristics that are used to address theoretical mechanisms. Researchers can use our process to identify which theory mechanisms are commonly or infrequently addressed by interventions, to determine if the selected theory is a feasible framework for development of future interventions for health conditions similar to those included in the review. This type of review is a source of information that illustrates examples of the intervention characteristics that are used to address theory mechanisms, and can provide direction for use of the characteristics in future interventions.

Of the 202 full text articles screened, 105 studies evaluating interventions using the social cognitive theory as a conceptual framework were excluded because they did not include self-monitoring as a core component of the intervention and therefore did not appropriately address the self-regulation concept of the theory. Studies evaluating interventions reporting use of the social cognitive theory as a conceptual framework, often either address only specific concepts of the overall theory, or report use of the theory without appropriately including intervention characteristics to approach its theoretical concepts. These findings are similar to those of a review exploring the general use of theory in health behaviour literature, which identified that 70% of all theories identified were merely mentioned within the research, rather than being appropriately applied.(70) Researchers and clinicians should cautiously interpret individual studies that report using theory as a conceptual framework, as we found many interventions appear to only cite the theory without actually describing how they addressed each of the main theory components. A systematic review as we have conducted can help to highlight the interventions that appropriately implement the theory.

In spite of our comprehensive search across multiple sources that identified over sixteen thousand citations, we retrieved only thirty-five self-monitoring interventions developed using the social cognitive theory of self-regulation, with less than ten interventions identified for four of the five health conditions, and only twenty-one interventions addressing all three of the main theory components. These numbers are not surprising, considering that only 8% of the published health behaviour literature reports interventions that apply theory as a conceptual framework during development.(70) Although our review process was successful for identifying interventions developed using a well-known theory, we did so across five health conditions. Researchers interested in exploring theories that are infrequently implemented, or are exploring uncommon health conditions, may find an insufficient availability of relevant reports evaluating interventions of interest.

None of the interventions included in this review were developed to manage chronic pain. Self-monitoring for chronic pain is an accepted and recommended clinical assessment tool (36-39), and studies testing the effects of self-monitoring assessment tools on chronic pain outcomes have found no significant differences between self-monitoring and no treatment.(53,54) Use of self-monitoring as a management strategy to influence chronic pain outcomes may be met with reservation and uncertainty, potentially slowing the process of evaluating its use in research. Future researchers may consider using our results to guide development and inclusion of intervention characteristics addressing mechanisms that are regularly applied when using the framework of the social cognitive theory of self-regulation for health conditions with similar characteristics to those included in our review, such as chronic pain, mood disorders, or chronic obstructive pulmonary disease.

We attempted to comprehensively retrieve information related to interventions through duplicate publications, available resources, and author contact, however, we were only able to judge intervention characteristics based on available information, often provided as a summary or table of contents. Only five of the authors of included interventions provided us with access to full treatment manuals. We were able to use the additional information to identify more theory mechanisms and components that were not addressed

in the published materials that we originally extracted. For example, we identified intervention characteristics guiding participants in self-evaluation in four interventions that were not previously identified as using this theory component. Most publications provided overviews of intervention content with broad overarching concepts. Through supplementing our extraction with information from available manuals, it became clear that publications were not comprehensively representing all of the intervention content and application to theory mechanisms and components that we were able to identify from their manuals. Without the option of reviewing entire intervention manuals for the remaining interventions, it is difficult to confirm that we have comprehensively identified all of the intervention characteristics related to relevant theoretical mechanisms. Poor description of intervention content is recognized as a common problem in the reporting of interventions.(122) To address the problem of underreporting and to improve clarity in the use of theoretically based interventions, intervention investigators should provide access to a comprehensive outline of intervention characteristics and how they apply to each of the related theory mechanisms.(123)

Fourteen of the thirty-five interventions did not address self-evaluation, one of the three main components of the social cognitive theory of self-regulation. We hypothesize that potential reasons for low frequency of identified self-evaluation mechanisms could be that the mechanisms were either more difficult for intervention researchers to implement, or they may have been incorporated but not reported in the available publications. The self-evaluation mechanism ‘External rewards’, addressed by only four interventions, may have been interpreted by developers as too expensive or time consuming to administer and therefore not addressed by the intervention. It is possible that the other two self-evaluation mechanisms were addressed by intervention characteristics that were not explicitly reported in the identified publications. The mechanism ‘Self-satisfaction’ is associated with positively recognizing achievement of progress or goals, and the ‘Self-incentive’ mechanism is associated with setting and administering personal rewards as sources of motivation and reward. For example, when participants were instructed to actively set goals (to address the ‘Motivation’ mechanism), they may also have been guided to react positively to achievement (‘Self-satisfaction’), or set personal rewards to administer upon achievement of the goals (‘Self-incentives’). Therefore the self-

evaluation component may have been underrepresented due to availability of resources, or not been identified due to inaccurate reporting. These issues highlight the importance of comprehensive reporting, to improve replicability of similar interventions, and facilitate empirical and clinical understanding of the mechanisms addressed and intervention characteristics used.(69)

Our search strategy identified publications evaluating interventions that used theory; we did not attempt to retrieve methods or process papers associated with intervention development and therefore did not investigate intervention authors' decisions about which theory mechanisms to address, and which intervention characteristics were chosen. Without this information, we can only suggest some reasons that mechanisms may not have been addressed. For example, some theory mechanisms may not have been incorporated because they did not fit the intervention format or capabilities. Social comparison with peers, for example, was used only in group or web-based formats by ten interventions and may be difficult to implement by formats of individualized therapy sessions. Other theory mechanisms may not have been incorporated because research teams decided they were not necessary or useful for the intervention. The self-judgement mechanism, 'Statistical comparison,' addressed by five interventions, is proposed to be helpful only if the normative group to which participants are being compared is representative. Investigators may have decided that their sample was not comparable to available research and therefore chose not to implement characteristics to address the 'Statistical comparison' mechanisms. Unfortunately, without detailed information about the process of intervention development, these are only suggestions as to some of the decisions that authors may have needed to make. Future researchers can use protocols and publications about intervention development as a source of understanding the selection process of which intervention characteristics were selected to address specific theory mechanisms. The development of consensus guidelines for guiding the use of theory within interventions is needed to improve both reporting use of theory use as well as implementation of theory throughout intervention development.

In our subgroup analyses that explored the number of theory components that were addressed according to assessed risk of bias, we found that nine of eleven interventions

with low risk of bias incorporated intervention characteristics associated with each of the three main theory components in contrast to only six of eleven and twelve interventions with high or unclear risk of bias, respectively. These small differences may have been influenced by poor reporting. Since risk of bias assessment relies on reported information (85), poor reporting may contribute to some interventions being assessed with high or unclear risk of bias and incomplete descriptions of theory mechanisms. These differences highlight the importance of accurate reporting to allow for understanding of mechanisms and intervention characteristics addressed.

2.4.1 Limitations

This review is not without limitations. We may have overlooked relevant interventions that were developed using the social cognitive theory of self-regulation, but that failed to cite either of the two publications we specified for inclusion. However, we expect that our inclusion criteria identified the best examples of interventions developed using the theoretical framework. We surmise that our database searching, citation searching, systematic review reference list searching, and reference list searching of included studies, limited the number of interventions missed in our investigation.

During our consensus process of determining how we would judge whether or not intervention characteristics address theoretical mechanisms, we identified some overlap in concepts of the theory. As a result of this overlap, we may have been overly inclusive when identifying whether each of the theory components and mechanisms were represented. For example, when participants were instructed to select their own rewards contingent on behavioural progress, the characteristic was judged to apply to both ‘Self-incentive’ of the self-evaluation component, and ‘Motivation’ of the self-monitoring component. The available descriptions of the social cognitive theory of self-regulation theory do not provide guidelines as to which mechanisms may overlap, or outline specifically which mechanisms or combination of mechanisms may be most relevant or useful for successful behaviour change. We therefore attempted to explicitly outline in our coding guide potential overlap across mechanisms, and set our criterion of identifying theory components at a minimum to provide a foundation upon which to build future exploration of applying the social cognitive theory of self-regulation in the development

of interventions for chronic health conditions. Research is needed to identify and evaluate which specific mechanisms and associated intervention characteristics are most important to address in behaviour change interventions. These evaluations may lead to the development of comprehensive guidelines suggesting how to use the theory mechanisms and components when developing interventions theory.

The social cognitive theory of self-regulation was originally proposed as an explanation of the mechanisms of human behaviour that may lead to effective self-regulation and behaviour change.(74,75) There are no existing guidelines for how to apply the theory to interventions, so we used a consensus process among three reviewers to determine our criteria for identifying how interventions addressed the theory components. We only identified what theory mechanisms and components the interventions addressed, rather than exploring the individuals experiences of participants interacting with the interventions. Exploring individual experiences and whether they support the proposed theory mechanisms and relationships may identify whether inclusion of specific intervention characteristics addressing theory mechanisms actually leads to better outcomes, as the theory would suggest.

2.4.2 Future Directions

We conducted this systematic review as a first-step method to inform the process that researchers can take during intervention development. For review authors conducting a similar review, we have some recommendations based on what we learned. First, we recommend the importance of a narrow search strategy, when possible, focused on important theory-related terms. Our search retrieved over 16,000 titles and abstracts. Minimizing the number of citations to screen will increase the efficiency of future reviews. Second, when screening the titles and abstracts we used two steps that we recommend for efficient screening. In the first step we conducted key word searches within our EndNote database for publication type (reviews, guidelines, theses), and for health conditions. We were able to quickly screen these citations and eliminate ineligible publications and health conditions. Third, at the full text screening level we conducted key word searching of retrieved manuscripts for citations of the social cognitive theory of self-regulation. Rather than screening entire articles for all of our inclusion criteria, we

were able to exclude over three thousand full text publications because they did not cite either of the two theory publications. Fourth, review authors exploring use of the social cognitive theory of self-regulation are encouraged to use our extraction guide (Appendix D) to identify intervention characteristics addressing the theory components. For review authors exploring a different theory, we recommend following a consensus procedure with two or three reviewers to develop an extraction guide that includes comprehensive understanding of the type of intervention characteristics that will be judged as addressing the theory mechanisms. We suggest using our extraction guide as a starting point and an example of how theory can be identified from exploring intervention characteristics.

If a review identifies that theory is comprehensively addressed across interventions, as our review did for the social cognitive theory of self-regulation for chronic health conditions, sufficient information is likely available to use the theory to guide development of a theory-driven intervention. Researchers can then use the review information to define which theory mechanisms to address, likely based off of frequency of implementation across interventions, and choose intervention characteristics to implement that are commonly used to address the theory mechanisms.

If, on the other hand, a review does not identify that theory is comprehensively used across studies, additional testing using alternative methods may be required to identify which, if any, of the theory mechanisms are applicable to the population of interest. When insufficient information is available, researchers may consider exploring the reported personal experiences of participants related to the theory of interest. Exploring participant experiences can identify which of the proposed theory mechanisms and relationships are supported from the perspective of the individual, and may inform the key characteristics that should be addressed when developing interventions.

We assumed for the purpose of this review that theory-driven interventions provide some benefit over atheoretical interventions. However, the effectiveness of theory-driven interventions compared to those developed without a theoretical framework is unclear. Future research should explore whether there are any benefits when implementing theory-driven in comparison to atheoretical interventions. Even if theory-driven interventions are identified equally as effective as atheoretical interventions, they build

on existing knowledge and provide explanations of specific interactions that influence how interventions may work, which is useful for informing improvement and modification of future intervention characteristics and implementation.(122)

2.4.3 Conclusions

The present review establishes that systematic review is a feasible method of identifying use of theory as a conceptual framework for existing interventions. We used the social cognitive theory of self-regulation as an example and identified that it is an adequate and practical theoretical framework to guide the development of interventions for some chronic health conditions. Researchers can use this type of systematic review to identify whether a selected theory is a feasible framework to guide intervention development, and which intervention characteristics are used to address the theoretical mechanisms. This work provides a preliminary investigation into exploring use of theory to inform the development of interventions.

CHAPTER 3: A Pilot Study Testing Methods of Examining Support for a Theory, a Precursor to Intervention Development

3.1 Introduction

Theory can help to guide hypotheses about potential relationships and interactions associated with intervention outcome for chronic health conditions.(66,67) Despite the potential benefits for using theory, it is infrequently incorporated during intervention development (76) with only 22-26% of interventions that report using theory identified in health behaviour literature (70,71), and only 6% report directly testing theory hypotheses during intervention design.(71)

In the early phases of intervention development, the UK Medical Research Council recommends using theory to define the components to include in an intervention by building an understanding of relevant theoretical mechanisms, identifying potential barriers to change, and exploring relationships between mechanisms and outcome that may influence behaviour change.(68) This step can be accomplished by modeling or simulating an intervention with participants, and performing initial testing through methods such as focus groups, surveys, or case studies.(69) Researchers can use these methods to attempt to identify from a participants' perspective which, if any of the theory mechanisms are applicable to the experiences of the population for which the intervention is being developed. The information from these evaluation methods may allow a more comprehensive understanding of the relevant theoretical mechanisms influencing behaviour change in the population of interest, and lead to the development of a more constructive intervention that is guided by the chosen theoretical framework.(68)

Although these recommendations are useful in providing an outline for the initial stages of developing theory-driven interventions, they fail to provide specific guidance on how to select and evaluate the appropriateness of theory for the particular health condition of interest. For this pilot study, we used headache as an example to test methods of exploring the applicability of a selected theory to a population of interest.

Headache affects a large proportion of the worldwide population, occurring with high prevalence, and associated with substantial physical, psychological, and economic

impacts.(124-127) Many treatment options are available for headache, however 17-23% of individuals with recurrent headache report dissatisfaction with their current pain management.(128,129) Although self-monitoring is commonly used as a clinical tool to help track headache characteristics, and monitor changes in headaches due to treatment, it has yet to be evaluated as an active management strategy for treating headache. In chronic health conditions such as arthritis, asthma, diabetes, heart disease, and weight, self-monitoring is used as an active behaviour change management strategy.(55,56,58,59,130) The social cognitive theory of self-regulation proposes self-monitoring as the first and possibly most important step to self-regulation leading to behaviour change.(74,75) Evidence from randomized controlled trials based on the social cognitive theory of self-regulation for health outcomes in arthritis (79), asthma (78), cardiac rehabilitation (81), and weight loss (80), supports the clinical benefits of interventions based on this theory. However, support of the proposed mechanisms and relationships of the social cognitive theory of self-regulation for explaining behaviour change in individuals with recurrent headache remains unknown.

The objective of this pilot study was to develop and test methods of examining the support for theoretical mechanisms by a population of interest in order to identify if the selected theory is appropriate as a framework to guide intervention development. As an example, we evaluated the support for self-monitoring mechanisms of the social cognitive theory of self-regulation by the experiences of individuals with recurrent headache. We pilot tested a novel approach of analysing questionnaire responses and interview transcripts from participants who had reported their experiences using an electronic self-monitoring tool. We used this data to identify which theory mechanisms associated with self-monitoring appeared to be supported or opposed by the participants' experiences with the intervention. We provide recommendations for the process of evaluating support for theory from a population of interest when evaluating reported participant experiences.

3.2 Methods

3.2.1 Study Design and Data Source

To test the process of identifying support for the social cognitive theory of self-regulation by individuals with recurrent headache, we analyzed semi-structured interview transcripts and open-ended questionnaire responses from individuals with recurrent headache who tested a two-week electronic headache diary. We used a coding guide derived from the self-monitoring component of the social cognitive theory of self-regulation to identify theory mechanisms that were supported or opposed based on participant experiences using the diary.

We used data collected from the testing of a comprehensive smartphone-based headache diary, created alongside the development of a web-based psychosocial cognitive behavioural intervention for adolescent and young adults with recurrent headache. The diary was created as an assessment tool to help individuals with recurrent headache become aware of headache symptoms and patterns, and to monitor their progress throughout the psychosocial intervention.(Huguet et al., in progress) The diary was not developed as an intervention with the purpose of changing headache outcomes. Although the diary was not developed specifically from components of the social cognitive theory of self-regulation, it addressed five of the eight mechanisms proposed to be associated with successful self-monitoring (Table 8).

Table 8 Overview of the electronic headache diary features that apply to the self-monitoring mechanisms proposed by the social cognitive theory of self-regulation.

Mechanism	Proposed contribution	Included in electronic headache diary
Feedback	Providing clear evidence of behaviour change progress	Smart-phone and web-based graphic reports. Users were given reports of how frequently they encountered and tracked each of their headache triggers. Using the diary at all provided users with new information.
Temporal proximity	Monitoring behaviour close in time to when the behaviour actually occurs	Users were asked to record their headaches and associated information in real-time as they occurred.

Mechanism	Proposed contribution	Included in electronic headache diary
Consistency	Regular rather than intermittent self-monitoring	Users were asked to record every headache, and to record daily events at the end of every day. Daily alarms encouraged consistency.
Focus on success	Attending to achievement rather than failure	N/A – Users were not guided to focus on accomplishments.
Value of behaviour	Self-monitoring behaviours with perceived importance, rather than behaviours of no importance	None of the diary items were mandatory. Users were provided with the option to track what was most important to them.
Control	Self-monitoring behaviours that are relatively easy to modify by deliberate effort	N/A – Users were not provided with strategies to manage their behaviour and/or headaches.
Motivation	Desiring to change the monitored behaviour	N/A – Users were not guided with strategies to increase motivation for change.
Self-diagnosis	Gaining new insight through identifying and noticing patterns of behaviour	Feedback visually displayed relationships between potential triggers and headaches.

The investigators created the diary using an empirically-driven approach, with diary content informed from a systematic review of headache diaries and a focus group study that tested the preferences of individuals with recurrent headache.(131) Using these information sources, a draft of the diary content was tested for face validity with headache experts and individuals with recurrent headache. Once the diary content was well-defined, the diary underwent initial stages of software development and testing with volunteers and colleagues of the investigators. After improving the prototype based on initial feedback, the diary went through three iterative cycles of testing and improvement with recruited headache participants. The investigators reached a final version of the diary once it was found to have acceptable feasibility and adherence from the headache participants. The diary was tested and found to have adequate convergent and concurrent validity. For this study we used data collected from the three cycles of diary testing with headache participants. Although we included participants who used the diary at various stages of testing, the content of the diary was not altered across these cycles of testing; only minor features were modified (e.g., addition of instructions) to improve the overall functionality of the diary.

3.2.1.1 Study Participants: Participants were eligible to take part if they were between 14-28 years old, experienced recurrent headaches two or more times a month for at least three months, reported that secondary causes for their headaches were ruled out by a health care professional, understood English, and owned an iPhone.

3.2.2 Data Collection

Participants were recruited internationally through online advertisements, social media, and posters displayed in headache clinics and public buildings. Prior to participation, eligible and consenting participants completed an online pre-study questionnaire. Participants were expected to use the diary for 14 days, track every headache and its associated characteristics upon occurrence, and complete daily diaries at the end of every day. Following the two-week study, participants completed an online post-study questionnaire. Ten percent of the completed participants were randomly selected to participate in post-study open-ended semi-structured interviews. For this study, we are using the data of participants who both completed the 14-day period and consented to their data being used for secondary research purposes.

3.2.2.1 Pre-study Questionnaire: We collected participants' demographic information (age, gender, and level of completed education) and headache characteristics (average intensity, average duration, and monthly frequency) from the pre-study questionnaire. Participants' headaches were classified based on reported headache symptoms using the criteria outlined in the International Headache Classification (132) to identify 1) migraine-like headaches, 2) tension-like headaches, 3) mixed headaches (meeting criteria for migraine and tension-like headaches, or 4) unclassifiable headaches.

3.2.2.2 Post-study Questionnaire: We collected participant responses to an open-ended question on the post-study questionnaire, asking participants to explain why or why not the diary was useful.

3.2.2.3 Post-study Interview: We used semi-structured interviews conducted over phone or Skype. The interviews were guided by an interview script developed a priori and facilitated by the study coordinator, and lasted approximately one hour (Appendix K). Participants were asked questions about their experiences using the diary, including

barriers, usefulness, burdens, goals, and suggestions for improvement. The interviews were not designed to assess the social cognitive theory of self-regulation. Interviews were audio recorded and transcribed verbatim.

3.2.3 Data Analysis

We used descriptive analysis to summarize the participant characteristics. We analyzed interview transcripts and participant responses to the open-ended question following methods similar to deductive thematic analysis.(133,134) We conducted our analysis with a coding guide derived from self-monitoring mechanisms proposed by the social cognitive theory of self-regulation. We did not separate results according to age, since the focus of this study was to explore theory and we felt that the experiences of adolescents and young adults would be similar enough to combine in the results.

3.2.3.1 Coding Guide and Database: We developed a coding guide to identify whether the interview and questionnaire data for each participant supported or opposed the self-monitoring mechanisms proposed by the social cognitive theory of self-regulation.(74,75) The theory identifies self-monitoring as the first component of self-regulation to initiate and inform behaviour change. The theory suggests that self-monitoring involves attention to, noticing, and tracking of personal behaviour, and proposes specific mechanisms that may be directly related to successful self-monitoring and contribute to behaviour change.

We created a coding guide that reflected the eight theory mechanisms proposed to be related to successful self-monitoring (see Table 8 for an overview of the self-monitoring mechanisms). We followed a consensus procedure to define the coding process. We developed the coding guide prior to reviewing interview transcripts or questionnaire responses, in order to develop unbiased codes that accurately reflected the mechanisms related to self-monitoring. We based the coding guide on information about the self-monitoring theory component from the two publications that describe the social cognitive theory of self-regulation.(74,75) Three reviewers (MT, JH, AH) independently reviewed two selected interviews using the theory definitions to identify participant experiences that addressed each of the specific mechanisms proposed to be associated with self-monitoring. The reviewers used the mechanism definitions to independently code the

reported participant experiences that addressed each theory mechanism. We explored agreements and disagreements and reached consensus through discussion about the types of participant experiences that were applicable to each of the self-monitoring mechanisms. We added descriptions to the coding guide based on the decisions made during consensus to clearly specify the type of participant experiences that addressed each theoretical mechanism, and to provide examples of participant reports that were consistent or inconsistent with the proposed mechanisms (Appendix L). Participants were aware that the purpose of the diary was to be used as an assessment tool to help provide understanding of headache and associated symptoms, and not to improve headache outcomes. To identify how the self-monitoring mechanisms were related to outcomes (potential behaviour change) experienced by participants, we considered statements associated with perceived usefulness and helpfulness of the diary as statements that implied a positive outcome related to using the diary.

Two reviewers (MT, SR) extracted the interview and questionnaire data using the coding guide (Appendix L). The reviewers manually entered codes for the interview and questionnaire data into a Microsoft Excel (2010) database.

3.2.3.2 Coding Process: We used two phases to code the interview and questionnaire data. In the first phase of coding, two reviewers (MT, SR) coded the interviews and questionnaire responses in their entirety to identify whether the theory mechanisms were addressed by each participant, and how they were addressed. The reviewers coded the participants' data as 'consistent' when all of the statements associated with a mechanism were interpreted to be congruent with the theory (e.g., Temporal proximity, 'consistent': *When I took medication I reported it into the diary right away*). The reviewers coded the participants' data as 'inconsistent' when all of the statements associated with a mechanism were interpreted to be incongruent with the theory (e.g., Temporal proximity, 'inconsistent': *When I took my medication I usually didn't report it into the diary until the end of the day*). The reviewers coded participants' data as 'mixed' when statements both congruent and incongruent with the theory were identified. The reviewers coded data as 'unclear' when they were unable to determine how the data applied to the theory mechanisms and 'none' when the data were not applicable to the theory mechanisms.

In the second phase of coding, the two reviewers (MT, SR) judged whether each theory mechanism was supported or opposed by each participant's data. The social cognitive theory of self-regulation proposes that specific mechanisms contribute to successful self-monitoring which then influences subsequent behaviour change. In the first phase of coding we identified which mechanisms were addressed by participants and whether they were consistent or inconsistent with the theory. In the second phase we considered whether the identified mechanisms were associated with successful self-monitoring for each participant. We judged overall support for each theory mechanism based on 1) the data from the first phase that were coded to address the mechanism, and 2) whether or not the participant found the diary 'helpful/ useful'. A participant's overall experience was considered 'supportive' of a theory mechanism when their assessed outcome and coded data corresponded with the proposed theory relationships: 1) the participant found the diary to be useful *and* the mechanism was addressed as 'consistent' across the participant's data, or 2) the participant did *not* find the diary to be useful, and the mechanism was addressed as 'inconsistent' across the participant's data. Conversely, a participant's experience was considered 'opposing' to the theory mechanism when their outcome and coded data differed from the proposed theory relationships: 1) the participant found the diary to be useful, however the mechanism was addressed as 'inconsistent' by the participant's data, or 2) the participant *did not* find the diary to be useful, and yet the mechanism was addressed as 'consistent' by the participant's data. The reviewers discussed any discrepancies during the coding process. Although a third reviewer was available, additional consultation was not needed to resolve any of the discrepancies.

3.2.3.3 Reliability: We calculated Cohen's Kappa to determine interrater reliability for coding the individual mechanisms, and for judging the overall support or opposition of the theory mechanism for each participant. We considered Kappa between 0.41-0.60 to be an indication of a moderate level of agreement.(83)

3.2.3.4 Data Synthesis: We report the feasibility of using questionnaire responses and interview transcripts to identify the applicability of self-monitoring mechanisms to individuals with recurrent headache. For descriptive purposes, we summarize the

characteristics of all participants together, and separately summarize the characteristics of the subsample of participants who completed the end of study interviews. We applied descriptive analysis using frequency counts and percentages to report sex, education, severity, and headache type. We used means, standard deviations, and ranges to summarize the age, headache frequency, and headache duration. We calculated the descriptive statistics using IBM Corp. SPSS, Version 22 software.(135) We used frequency counts to report how often participants' data were supportive or opposing of the theory mechanisms. To explore whether data were consistent and robust across data sources, we explored similarities and differences in how often data were supportive or opposing between the questionnaire and interview data sources.

3.3 Results

3.3.1 Feasibility

We conducted a pilot study to test whether our novel methods were appropriate for researchers to use when determining whether a selected theory is supported by a population of interest, and may be used for informing intervention development. We found our process suitable for identifying support for theory based on questionnaire responses and semi-structured interviews from participants who reported experiences using an electronic headache diary. From both data sources we identified support and opposition of the theory. We identified more support than opposition for all of the theory mechanisms within both data sources.

We used a convenience sample of individuals with recurrent headache between the ages of 14-28 who owned an iPhone. The recruited population was not generalizable to all individuals with recurrent headache. The data were collected from usability and feasibility testing of an electronic iPhone headache diary, resulting in a small available sample size, for a time period of only two weeks. This sample size was sufficient for pilot testing our methods, however, was insufficient for drawing conclusions regarding support or opposition for the self-monitoring mechanisms of the social cognitive theory of self-regulation.

For both the questionnaire responses and interview transcripts, some mechanisms were either never mentioned, or were addressed by only one or two participants. Because our data were previously collected and neither the electronic diary nor the questions asked participants were specific to the self-monitoring component of the social cognitive theory of self-regulation, we were unable to direct the questions for each participant to discuss each of the theory mechanisms.

Although both the questionnaire responses and interviews addressed some of the mechanisms and provided both support and opposition across participants, the interviews provided a greater number of theoretical mechanisms that were addressed by at least half of the participants. The questionnaire responses were answers to a direct question “Why or why not was the diary useful for you,” which did not probe participants for additional information. One open-ended response is not sufficient for evaluating support of theory. The interviews provided a greater depth of information, from which we were able to evaluate multiple responses across the entire interview to be able to interpret the participants’ experiences and how they addressed the theory mechanisms.

3.3.2 Study Participants

Of 167 eligible individuals, 107 initiated participation, and 88 completed the 14-day participation period. For this study, we used the data of 83 participants who completed the 14-day period and consented to their data being used for secondary research purposes. Nine of these participants completed the end of study interview. Demographic information, headache characteristics, and headache diagnoses are displayed in Table 9. Most participants were female, had at least an undergraduate degree, experienced moderate to severe pain, had nearly three headaches per month, had headaches that lasted almost 10 hours on average, and most frequently had unclassifiable headaches.

Table 9 Summary of participant characteristics for all participants, and a subsample of interviewed participants.

Characteristics	All participants (n=83) ¹	Interviewed participants (n=9) ¹
Age, years (Mean ± SD (Range))	22.72 ± 3.2 (16-27)	22.56 ± 3.4 (16-27)
Female, n (%)	70 (84%)	9 (100%)
Education, n (%)		
In high school/ high school diploma	12 (14%)	2 (22%)
In college/ university	21 (25%)	1 (11%)
College diploma	3 (4%)	--
Undergraduate degree	30 (36%)	4 (44%)
Graduate degree	12 (15%)	1 (11%)
Other	4 (5%)	1 (11%)
Missing	1 (1%)	--
Average pain severity, n (%)		
Mild	9 (11%)	1 (11%)
Moderate	38 (46%)	4 (44%)
Severe	34 (41%)	3 (33%)
Missing	2 (2%)	1 (11%)
Constant headaches, every day, n (%)	28 (34%)	44%
Participants without constant headaches:		
Average monthly headache frequency, headaches (Mean ± SD (Range))	2.76 ± 0.98 (1-4)	3 ± 1 (2-4)
Average duration of headache episodes, hours (Mean ± SD (Range))	9.76 ± 15.42 (0.17-72)	16.2 ± 12.79 (3-36)
Headache type, n (%)		
Migraine-like	26 (31%)	3 (33%)
Tension-type-like	2 (2%)	--
Unclassifiable	47 (57%)	6 (67%)
More than 1 type	7 (8%)	--
Missing	1 (1%)	--

¹ All percentages are rounded to the nearest whole number

3.3.3 Post-study Questionnaire Responses

All 83 participants responded to the post-study questionnaire inquiry, ‘Why or why not was the diary useful for you?’ On average, each participant supported 1.78 of the 8 self-monitoring mechanisms.

The most common mechanism supported from the participants’ questionnaire responses was ‘Value of behaviour’ (Table 10). Our coding guide specified that unless participants explicitly reported tracking irrelevant behaviours, we judged that the behaviours participants reported monitoring were relevant and of importance to them. We coded in

this way because participants were asked to monitor only the variables that were relevant to them. Therefore, the majority of participants who identified the diary as useful and who mentioned tracking a behaviour, were judged as supportive of the theory mechanism.

Value of behaviour, supportive: *“The diary was very useful for me because it reminded me at the end of each day to record events that happened during that day. It helped me keep track of the potential triggers of my headaches.”*

The mechanisms ‘Feedback’ and ‘Self-diagnosis’ were also frequently supported across participants’ questionnaire responses. Participants often reported finding the diary useful as a method for identifying previously unknown headache triggers, or for better understanding their headache patterns (‘Self-diagnosis’). We also coded that the mechanism ‘Feedback’ was present when participants perceived that the diary was useful as a source of new information, since any type of self-monitoring may provide additional information that was otherwise unavailable. Therefore, many of the participants who were supportive of the ‘Self-diagnosis’ mechanism, were also supportive of the ‘Feedback’ mechanism.

Self-diagnosis, Feedback supportive: *“I found it very helpful to be able to quantify exactly how often I get headaches, and what events during the day might be associated with their onset.”*

Only a small number of participant responses were identified as opposing any of the theory mechanisms. The most opposition was found for the ‘Self-diagnosis’ and ‘Feedback’ mechanisms; two participants reported finding the diary helpful, yet they also specified that they did not gain any new understanding from using the diary.

Self-diagnosis, Feedback opposing: *“It [the diary] was helpful to fill out, but I didn’t see any new patterns other than what I already knew.”*

The remaining mechanisms were infrequently addressed by any participant, with the mechanisms ‘Focus on success’ and ‘Temporal proximity’ each addressed by only three participants.

Table 10 Summary of participants' questionnaire and interview responses that addressed the self-monitoring mechanisms as proposed by the social cognitive theory of self-regulation.

Mechanism	Response	Number of question responses (of 83) N (%¹)	Number of interviews (of 9) N (%¹)
Feedback	Supportive	36 (43%)	8 (89%)
	Opposing	2 (2%)	--
	Mixed	3 (4%)	--
	None	44 (52%)	1 (11%)
Temporal proximity	Supportive	1 (1%)	1 (11%)
	Opposing	2 (2%)	--
	Mixed	--	8 (89%)
	None	80 (96%)	--
Consistency	Supportive	3 (4%)	5 (55%)
	Opposing	--	--
	Mixed	1 (1%)	4 (45%)
	None	79 (95%)	--
Focus on success	Supportive	4 (5%)	2 (22%)
	Opposing	--	--
	Mixed	--	--
	None	79 (95%)	7 (78%)
Value of behaviour	Supportive	61 (73%)	6 (67%)
	Opposing	1 (1%)	1 (11%)
	Mixed	3 (4%)	2 (22%)
	None	19 (23%)	--
Control	Supportive	8 (10%)	1 (11%)
	Opposing	--	1 (11%)
	Mixed	--	--
	None	75 (90%)	7 (78%)
Motivation	Supportive	8 (10%)	6 (67%)
	Opposing	--	2 (22%)
	Mixed	--	--
	None	75 (90%)	1 (11%)
Self-diagnosis	Supportive	35 (42%)	8 (89%)
	Opposing	2 (2%)	--
	Mixed	2 (2%)	--
	None	44 (53%)	1 (11%)

¹All percentages are rounded to the nearest whole number

3.3.4 Post-study Interviews

Based on coded transcripts of the nine semi-structured post-study interviews, on average four of the eight self-monitoring theory mechanisms were supported by each of the participants' reported experiences using the two week electronic headache diary.

The two self-monitoring mechanisms that were supported most often across the interviews were 'Feedback' (8 of 9 participants), 'Self-diagnosis' (8 of 9 participants), (Table 10). Six participants who reported finding the diary useful also perceived that the diary provided them with clear information about their monitored behaviour ('Feedback'), and that they gained self-insight as a direct result of using the diary ('Self-diagnosis'). Conversely, there were two participants who did *not* find the diary useful, and who reported both an absence of informative feedback from the diary ('Feedback'), and also a failure to identify any new understanding of their monitored behaviour ('Self-diagnosis'). The reported experiences of these participants all exhibited support for the proposed self-monitoring mechanisms 'Feedback' and 'Self-diagnosis,' of the social cognitive theory of self-regulation.

Self-diagnosis, Feedback supportive: *"It's [the diary] been most helpful pointing out that I have two types of headaches. I have migraine headaches, and also daily, dull headaches. So it's been helpful for me in figuring out what has been making the daily headaches worse."*

"It wasn't [useful]. I think it's just because of the types of headaches that I suffer, I didn't really feel like it was telling me anything that I didn't already know."

The mechanism 'Motivation' was also supported by the majority of participants, in that those who found the diary to be useful were invested in understanding or changing their behaviour, and one participant who *did not* find the diary useful also did not desire to learn anything new about their headaches. However, one participant who reported that the two-week diary was not helpful also reported that her goals for participating in the study were to gain more insight about her headaches ('Motivation'). This participant's experience was inconsistent with the theory hypothesis that motivated individuals are more likely to improve their behaviour.

Motivation, opposing: *"I figured that it's a new thing to try [the diary], and maybe something will come of it, more insight."* Interviewer: Did it help you?
"Not yet...but I can see that in a year's time I could see changes or notice something."

All nine participants discussed whether or not they monitored their behaviour in real-time ('Temporal proximity'), with most participants reporting mixed experiences, both monitoring behaviour as it happened (usually headache episodes) and monitoring behaviour by recall (usually at the end of the day). All participants also discussed the mechanisms 'Value of behaviour', and 'Consistency'. Participants tended to report monitoring behaviours they perceived as valuable, regardless of whether they found the diary useful or not. As a result, we identified a variety of experiences reported by participants that were mixed, supportive and opposing of the 'Value of behaviour' mechanism. Two self-monitoring mechanisms, 'Control', and 'Focus on success' were never, or rarely discussed by participants.

3.3.5 Exploring differences in identification of theory mechanisms

We identified that the interviews provided a more comprehensive exploration of the self-monitoring mechanisms than the questionnaire responses. From the interviews we identified support for the mechanisms 'Consistency', 'Motivation', and 'Self-diagnosis', when these were infrequently addressed and supported by the questionnaire data. We did not identify any obvious differences in questionnaire data versus interview data, with regard to how often the data were opposing the mechanisms that were addressed by both of the data sources.

3.4 Discussion

This pilot study provides an example of methods that can be used to identify whether reported participant experiences using a model or simulated intervention can be explored to identify if a selected theory is supported or opposed by a population of interest. We found that participant reported experiences from collected interviews were useful for identifying theory support. From this process we have identified recommendations for future researchers to improve these methods when exploring theory as a potential framework for intervention development. As an example, we explored participant experiences using an electronic headache diary as a model of a self-monitoring intervention. The self-monitoring mechanisms of the social cognitive theory of self-regulation that were supported by the majority of participant interview and questionnaire

responses were 'Value of behaviour,' 'Self-diagnosis,' and 'Feedback,' while the mechanisms 'Control' and 'Focus on success' were infrequently addressed.

We were able to identify support for theoretical mechanisms using both semi-structured interviews, and questionnaires from the participants' reported experiences. The questionnaire had a rigid structure, with all of the participants responding to a single question, 'Why or why not was the diary useful for you?'. As a result, we found the questionnaire responses were direct, concise, and straightforward to code. However, we do not consider this data on its own as necessarily being representative of the participants' overall experiences using the diary, because the question was very broad and each participant may have interpreted it in a variety of ways for various aspects or features of the diary. We identified that the reported participant experiences from the interviews were more comprehensive and explanatory than those of the open-ended question responses. The interviews were semi-structured; all participants were asked the same basic questions, however the flexible structure allowed for further probing and exploration by the interviewer. The interviews provided a more comprehensive understanding of participants' experiences than the single open-ended question from the post-study questionnaire and approached a wider range of mechanisms for a greater proportion of the sampled population. Using interviews that explore participants' experiences with an intervention is a feasible option for identifying whether proposed theoretical mechanisms are applicable to a population of interest. Since feasibility testing is often an early step during the development of interventions to identify whether an intervention should be explored for efficacy (136), interviews can be incorporated during feasibility testing to identify theory support or opposition and help to define the mechanisms that should be addressed by intervention characteristics.(68,69,119)

Our data sources were convenient and previously collected for other research purposes, the electronic headache diary, post-study questionnaire, and post-study interviews were not explicitly designed to assess our theory of interest. We found consistent support across the two data sources for three of the eight theory mechanisms that were explored and only a small proportion of participants reported experiences that were opposing the proposed theory. However, because the questions were not designed to specifically

address the theory, we are unable to determine whether these findings are spurious as a result of the questions asked and assumptions that we made, or if the participant experiences actually were supportive of the theory. If participants reported finding the diary useful in general, we interpreted the experience as useful for understanding or improving headaches. We also made an overall judgement about whether or not a theory mechanism was supported, by connecting participants' reported outcomes (perceived useful/helpfulness of the diary) with their statements associated with the self-monitoring mechanisms. For example, if a participant stated in one part of the interview that they did not identify any new information about their headaches ('Self-diagnosis'), and in another part of the interview reported that they didn't find the diary useful, we considered this participant's experience supportive of the theory mechanism, because both statements were consistent with the theory mechanism. To avoid these uncertainties, researchers exploring theory support should ensure that the questions asked to participants specifically address each of the theory mechanisms and prompt elaboration for understanding of how these directly apply to participants' perceived influence on their health condition. Direct questions investigating the theory could increase confidence in how accurately and comprehensively the theory is explored, while reducing the assumptions that need to be made.

Our data were collected from participants who tested an electronic diary designed as an assessment tool to be used in conjunction with a web-based cognitive behavioural therapy. The diary design tested in this pilot study was not developed specifically from components of the social cognitive theory of self-regulation, and addressed only five of the eight self-monitoring mechanisms. The ideal design for this evaluation process would have been to use a diary that specifically addressed each of the self-monitoring mechanisms, and that was assessed using semi-structured interviews that were specifically constructed to address the self-monitoring mechanisms as an informative source with which to identify the relevance of theoretical mechanisms.

This pilot study provides preliminary insight into evaluating the applicability of self-monitoring mechanisms, proposed by the social cognitive theory of self-regulation, to the experiences of individuals with recurrent headache using an electronic headache diary.

The mechanisms that were supported by the majority of participant interview and questionnaire responses were ‘Value of behaviour,’ ‘Self-diagnosis,’ and ‘Feedback,’ while the mechanisms ‘Control’ and ‘Focus on success’ were infrequently addressed. Due to limitations in the available data and the small sample size, we hesitate to draw conclusions about whether or not the theory is a feasible framework to guide self-monitoring interventions for headache.

3.4.1 Limitations

Due to the nature of this preliminary pilot testing, our methods have several limitations, most of which have already been discussed. Our sample was convenient, small in size, and only generalizable to individuals with recurrent headache, between the ages of 14-28, who understand English, and own an iPhone. This was an analysis of a headache diary not designed specifically to incorporate mechanisms adhering to the self-monitoring component of the social cognitive theory of self-regulation. We analyzed participant experiences reported in questionnaires and interviews that were not designed to address theory mechanisms. We therefore made assumptions about how the participants’ experiences applied to the theory.

3.4.2 Future Directions

These findings present both a starting point for, and an example of evaluating theory in the development process of theory-driven interventions. To address the limitations from our pilot assessment the next step is to conduct a fully developed feasibility study to assess support for the social cognitive theory of self-regulation for individuals with recurrent headache. Feasibility studies are appropriate when there are few previously published studies or existing data.(136) Since the proportion of studies using theory is so small (70,71), researchers wishing to draw information from previously published interventions using theory may not identify sufficient information from existing literature. Feasibility studies are therefore useful to explore support for a theory, prior to development and implementation of an intervention when no other information is available.

A future study using our methods of exploring support or opposition for a theory to determine its applicability as a framework to guide intervention development should consider following our recommendations. Studies should gather participant reports from those testing an intervention that has been developed to address the theory mechanisms, rather than an available intervention developed for other purposes. Evaluation of experiences using the intervention should also be formulated to specifically investigate the proposed theoretical mechanisms and relationships. We encourage researchers to use our coding guide as an example for how support or opposition for theory mechanisms can be identified from participant experiences (Appendix L). We recommend evaluation to be conducted through interviews, rather than questionnaires, and in a population that is generalizable to which the intervention will be delivered. As recommended by the UK Medical Research Council, a process of testing the intervention can improve understanding of the characteristics that should be included in an intervention.(68,69,119)

3.4.3 Conclusions

The present pilot study illustrates that exploring participants' reported experiences using semi-structured interviews and questionnaire responses is a feasible method with which to identify theory relevance for a population of interest, when beginning to explore theory in the development of interventions for chronic health conditions. By identifying applicable theoretical mechanisms proposed to be associated with behaviour change, researchers developing interventions can identify applicable mechanisms to target using specific intervention characteristics.

CHAPTER 4: Discussion

4.1 Summary of Methods and Findings

The objective of this thesis was to test two novel approaches that can be used to explore the use of theory as a framework in the initial stages of development and testing theory-driven interventions. As an example, we explored the social cognitive theory of self-regulation as a potential framework to guide using self-monitoring as a management strategy for behaviour change in chronic pain. First, we conducted a systematic review of the literature to assess how the social cognitive theory of self-regulation is used as a conceptual framework for guiding interventions of chronic health conditions. Second, we conducted a pilot study to explore how to test the applicability of self-monitoring mechanisms from the social cognitive theory of self-regulation to individuals with recurrent headache.

4.1.1 Systematic Review

For researchers in the preliminary stages of intervention development and are defining the components to include within an intervention, the UK Medical Research Council suggests that researchers begin by gathering information from existing interventions of similar purpose from previous studies in closely related conditions.(68) Reviewing existing interventions can help to identify what methods were used in the development and evaluation of these interventions, and determine what theory mechanisms are most often addressed. Guidelines are not provided within these recommendations to suggest the process that researchers should take to investigate theory as a potential intervention framework. We were interested in exploring how to identify which theory components and mechanisms are incorporated by interventions, and which intervention characteristics are used to address each theory mechanism. To test this process, we conducted a systematic review to identify whether the social cognitive theory of self-regulation can provide an informative framework to guide the development of self-monitoring interventions for chronic health conditions.

We selected the social cognitive theory of self-regulation, as it provides a comprehensive proposal of how self-monitoring is the first and possibly most important step to self-

regulation, potentially leading to successful behaviour change.(74,75) In addition to chronic pain, we searched for interventions developed using the theory to manage arthritis, asthma, diabetes, heart disease, and weight management. We selected these health conditions as they all have similar characteristics, being non-communicable, long-lasting, with a constant non- or slowly-progressive course, and with associated health episodes or behaviour suitable for monitoring. We identified thirty-five interventions that reported using the social cognitive theory of self-regulation to inform some, or all of the administered intervention characteristics. We found that twenty-one interventions addressed all of the main theory components, while fourteen interventions did not address one of the main theory components. This process was driven from available descriptions about the mechanisms proposed to be involved in behaviour change by the social cognitive theory of self-regulation. From this we were able to identify which theory components and associated mechanisms were addressed by included interventions.

Future researchers developing theory-driven interventions can use this process to identify how comprehensively theory is addressed in existing primary studies. This provides informative guidance about the mechanisms that were deemed important enough by previous researchers to address using intervention characteristics. A synthesis of available interventions can guide researchers in identifying the mechanisms frequently used across interventions, and which intervention characteristics are often used to address each of the theory mechanisms. This information can be used to target specific mechanisms within future interventions. If sufficient information is unavailable from a systematic review about use of theory in the condition of interest or in conditions with similar characteristics, researchers using theory to develop interventions should conduct additional testing to explore which theory mechanisms are supported by the population of interest.

4.1.2 Pilot Study

The recommendations for development of theory-driven interventions suggest that prior to defining intervention design and components, preliminary pilot testing and exploration of theory related mechanisms and relationships can guide understanding what mechanisms may obstruct or enhance behaviour change.(68) However, these guidelines

do not suggest how to evaluate the support for theory by a population of interest.(137) We therefore conducted a pilot study to explore whether support of theory-related mechanisms can be assessed from reported experiences of previously collected data.

We explored semi-structured interview transcripts and a single-item post-study questionnaire to investigate whether the experiences of individuals with recurrent headache using an electronic headache diary were supported by the self-monitoring mechanisms of the social cognitive theory of self-regulation. We identified that three of the eight self-monitoring mechanisms were supported by participant experiences in the study, despite the diary, interviews and post-study questionnaire not being developed to specifically address the social cognitive theory of self-regulation. However, our sample size was small and we made several assumptions about whether the data supported the theory or not. Nonetheless, this study illustrated that semi-structured interviews and open-ended questionnaire responses are feasible data sources to test the support of a theoretical framework by a population of interest. To further investigate how the theory is applicable to individuals with recurrent headache and chronic pain, future work needs to comprehensively explore whether the theory mechanisms are applicable to individuals using self-monitoring management specifically developed to address each of the theory components.

Future researchers developing theory-driven interventions can use this process to identify whether or not theory mechanisms and proposed relationships are applicable to the population of interest. Investigating reported experiences from the population provides an in depth understanding of whether important proposed theoretical mechanisms lead to behaviour change. This exploration can identify important mechanisms that should be targeted within interventions, and are found to lead to proposed outcomes within that population.

The majority of literature exploring theory use in interventions is focused on identifying what theories are used most often (70,71), testing what theoretical mechanisms are associated with intervention outcomes (120,121), and classifying what intervention techniques are associated with theoretical concepts.(122) Literature rarely explores how theory is specifically addressed within interventions to identify which mechanisms are

addressed, and by what intervention characteristics. Available studies and methods of testing support of theory for a population are lacking.(137) Our methods of identifying and evaluating support of theory can be used to guide future researchers in the development process of theory-driven interventions.

4.2 Self-monitoring as a Chronic Pain Management Strategy: Support of the Social Cognitive Theory of Self-regulation

From our systematic review we identified that the social cognitive theory of self-regulation is a feasible framework for guiding the development of interventions for chronic health conditions. Although none of the interventions included in our review were for managing chronic pain, they were of similar characteristics. Considering the comprehensive use of the theory across health conditions, we feel that the social cognitive theory of self-regulation is a sufficient framework to inform the development of a self-monitoring intervention for chronic pain. Although self-monitoring is typically used in the clinical setting as an assessment tool for chronic pain (36-39), our findings are encouraging that self-monitoring may be a useful management strategy for chronic pain conditions. Although our pilot sample size was small, we found consistent support from both participant questionnaire and interview responses for the mechanisms ‘Value of behaviour,’ ‘Self-diagnosis,’ and ‘Feedback,’ all of which were frequently addressed by interventions from our systematic review. These preliminary findings across both the review and pilot study are encouraging support for use of the social cognitive theory of self-regulation to inform the development of a chronic pain self-monitoring management strategy.

According to the UK Medical Research Council recommendations, once we have gathered information from reviewing existing literature, and have improved our understanding of the theory through modeling or simulation techniques of the defined the intervention characteristics, the next phase is to develop the optimal intervention and study design.(68) We can use information from both feasibility testing and the review to build our ideal intervention. The feasibility testing provided insight from an individuals’ perspective about which intervention components contribute to behaviour change. Results from the feasibility testing can contribute to enhancing the intervention characteristics by

understanding the reactions that participants had to intervention characteristics that addressed the theory mechanisms. The intervention characteristics can be developed in consideration of those commonly used for self-monitoring interventions identified from our systematic review. Once the intervention is developed, we can then evaluate whether a self-monitoring intervention is acceptable as a management strategy for chronic pain.

4.3 Limitations

The limitations of each individual study have been addressed within their respective chapters. However, there are some overall limitations of this thesis to address.

Neither the systematic review, nor the pilot study was conducted entirely in chronic pain populations. The systematic review did not identify any interventions managing chronic pain. The UK Medical Research Council suggests that when information is unavailable in the population of interest, existing research in similar populations should be explored, which we addressed in our review by including health conditions with characteristics similar to chronic pain. The pilot study was conducted in adolescents and young adults with recurrent headaches and therefore is not directly applicable to all chronic pain populations. Future testing of the applicability of the theory to chronic pain populations is needed.

The social cognitive theory of self-regulation was the focal point of this thesis. However, there are no existing guidelines on how to interpret the use of the theory for its application in interventions, or how to detect the presence of the theory mechanisms as they apply to individuals using self-monitoring. Our results are therefore based on our judgement and interpretation of the theory and its mechanisms. In an attempt to operationalize the theory for our purposes, we used a consensus procedure for each study to determine a priori how to identify the theory mechanisms when coding the interventions and the participant experiences.

Although the systematic review addressed all three of the main theory components proposed in the social cognitive theory of self-regulation, the pilot study only assessed the applicability of self-monitoring mechanisms to individuals with recurrent headache.

Future research is needed to investigate how the entire theory, its main three components and respective mechanisms are applicable to individuals with chronic pain.

We have selected the social cognitive theory of self-regulation as the foundation for this thesis because it provides a comprehensive description of possible mechanisms and relationships that influence self-monitoring and subsequent self-judgement, self-evaluation, and ultimately self-regulation. This is not to say that the theory is the most precise option for explaining behaviour change, or that self-monitoring interventions should only consider the social cognitive theory of self-regulation. Many existing theories are available, with some overlap in the behaviours and mechanisms that they address.(64) Interventions may benefit from being informed by more than one theory in order to address multiple health behaviour constructs. However, this was outside of the scope of this thesis, and we selected the social cognitive theory of self-regulation as the most relevant theory available for our purposes. It is frequently used in health behaviour literature (70), and provides a comprehensive overview of the potential influence that self-monitoring may have on behaviour change.(74,75)

The majority of behaviour change interventions in health research are atheoretical.(70,71) Using theory to inform the development of behaviour change interventions has yet to be identified as more or less effective than atheoretical interventions. To explore the benefit of using theory, we need studies testing the effectiveness of theory-driven interventions in comparison to those without any theoretical framework. Our systematic review did not identify any studies that attempted to explore this.

Theory has the potential to help improve the state of health behaviour literature by decreasing heterogeneity in the techniques used across interventions, and by improving replication for future interventions and in clinical practice.(65,122) The interventions in our systematic review, however, addressed a variety of the theory mechanisms, without providing clear explanation of which behaviour change techniques were implemented to address which of the theoretical mechanisms, and so we used our judgement to identify which intervention characteristics may have applied to the theoretical mechanisms. Unfortunately, underreporting of intervention characteristics is a common problem in health behaviour literature.(123) For theory-driven research to improve the health

behaviour literature, complete reporting of the testing, development, and implementation of theory-driven interventions at every stage will enhance the ability for both replication in future research, and application in clinical practice.(69) Complete reporting of how theory has been addressed will guide the understanding of the specific mechanisms and relationships that may contribute to intervention outcome.(67,76)

4.4 Conclusions

This thesis uses two novel approaches to explore the use of theory as a conceptual framework for the development of theory-driven interventions. As an example, we used the social cognitive theory of self-regulation to explore the role of self-monitoring as a potential chronic pain management strategy. We were able to use theory to 1) identify the extent to which the social cognitive theory of self-regulation is a useful framework to inform the development of interventions with a focus on self-monitoring and, 2) explore testing some of the theoretical self-monitoring mechanisms that are clearly supported by individuals with recurrent headache using a basic self-monitoring assessment tool. More investigation for applying the social cognitive theory of self-regulation to chronic pain populations is needed before development of a self-monitoring management option is possible. However, this thesis provides a preliminary foundation of exploring theory in the use of intervention development, upon which to guide investigating this future possibility.

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APPENDIX A: Self-monitoring of chronic pain: A preliminary review

The goals of this review were to explore and clarify the role that self-monitoring may have in controlling pain conditions by answering the following question: In *populations* of all ages with chronic non-cancer pain lasting for at least 3 months duration, does self-monitoring pain (at least pain intensity) once a day or more, using paper- or electronic- based pain diaries as a stand-alone *intervention*, influence change in the *primary outcome* pain intensity and *secondary outcomes* pain duration, frequency, disability over a 1-week or longer period of time, in *comparison* to treatment or control (waiting list, treatment as usual) as measured through randomized or controlled clinical trial *study designs*?

METHODS

Selection criteria: Studies were included if they met the following criteria:

Types of studies: Studies were published reports of completed randomized controlled trials (RCTs), conference proceedings, registered trials, abstracts, theses, and protocols (not including reviews, summaries, commentaries, editorials, letters to the editor).

Types of participants: Participants were chronic or recurrent pain subjects, with pain lasting at least 3 months or more in duration. All types of pain not related to chronic life threatening illness (e.g., cancer), or specific conditions (e.g., pregnancy) were included. No age or setting restrictions were applied. Populations were excluded if more than 30% of the participants had psychiatric impairment, cognitive handicap, intellectual disabilities or visual problems that may interfere with self-monitoring participation.

Types of interventions: Studies were included when self-monitoring was used as a stand-alone condition, recording at least pain intensity once or more per day for a consecutive period of at least 7 days. Studies were not included when self-monitoring was provided in conjunction with another treatment (e.g., biofeedback + self-monitoring). Studies were required to present a comparison of self-monitoring and control conditions through statistical analysis (not only descriptive) to determine the efficacy of self-monitoring in comparison to control, however the comparison did not need to be the main goal of the study; evaluation of self-monitoring in comparison to control as subgroup analyses was acceptable.

Types of controls: Studies were included when self-monitoring alone was compared to inactive controls (e.g., waiting list, standard care, no treatment), or active controls (e.g., another type of treatment such as psychological, cognitive behavioral therapy (CBT), biofeedback relaxation, pharmacological, another type of self-monitoring). Studies were excluded if both conditions included the same self-monitoring assessment (e.g., self-monitoring vs. self-monitoring + CBT).

Types of outcomes: The primary outcome of interest was pain intensity, measured before and after the study period, with analyses assessing the change in variables over time and comparing the difference in change between study groups. If pain intensity was not measured, studies were excluded.

Literature search: A systematic search of the PubMed database was conducted and searched from inception to June, 2013 without restriction to language. Reference lists of included studies were reviewed for additional studies. The search strategy was developed using MeSH and Boolean operators, adapted from systematic reviews of the use of self-monitoring for health conditions other than pain, to search for key words related to pain (e.g., Chronic Pain [MeSH], Pain [tiab]), and terms related to self-monitoring (e.g., “self-monitoring”, “diary”, “electronic diary”), see Appendix A1 for the full PubMed search strategy. A scoping search of the literature was conducted using the terms “pain” and “self-monitoring”. No restrictions on language were applied during the screening phase of the study. One independent reviewer (MT) screened titles and abstracts of all relevant articles retrieved. Relevant articles were read in full.

Data extraction: A data extraction form was developed and pilot tested with two reviewers (MT, AR). Discrepancies were discussed and consensus was reached for the extraction form. Extraction was conducted by one reviewer (MT) using the tested data extraction form. Data extraction included participant characteristics (age, sex, and socioeconomic status), study design, inclusion/exclusion criteria, pain characteristics (type of pain, duration, and frequency), outcome assessment, self-monitoring characteristics, comparison characteristics, and relevant data. Study authors were contacted when important information was judged to be missing from the manuscripts.

Critical appraisal of methods: One reviewer (MT) conducted risk of bias assessment. The internal validity assessing risk of bias of the included primary studies will be assessed using The Cochrane Collaboration’s Risk of Bias tool.(85) This tool assessed selection bias (through judgement of randomization and allocation concealment), performance bias (through judgement of blinding participants and study personnel), detection bias (through judgement of procedures for blinding outcome assessors to allocation of study condition), attrition bias (through judgement of the completeness of the data in relation to attrition), and reporting bias (through judgement of potential selective outcome reporting). Studies were assessed with overall ‘high risk of bias’ when at least one of the key domains had high risk of bias, ‘and ‘low’ risk of bias when all of the domains were rated as low risk.. Studies in which all of the key domains were rated as some combination of low or unclear risk were rated as ‘unclear’ risk.(84)

Data were synthesized when sufficient data were available from the individual studies. RevMan 5 software was used to calculate standardized mean difference between self-monitoring and treatment or control groups with regard to their experienced pain intensity and secondary outcome measures. Measures of consistency using I^2 were calculated to identify heterogeneity between studies.

Risk of bias across studies: To rate the overall risk of bias of evidence and the strength of recommendations, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool was used.(138) The GRADE tool has been developed as an approach to grade the quality of evidence and the strength of recommendations associated with synthesized findings from randomized controlled trials.

RESULTS

Results of the initial literature search: The PubMed database search strategy presented in Appendix A1 retrieved 2232 abstracts (see Appendix A2 for the PubMed results) in June, 2013. When filtering the search results to clinical trials and randomized controlled trials, 1056 articles were identified for review. One reviewer (MT) screened all of the titles and abstracts of the 1056 articles, identifying 50 articles in total to be read in full. Of these, 5 were identified for inclusion in the review. The preliminary scoping search of the literature identified 35 articles for screening, and 1 article to be included in the review, for a total of 6 (see Appendix A3 for the flow chart of the review process). At the full text screen stage, studies were most often excluded due to comparison groups having a self-monitoring condition (n=15), and due to studies being observational in design (n=7) (see Appendix A3 for all of the causes of exclusion at the full-text screening stage). Two study authors were contacted with inquiries regarding methods of the review, with no response.

Included reviews and review characteristics: Six randomized control trial articles were selected for inclusion.(49-54) Among the included studies, four compared self-monitoring to active treatment conditions.(49-52) The other two articles included studies compared self-monitoring to no self-monitoring waiting list conditions.(53,54) Sample sizes ranged from 30-91 participants with ages ranging from 8-80 years old , and years of publication of the articles ranging from 1987-2005 and. Pain conditions included headache (50-52), fibromyalgia (49), low back pain (54) and chronic pain (including diagnosis of fibromyalgia, arthritis, osteoarthritis, and ankylosing spondylitis).(53) The two studies comparing self-monitoring to waiting list conditions were short in study duration, ranging from 8 to 14-days long.(53,54) The four studies comparing self-monitoring to active treatments were longer in duration, with 5 to 8-week study periods.(49-52) All of the studies had very simplistic self-monitoring conditions, with the majority measuring only pain intensity and medication using paper-based diaries.(49-54)See Appendix A4 for a summary of characteristics of the included studies.

Risk of bias assessment: The risk of bias for the 6 included studies was low for two studies (49,53), high for three studies (50-52), and unclear for one study (54), according to the Cochrane Collaboration's Risk of Bias tool.(85) Identified limitations were most often due to inadequate reporting of randomization, allocation concealment, and blinding of participants (see Risk of Bias graph and summary in Appendix A5). Interestingly, the studies with high and unclear risk of bias were older in their publication dates (1987-1995); the early stage of the available reporting guidelines may have been a factor in these risk of bias scores.

Effect of self-monitoring on the primary outcome, pain intensity: All six included studies assessed pain intensity as an outcome. The four studies comparing self-monitoring to active treatment provided enough data for meta-analysis. (49-54) These studies assessed averaged pain intensity 2 (49) to 4 weeks (50-52) post-treatment using diary methods in both self-monitoring and treatment groups. A meta-analysis using random effects calculated the mean difference between self-monitoring and active treatment groups. A significant difference in favor of active treatment was found (mean difference 1.77 95% confidence interval (1.08-2.47), with an I² of 0%). These results indicate that there is a 17% difference in the mean decrease of pain intensity

post-treatment, or a 1.7 difference on a 10-point visual analog scale. Although a significant difference is identified, it is only borderline of a clinically meaningful difference (typically a cut off of 2.0, or 20%).(139) See Figure for a forest plot of the meta-analysis.

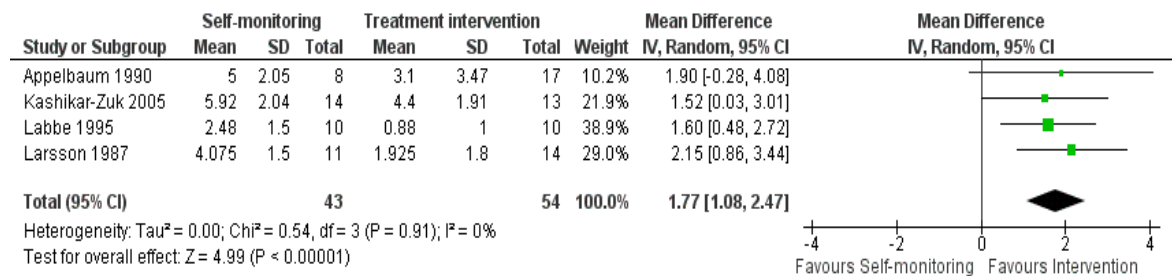


Figure A1 Forest plot of met-analysis comparing self-monitoring to active treatment for pain intensity

Two studies compared self-monitoring of daily pain intensity to no-treatment control (waiting list (53) or checklist of daily food intake (54)). These studies assessed averaged weekly pain intensity and found no significant differences between self-monitoring and control conditions over 8-14 day periods.

Overall quality of evidence (GRADE) for the primary outcome, pain intensity: Using the GRADE framework (138), the overall quality of evidence for the use of self-monitoring as a treatment to change pain intensity in chronic pain conditions was very low. The quality of evidence was lowered due to methodological bias, very serious indirectness of the self-monitoring conditions assessed, and potential publication bias. The most important limitation to the overall quality of evidence for this review was the lack of generalizability to the review question, where the included studies failed to approach self-monitoring as an intervention.

Additional analyses: There were not enough studies available to conduct sensitivity analyses.

DISCUSSION

Summary of evidence: With very low overall quality of evidence, studies testing the use of self-monitoring in comparison to active treatments (including cognitive behavioral therapy, biofeedback, and relaxation), show that treatment conditions are significantly more effective than self-monitoring in reducing pain intensity. (49-54) However, these findings are bordering the cut off for clinical significance indicating that self-monitoring may be playing an active role in reducing pain intensity over time. When comparing self-monitoring to no-treatment control conditions, the available evidence indicates that there are no significant differences between self-monitoring and control.(53,54) These assessment periods were short in duration (8-14 days), and indicate that self-monitoring is not effective over a short period of time, however, further testing of longer durations is needed.

Limitations: At the study level, limitations in internal validity were related to inadequate reporting of randomization, allocation concealment, and blinding of study personnel/participants.

This is likely due to the older publication dates with studies published prior to available standard guidelines for the reporting of randomized control trials (e.g., PRISMA).

The overall quality of evidence according to the GRADE framework (138) is very low due to methodological bias, lack of generalizability and potential publication bias. The most important factor lowering overall quality of evidence for these findings is that these results are not generalizable to the consideration of self-monitoring as a stand-alone intervention. The included studies treated self-monitoring as an assessment, waiting-list condition, with the self-monitoring being very simplistic in design, mostly paper-based, and typically assessing only pain intensity and medication intake. The studies failed to include the self-monitoring features that the self-regulation theory proposes as most likely to lead to effective self-monitoring through the enhancement of self-evaluation, and self-directed change.(74)

Conclusions: Despite the lack of available evidence for assessing the use of self-monitoring as a treatment intervention, the results from this review are valuable because they show that there is a huge gap in the literature and research for the use of a potentially effective, cost-efficient, and low-burden intervention. There is great potential for the use of this type of intervention in standard care, and this is the suggested direction for future research. To begin bridging this gap, the next step for future work should be the development of an ‘ideal’ self-monitoring intervention that adheres to the suggested self-regulation theory to allow for enhancement of self-observation, evaluation, and self-directed change.(74)

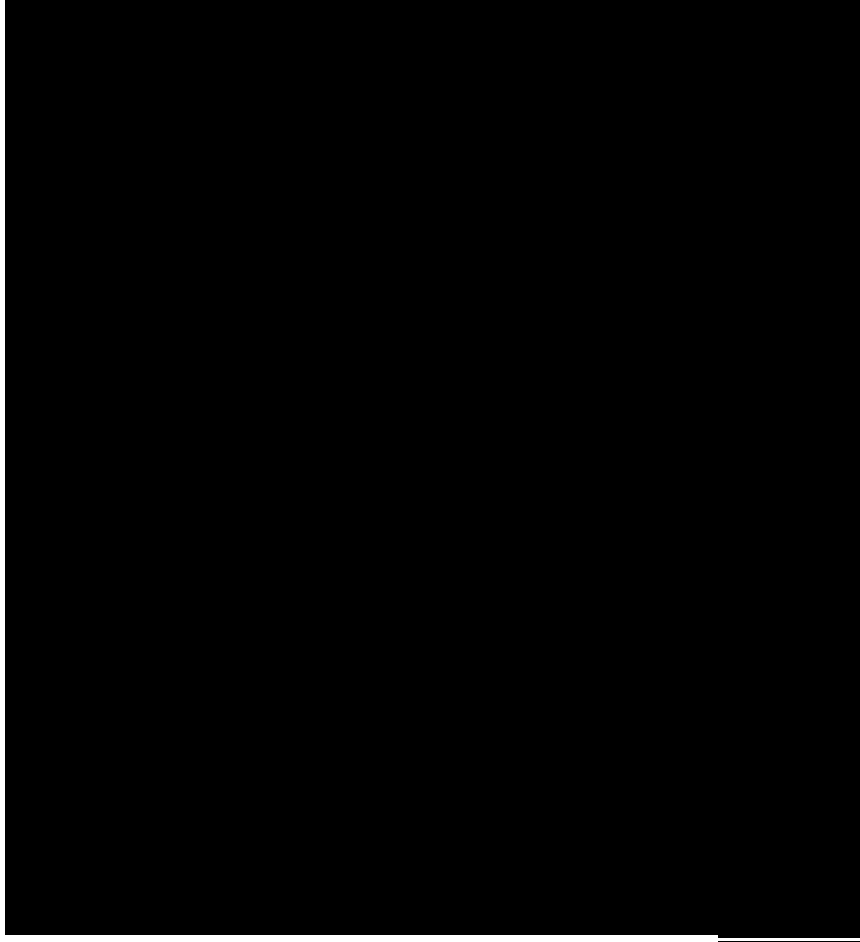
Appendix A1: PubMed Search Strategy

("pain"[MeSH Terms] OR pain[tiab]) AND (((((((((((((((("computer diary"[All Fields] OR "mobile phone"[tiab] OR "personal digital assistant"[tiab] OR "handheld computer"[tiab] OR "handheld device"[tiab] OR "Cellular phone"[Mesh]) OR "Smartphone"[tiab] OR "Smart phone"[tiab] OR "iPhone"[tiab] OR "mobile phone"[tiab] OR "android"[tiab] OR "blackberry"[tiab] OR "electronic assessment"[tiab] OR "electronic diary"[tiab] OR "electronic diaries"[All Fields]) OR "ecological momentary assessment"[tiab] OR "momentary assessment"[tiab] OR diary[tiab] OR diaries[tiab] OR "selfmonitoring"[tiab] OR "self-monitoring"[tiab]))))))))))))

Appendix A2: Search Results in PubMed

Search	Add to builder	Query	Items found	Time
#1	Add	Search (((((((((((((((("computer diary"[All Fields] OR "mobile phone"[tiab] OR "personal digital assistant"[tiab] OR "handheld computer"[tiab] OR "handheld device"[tiab] OR "Cellular phone"[Mesh]) OR "Smartphone"[tiab] OR "Smart phone"[tiab] OR "iPhone"[tiab] OR "mobile phone"[tiab] OR "android"[tiab] OR "blackberry"[tiab] OR "electronic assessment"[tiab] OR "electronic diary"[tiab] OR "electronic diaries"[All Fields]) OR "ecological momentary assessment"[tiab] OR "momentary assessment"[tiab] OR diary[tiab] OR diaries[tiab] OR "selfmonitoring"[tiab] OR "self-monitoring"[tiab]))))))))))))	2232	22:44:08
#2	Add	Search (((((((((((("computer diary"[tiab] OR "mobile phone"[tiab] OR "personal digital assistant"[tiab] OR "handheld computer"[tiab] OR "handheld device"[tiab] OR "Cellular phone"[Mesh]) OR "android"[tiab] OR "blackberry"[tiab]) OR (((("electronic assessment"[tiab] OR "electronic diary"[tiab] OR "electronic diaries"[tiab]) OR (((("ecological momentary assessment"[tiab] OR "momentary assessment"[tiab] OR diary[tiab] OR diaries[tiab] OR "selfmonitoring"[tiab] OR "self-monitoring"[tiab]))	24078	22:44:00
#3	Add	Search (((("ecological momentary assessment"[tiab] OR "momentary assessment"[tiab] OR diary[tiab] OR diaries[tiab] OR "selfmonitoring"[tiab] OR "self-monitoring"[tiab]	10345	22:43:39
#4	Add	Search (((("electronic assessment"[tiab] OR "electronic diary"[tiab] OR "electronic diaries"[tiab]	344	22:42:44
#5	Add	Search (((((((("computer diary"[tiab] OR "mobile phone"[tiab] OR "personal digital assistant"[tiab] OR "handheld computer"[tiab] OR "handheld device"[tiab] OR "Cellular phone"[Mesh]) OR "android"[tiab] OR "blackberry"[tiab]	5234	22:41:44
#6	Add	Search (pain [mesh]) OR pain [tiab]	510094	22:37:46

Appendix A3: Flow Chart of Review Process



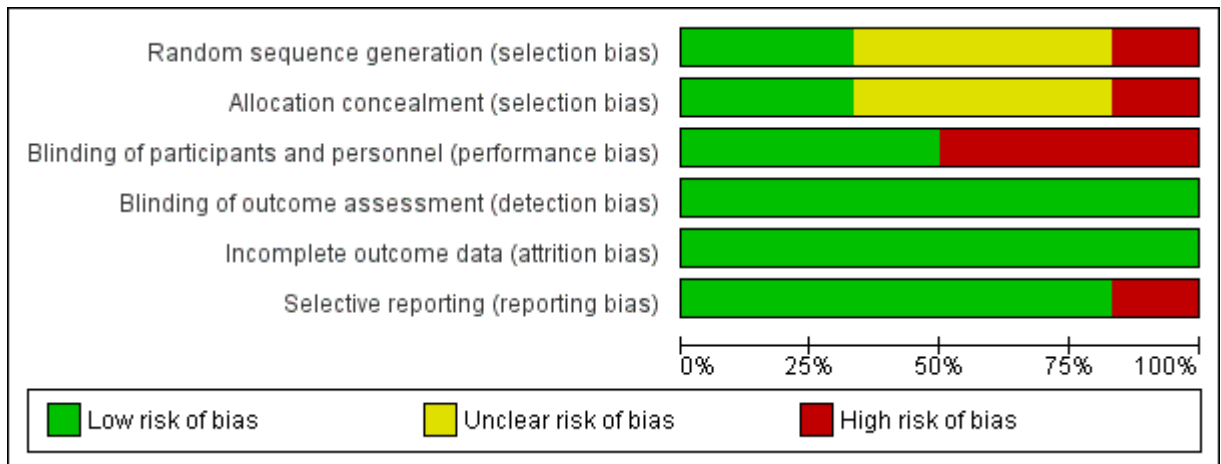
Appendix A4: Summary of Characteristics of Included Studies

First author	RCT Design	Pain condition	Age range (sample size)	Type of self-monitoring (SM)	Diary Variables assessed	Type of control	Duration	Outcome measurement	Overall Risk of Bias
Appelbaum (52)	SM vs. PMR + CBT	Tension headache	16-62 (n=41)	Paper-based	Pain intensity (0-5 VAS), 4 times daily, medication intake	PMR + Cognitive stress coping	8 weeks	Changes in pre-post measurement, 4 weeks headache monitoring: averaged headache index (given in mean & SD)	High
Kashikar-Zuck (49)	SM vs. CBT	Fibromyalgia	13-17 (n=30)	Paper-based	Average pain level for each day (0-10 VAS), medication intake, sleep quality	CBT coping-skills training (relaxation, pacing, distraction, problem-solving, sleep hygiene)	8 weeks	Pain intensity VAS (no pain – worst pain) for average and worst intensity over previous 2 weeks (given in mean & SD)	Low
Larsson (51)	SM vs. Relaxation	Chronic headache	16-18 (n=41)	Paper-based	Pain intensity (0-5 VAS), 4 times daily, medication intake	Therapist-assisted relaxation, Self-help relaxation	5 weeks	4-week pre and post-treatment diary assessment for pain intensity	High
Labbe (50)	SM vs. BFB+AT	Migraine	8-18 (n=46)	Paper-based	Pain intensity (0-5 VAS), 4 times daily, medication intake	Biofeedback with autogenic training	7 weeks	4-week pre and post-treatment diary assessment for pain intensity	High
Stone (53)	SM vs. no SM	Chronic pain (fibromyalgia, arthritis, osteoarthritis, ankylosing spondylitis)	18-80 (n=91)	Electronic	Immediate pain intensity (100 point VAS), location, pain characteristics, disability	No daily diary	2 weeks	Temporal trend differences in pain intensity	Low
Von Baeyer (54)	SM vs. Control group tracking food	Low back pain	Mean 44 (n=54)	Paper-based	Pain intensity (0-5 VAS), 4 times daily, pain duration	Checklist of foods consumed during the day (no reference to pain)	8 days	Pain intensity VAS average pain	Unclear

SM = Self-monitoring, PMR= Progressive muscle relaxation, CBT = Cognitive behavioral therapy, BFB= biofeedback, AT = Autogenic training, HA = headache, VAS=visual analog scale

Appendix A5: Risk of Bias Graph for Included Studies and Summary of Risk of Bias Across Studies

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Appelbaum 1990	?	?	-	+	+	-
Kashikar-Zuk 2005	+	+	+	+	+	+
Labbe 1995	?	?	-	+	+	+
Larsson 1987	-	-	-	+	+	+
Stone 2003	+	+	+	+	+	+
von Baeyer 1994	?	?	+	+	+	+



APPENDIX B: Systematic Review PubMed Search Strategy

(((((((((((((obes*[tw] OR overweight[tw] OR over weight[tw])) OR (heart failure[tw] OR cardiac rehabilitation[tw] OR cardiovascular disease[tw])) OR asthma[MeSH]) OR arthritis[MeSH]) OR Diabetes Mellitus[MeSH]) OR (pain*[tw] OR pain[MeSH]))) AND (((diary*[tw] OR intervention*[tw] OR therap*[tw]))) AND (self regula*[tw] OR self monitor*[tw] OR self manag*[tw] OR social cognitive theory[tw] OR Bandura[tw] OR behaviour change[tw] OR behavior change[tw])))

APPENDIX C: Data Extraction Form Used to Extract Study Characteristics of Included Interventions

General Information

Study author	
Study year	

Characteristics of included studies

Methods

	Description
Aim of study (e.g. testing diary efficacy, testing intervention)	
Design (e.g. RCT, longitudinal)	
Length of intervention (e.g., 7 days)	

Participants

	Description
Health condition	
Inclusion criteria	
Exclusion criteria	
Age group (Adults, Children, Adolescents, General)	
Type(s) of health conditions	
Other relevant information	

Intervention

	Description
Intervention name	
Delivery method	
Description (include sufficient detail for replication, e.g. treatment components, type of diary, diary components)	
Describe the role of the theory for intervention development	
Where is the theory cited in the article (Introduction, methods, results, discussion)	
Which theory reference was cited?	
Describe any additional characteristics incorporated in the intervention	
Describe any other theories used to guide the intervention	

APPENDIX D: Coding Guide of Intervention Characteristics Addressing the Social Cognitive Theory of Self-regulation

Self-monitoring mechanisms		
What is the outcome of interest?		
Mechanism	Theoretical explanation	Description of how to recognize theory application in interventions
Self-monitoring behaviour	Self-monitoring provides information for the individual to evaluate their ongoing progress, leading to behaviour change.	Does the intervention explicitly state the behaviour that is being monitored?
Feedback	Self-monitoring enhances performance when individuals have clear evidence of progress on the monitored behaviour. Knowledge of how one is doing influences behaviour change, goal-setting, and self-evaluation.	Does the intervention provide participants with information that allows them to examine their progress on the monitored behaviour? <ul style="list-style-type: none"> - Participants actively self-monitor their behaviour through increased attention and tracking of the behaviour and its patterns - Participants receive information through the use of a diary, data summaries or graphs, or professional guidance
88 Temporal proximity	Self-directed change is easier for behaviours that are monitored as they occur, in real-time. Immediate self-monitoring gives continuing information. Attention to ‘distal’ behaviours through recall is less likely to provide useful information or lead to successful behaviour change.	Does the intervention expect participants to monitor their behaviour^{1,2} close in time to when it happens? <ul style="list-style-type: none"> - Participants expected to monitor behaviour close to when it occurs. - Participants may be requested to monitor behaviour using multiple methods (e.g., monitoring steps taken throughout the day using a pedometer, and recording the total number of steps at the end of the day). When coding temporal proximity, do so using the method that best reflects how the behaviour was measured. <p>¹Participants may be expected to monitor behaviour and outcome. When coding temporal proximity, code monitored behaviour, not outcome</p> <p>²The type of behaviour that is being monitored is important to consider. If, for example, participants are expected to monitor their daily footsteps - using a pedometer in real-time is an acceptable method of doing so. If, on the other hand, participants are requested to monitor their level of weekly activity - monitoring daily exercise at the end of each day is acceptable proximity to the behaviour.</p>

Mechanism	Theoretical explanation	Description of how to recognize theory application in interventions
Consistency	Regular self-monitoring of behaviour is more informative than intermittent self-monitoring, because it provides continuous attention to performance.	<p>Does the intervention expect participants to regularly monitor their behaviour?</p> <ul style="list-style-type: none"> - Participants are expected to monitor their behaviour following a specific rule, such as every time it occurs, or on a daily basis (e.g., monitoring every meal, daily activity, exercise)
Focus on success	Attending to positive behavioural accomplishments is more encouraging for behaviour change than paying attention to failures, which can lower subsequent performance and accomplishments.	<p>Does the intervention encourage participants to focus on achievements or accomplishments with regard to behaviour change?</p> <ul style="list-style-type: none"> - Participants receive information or training about focusing on positive or successful behaviour changes (e.g., learning to focus on healthy eating choices, instead of focusing on the foods that have been given up) - Participants are guided to implicitly focus on positive changes through rewards for positive progress on their behaviours (rewards direct attention toward achievement)
Value of behaviour	Behaviours with perceived importance are likely to receive more attention when self-monitored, than are behaviours not perceived to be important. Perceived importance can be established naturally from personal experiences, or it can be taught (externally established), from assigned positive or negative values.	<p>1) Does the intervention encourage participants to monitor behaviours that are naturally perceived as important to them?</p> <ul style="list-style-type: none"> - Participants can choose to monitor behaviour that they think is important and worth exploring. <p>2) Does the intervention educate participants about the importance of the monitored behaviour (that is predetermined by the intervention) in relation to health outcome?</p> <ul style="list-style-type: none"> - Participants receive instruction on how the behaviour (e.g., physical activity) is important for health outcome (e.g., weight) - Participants receive instruction on the importance of monitoring the behaviour in relation to health outcome

Mechanism	Theoretical explanation	Description of how to recognize theory application in interventions
Control	Self-monitoring is more likely to produce lasting effects in behaviours that are relatively easy for the individual to modify. Self-monitoring only has minor effects on behaviours that are resistant to change.	<p>Does the intervention actively teach participants the skills necessary to help deliberately modify their behaviour?</p> <ul style="list-style-type: none"> - Participants are taught how to overcome their personal barriers to behaviour change - Active problem-solving is provided about the steps to increase the presence of good behaviours, and decrease unwanted behaviours - Personalized ‘action plans’ or ‘relapse prevention plans’ are created for planning the continuation of behaviour change <p>Note: Passive education about behaviour change skills is not sufficient to be coded as guiding participants in how to ‘control’ their behaviour</p>
Motivation	People who want to change the behaviour they are monitoring and who set goals are more likely to react positively to the progress they are making. Similar to ‘value of behaviour,’ motivation can be implicit based on personal experiences, or it can be externally established by instruction about setting goals.	<p>1) Does the intervention guide participants in selecting goals related to behaviour change that are personally important to them?</p> <ul style="list-style-type: none"> - Participants are guided in setting their own behaviour change goals - Participants set their own rewards as incentives - Participants develop and sign behavioural contracts <p>2) Does the intervention give participants pre-set goals selected by the intervention?</p> <ul style="list-style-type: none"> - Participants are provided with goals for change already set by the intervention (e.g., specific calorie intake) - Participants are made aware of external rewards provided by the intervention that are contingent upon progress
Self-diagnosis	Self-monitoring behaviour can identify new patterns or insights among situations, thoughts, and actions. Self-insights related to behaviour can lead to behaviour change.	<p>Does the intervention educate participants about important cues or associations that are linked with or lead to the behaviour or outcome?</p> <ul style="list-style-type: none"> - Participants receive training about the associations between environmental triggers and the onset of a behaviour - Associations, cues, barriers, or facilitators to behaviour are identified (e.g., understanding cues to over-eating)

Mechanism	Theoretical explanation	Description of how to recognize theory application in interventions
Self-judgement	Personal standards guide the appraisal and understanding of the self-monitored information, influencing both self-evaluation and self-directed behaviour change.	<p>Does the intervention encourage participants to reflect on their behaviour with regard to their own personal standards, in order to judge the progress of the behaviour?</p> <ul style="list-style-type: none"> - Participants identify changes in behaviour (e.g., noticing that physical activity has increased) - Participants identify changes in outcome (e.g., progress with increasing physical activity may lead to a change in weight)
Social comparison	<ul style="list-style-type: none"> - Behaviour is easier to regulate when there is some measurement of adequacy/ achievement in comparison to peers, in order to determine a ‘relative’ standing. Social comparison allows for evaluating the progress of behaviour change based on that of peers in similar situations, in particular those with similar capabilities. 	<p>Does the intervention explicitly state that participants are encouraged, or provided with the opportunity to judge the progress of their behaviour change against their peers?</p> <ul style="list-style-type: none"> - Peer group-based discussion of progress is encouraged or facilitated - Competition with peers is encouraged or facilitated - Peer group-based discussion of problems or successes is encouraged or facilitated - Behaviour comparison is encouraged or facilitated through groups
Self-comparison	Previous behaviour is used as a contrast to ongoing performance. People usually try to surpass their previous accomplishments, seeking self-satisfaction from progressive improvement.	<p>Does the intervention explicitly encourage or expect participants to judge their <i>own</i>¹ progress based on previous behaviour?</p> <ul style="list-style-type: none"> - Participants are encouraged to reflect on their progress - Progress is identified using monitored data - Monitored data is compared with goals - Participants are encouraged to compare previous experiences with ongoing ones (e.g., think back to how you used to feel in comparison to how you feel now) <p>¹Note: Self-comparison is only present if participants are evaluating their behaviour on their own, without any external guidance from an instructor. They are creating their <i>own</i> judgements, without any input from others.</p>

Mechanism	Theoretical explanation	Description of how to recognize theory application in interventions
Statistical comparison (Normative comparison)	Evaluating behaviour progress based on normative data using statistics such as percentiles and deviance from the mean can guide the judgement of progress relative to a large sample. However, it is important that the comparison sample is representative of the intervention group.	<p>Does the intervention provide or guide the comparison of participants' progress with normative data?</p> <ul style="list-style-type: none"> - E.g., national nutritional intake, or daily activity recommendations - E.g., Evidence-based research providing population-based statistics
Modeling	Standards can be formed by viewing the performance of others with proven success, and how those others respond to their own behaviour. Forming standards of behaviour progress through examples is especially useful when people have little personal experience in the performance domain.	<p>Does the intervention provide examples of successful behaviours or encourage the identification of individuals with successful behaviour change, to which participants can compare their progress?</p> <ul style="list-style-type: none"> - Appropriate people are provided as models (e.g., physiotherapist demonstrating the appropriate way to do strength training exercises) - Intervention materials provide examples of models (e.g., DVDs, pictures, vignettes of people) – as long as these are connected to an outcome to guide participants in understanding what is correct/appropriate/successful - Participants are encouraged to identify their own role models
Engagement/encouragement/reactions	Personal standards about the progress of behaviour change can come from the direct guidance/teaching of influential and significant persons. Standards can also be formed based on the reactions of others to the behaviour, especially the reactions of influential and significant persons.	<p>Does the intervention provide engagement, encouragement, or positive reactions from the individuals leading the interventions, in order to help the participants understand the progress of their behaviour change?</p> <ul style="list-style-type: none"> - Instructors work with participants to identify progress - Instructors inform participants of the progress they have made - Instructors give participants praise for progress or encouragement to continue making improvements

Mechanism	Theoretical explanation	Description of how to recognize theory application in interventions
Self-evaluation	A positive appraisal of oneself can result in a gain in self-respect, leading to behaviour change through reinforcement based on personal standards.	Does the intervention explicitly encourage and guide participants to personally evaluate their own behaviour?
Self-satisfaction	People pursue actions that produce positive self-respect. Anticipated self-approval when personal standards are fulfilled increases the likelihood of performance.	Does the intervention explicitly encourage or guide participants towards feeling self-approval or self-respect associated with behaviour change? <ul style="list-style-type: none"> - Participants are encouraged to recognize self-efficacy or outcome expectations related to their behaviour - Participants receive education about recognizing goal attainment - Participants are encouraged to change negative thoughts about behaviour to positive thoughts
Self-incentives	By personally setting tangible rewards that are conditional upon accomplishments, people can get themselves to do things they otherwise would not.	Does the intervention explicitly encourage participants to personally set and administer their own rewards for behaviour change? <ul style="list-style-type: none"> - Participants are guided to actively set rewards for themselves based on progress
External rewards	Individuals are more likely to complete behaviours when rewards are contingent on the successful behaviour completion	Does the intervention set tangible rewards for participants, contingent on behaviour change? <ul style="list-style-type: none"> - Rewards are distributed following behaviour change (e.g., achievement certificates, small gifts)

APPENDIX E: Cochrane Collaboration's Risk of Bias Tool(84)

Domain	Support for judgement	Review authors' judgement
<i>Selection bias.</i>		
Random sequence generation.	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.
Allocation concealment.	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.
<i>Performance bias.</i>		
Blinding of participants and personnel <i>Assessments made for each main outcome</i>	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.
<i>Detection bias.</i>		
Blinding of outcome assessment <i>Assessments should be made for each main outcome (or class of outcomes).</i>	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.
<i>Attrition bias.</i>		
Incomplete outcome data <i>Assessments should be made for each main outcome (or class of outcomes).</i>	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Attrition bias due to amount, nature or handling of incomplete outcome data.
<i>Reporting bias.</i>		
Selective reporting.	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Reporting bias due to selective outcome reporting.

APPENDIX F: Characteristics of Randomized Controlled Trials^a Evaluating Self-monitoring Interventions for Adults^b that were Developed Using the Framework of the Social Cognitive Theory of Self-regulation

First Author	Description of intervention	Outcome	Monitored behaviour	Use of theory components	Risk of Bias
Weight problems					
95 Annesi (87)	The Coach Approach: 26-week intervention led by a wellness specialist for severely obese people. Focused on enhancing self-efficacy and self-regulation of exercise adherence through individualized education, exercise sessions, and group-based nutritional dietary control	Controlled eating, weight	-Food and calorie intake	All 3	Unclear
Burke (88)	PREFER: 18-month group-based dietitian and exercise physiotherapist-led behavioural and weight loss intervention to increase self-efficacy and dietary adherence	Weight	-Food intake -Physical activity	All 3	High
Collins (89)	The Biggest Loser Club: 12-week commercial web-based behaviour change weight loss program targeting behaviour change through self-efficacy, goal setting, and self-monitoring	Weight	-Food intake -Physical activity	All 3	Low
Gallagher (90)	HEELP (Healthy Eating and Exercise Lifestyle Program): 16-week group-based program with supervised exercise and education sessions on nutrition, exercise, and behaviour change from a professional multidisciplinary team	Weight	-Physical activity	All 3	High
Gray (80)	FFIT (Football Fans In Training): 12-week group-based football club program delivered by community coaching staff. Focused on weight management education, and coach-led physical activity sessions	Weight	-Physical activity	All 3	Unclear
Hollis (91) ^a	6-month group-based led by nutritionists and behavioural counsellors to encourage a nutrition-driven eating style, and regular exercise with emphasis on group-based problem solving and social support	Weight	-Food intake -Physical activity	2	Low
Kiernan (92)	20-week group-based weight loss program for women led by intervention staff. Focus on problem-solving and setting goals. Randomized to either 8-week stability module prior to the program or an 8-week problem-solving module after the program	Weight	-Food intake -Physical activity	All 3	Low
Ma (118)	E-LITE(Elevated Cardiometabolic Risk in Primary Care): 12-week group-based dietitian and fitness instructor-led behaviour change intervention focusing on healthy eating, physical activity, problem solving, and physical activity training	Weight	-Food intake -Physical activity	All 3	High

First Author	Description of intervention	Outcome	Monitored behaviour	Use of theory components	Risk of Bias
Mockus (94) ^{a,b}	20-week dietary self-monitoring intervention for weight loss in children focused on diet modification, physical activity, and behavioural skills	Weight	-Food intake	2	High
Morgan (95)	SHED-IT: 12-week Internet-based weight loss program for men to make changes in physical activity and dietary behaviours	Weight	-Food intake -Physical activity	All 3	Low
Morgan (96)	Healthy Dads, Healthy Kids: 12-week group-based program for overweight fathers with children, in order to lose weight and become healthy role models	Weight	-Food intake	2	Low
Patrick (97)	1-year web-based weight loss intervention designed to improve diet and physical activity behaviours through goal-setting	Weight	-Physical activity	2	Unclear
Short (98)	ManUP: 9-month web-based physical activity and nutrition behaviour intervention for men to promote self-monitoring of exercise and diet	Weight	-Food intake -Physical activity	2	High
Shuger (99)	LEAN (Lifestyle Education for Activity and Nutrition): 14-week group-based intervention focused on physical activity and nutritional lifestyle changes for weight loss	Weight	-Food intake -Physical activity	All 3	High
Diabetes					
Lawler (100)	Living well with diabetes: 18 month physical activity and dietary behaviour intervention focusing on behavioural skills (self-efficacy, problem-solving, goal setting) for increasing physical activity and reducing energy intake for weight loss in Type II diabetes	Diabetes management	-Food intake -Physical activity	All 3	High
Liebreich (101)	Diabetes NetPLAY: 12-week web-based and email counseling physical activity behaviour change intervention	Diabetes management	-Physical activity	2	Unclear
Miller (102)	10-week nutritional education, food purchasing, and meal planning intervention for older adults with diabetes	Glycaemic control	-Food intake	All 3	Unclear
Nansel (103) ^b	Diabetes personal trainer: 8-week individualized problem solving intervention for self-management of diabetes in adolescents with type I diabetes	Self-management	-Self-selected	All 3	Unclear
Tan (104)	12-week educational program focused on enhancing self-efficacy to improve self-monitoring of blood glucose in diabetes management	Glycaemic control	-Blood glucose	2	Unclear
Tudor-Locke (105)	First Step program: 16-week group-based lifestyle program delivered by physical activity experts to increase activity levels	Health outcomes	-Physical activity	2	High
Van Dyck (106)	24-week telephone support psychologist-led behavioural modification program to increase physical activity for sedentary behaviour in Type II diabetes patients	Diabetes management	-Physical activity	All 3	Low

First Author	Description of intervention	Outcome	Monitored behaviour	Use of theory components	Risk of Bias
Heart disease					
Furber (81)	6-week pedometer-based, telephone behavioural counselling physical activity intervention focused on increasing self-efficacy, health beliefs, and physical activity goals	Physical activity levels	-Physical activity	All 3	Low
Moore (107)	CHANGE: 12-week nurse-taught group-based lifestyle modification intervention to increase exercise through increasing expectancy, self-efficacy, problem solving, and relapse prevention skills	Long-term exercise	-Physical activity	All 3	Low
Padula (108)	12-week nurse-led inspiratory muscle training intervention for people with heart failure to increase inspiratory muscle strength	Inspiratory muscle strength	-Inspiratory muscle training intensity, duration, frequency	2	Unclear
Peterson (109)	12-month individualized telephone-based intervention focused on enhancing positive affect and self-affirmation to increase physical activity for coronary artery disease	Energy expenditure	-Physical activity	2	Low
Pinto (110)	14-week telephone home-based exercise intervention focused on activity counseling and problem-solving about barriers for activity	Activity levels	-Physical activity	2	High
Shao (111)	12-week self-management, self-efficacy intervention to improve health outcomes in older people with heart failure	Self-management	-Sodium, fluid intake	2	Unclear
Arthritis					
Hughes (112)	Fit and Strong: 8-week group-based lower extremity osteoarthritis strengthening, fitness walking, and behaviour change intervention	Exercise self-efficacy	-Physical activity	All 3	Low
Kovar (79)	Sidewalkers Walking Program: 8-week group-based hospital fitness walking and behavioural educational program for osteoarthritis of the knee	Functional capacity	-Physical activity	All 3	Unclear
Manning (113)	EXTRA (Education, Self-Management, and Upper Extremity Exercise Training in People with Rheumatoid Arthritis) program: 12-week physiotherapist-led group-based training sessions, with education targeting rheumatoid arthritis knowledge, self-efficacy, and disease self-management, and supervised upper extremity exercises. Participants were asked to complete and monitor daily home-exercise	Arthritis disability	-Physical activity -Exercise intensity	All 3	Low
Shigaki (114)	RA Help: 10-week web-based online self-management intervention for rheumatoid arthritis to increase self-efficacy and quality of life	Arthritis self-management	-Pain -Stress	2	High
Asthma					
Baptist (78)	6-week health educator-led telephone and group-based asthma problem-solving, goal setting intervention	Asthma quality of life and control	-Management barriers	2	Low

First Author	Description of intervention	Outcome	Monitored behaviour	Use of theory components	Risk of Bias
Burkhardt (115) ^b	16-week individualized nurse-led asthma intervention for children, teaching peak flow meter use and asthma education to improve health outcomes	Asthma control	-Peak airflow -Asthma -Medication	All 3	Low
Clark (116)	Women breathe free: 6-month nurse health educator-led telephone counseling asthma intervention for women; focused on the role of sex and gender on asthma, and on problem-solving management skills	Asthma control	-Daily activities	All 3	Unclear
McGhan (117) ^b	Roaring Adventures with Puff (RAP): 6-week group-based asthma intervention for children to build asthma self-management skills	Asthma control	-Peak airflow -Asthma symptoms -Medication	All 3	High

^aObservational study design, ^bChild or adolescent populations

APPENDIX G: Frequency of Self-monitoring Mechanisms Addressed by at Least One Intervention Characteristic for each Included Intervention

First author	Feed-back 35/35	Temporal proximity Real-time 16/35	Consistent 35/35	Control 24/35	Focus success 16/35	Motivation (goals) 32/35	Self-diagnosis 25/35	Value of behaviour 33/35	Total per Avg. 6.17
Used all three theory components									
Annesi (87)	Yes	Recall	Consistent	Yes	X	Self-set	Yes	Yes	6
Burke (88)	Yes	Recall	Consistent	Yes	Yes	Self-set	Yes	Yes	7
Burkhart (115)	Yes	Real-time	Consistent	Yes	Yes	Pre-set	X	Yes	7
Clark (116)	Yes	Recall	Consistent	Yes	Yes	Self-set	Yes	Self-set	7
Collins (89)	Yes	Recall	Consistent	X	X	Pre-set	X	Yes	4
Furber (81)	Yes	Real-time	Consistent	Yes	Yes	Pre-set	X	Yes	7
Gallagher (90)	Yes	Real-time	Consistent	X	X	X	Yes	Yes	5
Gray (80)	Yes	Real-time	Consistent	Yes	Yes	Self-set	Yes	Yes	8
Hughes (112)	Yes	Real-time	Consistent	Yes	Yes	Self-set	X	Self-set	7
Kiernan (92)	Yes	Recall/ Real-time ¹	Consistent	Yes	Yes	Self-set	Yes	Yes	7
Kovar (79)	Yes	Real-time	Consistent	Yes	Yes	Self-set	Yes	Yes	8
Lawler (100)	Yes	Real-time	Consistent	Yes	Yes	Self-set	Yes	Yes	8
Ma (93)	Yes	Recall/ Real-time ¹	Consistent	Yes	Yes	Self-set	Yes	Yes	7
Manning (113)	Yes	Real-time	Consistent	Yes	X	Self-set	Yes	Yes	7
McGhan (117)	Yes	Recall	Consistent	Yes	X	Self-set	Yes	Yes	6
Miller (102)	Yes	Recall	Consistent	X	Yes	Self-set	Yes	Yes	6
Moore (107)	Yes	Real-time	Consistent	Yes	X	X	Yes	Yes	6
Morgan (95)	Yes	Recall/ Real-time ¹	Consistent	X	Yes	Self-set	Yes	Yes	6
Nansel (103)	Yes	Unclear	Consistent	Yes	Yes	Self-set	Yes	Self-set	7
Shuger (99)	Yes	Recall/ Real-time ¹	Consistent	Yes	Yes	Self-set	Yes	Yes	8
Van Dyck (106)	Yes	Real-time	Consistent	Yes	Yes	Self-set	Yes	Yes	8
Used two theory components									
Baptist (78)	Yes	Unclear	Consistent	Yes	X	Self-set	Yes	Self-set	6
Hollis (91)	Yes	Recall	Consistent	Yes	X	Self-set	Yes	Yes	6
Liebreich (101)	Yes	Recall	Consistent	X	X	X	X	Yes	3
Mockus (94)	Yes	Recall	Consistent	X	X	Pre-set	X	Yes	4
Morgan (96)	Yes	Recall/ Real-time ¹	Consistent	X	X	Self-set	Yes	Yes	5
Padula (108)	Yes	Real-time	Consistent	Yes	X	Self-set	X	X	5
Patrick (97)	Yes	Real-time	Consistent	X	X	Pre-set	X	Yes	5
Peterson (109)	Yes	Real-time	Consistent	X	X	Self-set	Yes	Yes	6
Pinto (110)	Yes	Real-time	Consistent	Yes	X	Self-set	Yes	Yes	7
Shao (111)	Yes	Recall	Consistent	Yes	X	Pre-set	X	Yes	5
Shigaki (114)	Yes	Recall	Consistent	X	Yes	Pre-set	Yes	X	5
Short (98)	Yes	Recall	Consistent	X	X	Pre-set	X	Yes	4
Tan (104)	Yes	Real-time	Consistent	Yes	X	Self-set	Yes	Self-set	7
Tudor-Locke (105)	Yes	Real-time	Consistent	Yes	X	Self-set	Yes	Yes	7

¹Participants monitored physical activity in real-time and nutritional intake by recall

APPENDIX H: Examples of Characteristics Addressing Each Theory Mechanism

Theory	Mechanism	Intervention characteristics
Self-monitoring	Feedback	Personal patterns of exercise in cardiac rehabilitation patients were discussed with the health professional by reflecting on exercise logs from the past week (107)
	Temporal proximity	Diabetic participants were asked to wear a pedometer which recorded their physical activity type, duration, and number of steps (106)
	Consistency	Diabetic participants were asked to check their blood glucose level and record their readings before and 1-2 hours after every meal (102)
	Focus on success	Participants were instructed to focus on what had been achieved from a weight loss intervention, rather than what was given up (100)
	Value of behaviour	Weight loss participants were taught about the importance of self-monitoring their diet and physical activity, as well about the importance of nutrition and physical activity (91)
	Control	Cardiac rehabilitation participants were taught to increase their beliefs about the positive consequences of taking action over their health. They were asked to develop strategies to overcome existing barriers to their physical activity (81)
	Motivation	Weight loss participants identified and documented their long-term goals. These were broken down into short-term goals and they tracked their progress towards achieving their goals (87)
	Self-diagnosis	Participants were taught about potential external and internal factors that may be associated with their asthma symptoms. They were asked to observe these potential influences on their peak air flow (116)
Self-judgement	Social comparison	Each group-based weight loss session began with an open review of each participant's weight loss goals. Participants were encouraged to discuss problems and generate effective solutions for one another (92)
	Self-comparison	Participants were asked in their individual sessions with a health care professional to think back to how they felt in the first week of the study and compare it to how they felt in the last; discussion about what did and did not go well was encouraged (80)
	Statistical comparison	Diabetic participants assessed their current eating patterns and identified differences in comparison to national dietary recommendations (102)
	Modeling	Cardiac rehabilitation patients were shown vignettes and images to provide real life and relatable examples of participants who achieved successful behavior change (95)
	Education/reaction	The interventionist provided arthritis patients with specific corrective and reinforcing feedback during early walking sessions to help participants gauge and monitor their performance (79)
Self-evaluation	Self-satisfaction	Acceptance of the self as a child with asthma was encouraged in peer groups (117)
	Self-incentives	Weight loss participants were instructed to identify personal rewards for achieving all of their monthly goals(95)
	External rewards	Parents reinforced their child's progress with sticker stars. After 5 stars, the child received a negotiated reward (115)

APPENDIX I: Frequency of Self-judgement Mechanisms Addressed by at Least One Intervention Characteristic for each Included Intervention

First author	Self-comparison 20/35	Social comparison 11/35	Statistical comparison 7/35	Modeling 18/35	Instructor feedback 27/35	Total per intervention Avg. 2.37
Used all three theory components						
Annesi (87)	Yes	X	X	X	Yes	2
Burke (88)	Yes	Yes	X	Yes	Yes	4
Burkhart (115)	X	X	X	Yes	Yes	2
Clark (116)	X	X	X	X	Yes	1
Collins (89)	X	X	Yes	Yes	Yes	3
Furber (81)	X	X	X	X	Yes	1
Gallagher (90)	Yes	X	X	X	X	1
Gray (80)	Yes	Yes	Yes	Yes	Yes	5
Hughes (112)	Yes	X	X	X	Yes	2
Kiernan (92)	X	Yes	X	X	Yes	2
Kovar (79)	Yes	Yes	X	Yes	Yes	4
Lawler (100)	X	X	Yes	X	Yes	2
Ma (93)	Yes	X	X	Yes	Yes	3
Manning (113)	Yes	Yes	Yes	Yes	Yes	5
McGhan (117)	Yes	Yes	X	Yes	Yes	4
Miller (102)	X	Yes	Yes	Yes	Yes	4
Moore (107)	Yes	X	X	Yes	X	2
Morgan (95)	Yes	Yes	X	Yes	Yes	4
Nansel (103)	Yes	X	X	X	Yes	2
Shuger (99)	Yes	Yes	X	X	Yes	3
Van Dyck (106)	X	X	X	X	Yes	1
Used two theory components						
Baptist (78)	X	Yes	X	X	Yes	2
Hollis (91)	Yes	X	X	Yes	X	2
Liebreich (101)	X	X	X	X	Yes	1
Mockus (94)	Yes	X	X	X	X	1
Morgan (96)	X	X	X	Yes	Yes	2
Padula (108)	Yes	X	X	Yes	Yes	3
Patrick (97)	X	X	X	X	Yes	1
Peterson (109)	Yes	X	X	Yes	X	2
Pinto (110)	X	X	X	X	Yes	1
Shao (111)	X	X	X	Yes	Yes	2
Shigaki (114)	Yes	X	X	X	X	1
Short (98)	Yes	Yes	X	X	X	2
Tan (104)	X	X	Yes	Yes	Yes	3
Tudor-Locke (105)	Yes	X	Yes	Yes	X	3

APPENDIX J: Frequency of Self-evaluation Mechanisms

First author	Self- satisfaction 16/35	Self- incentives 6/35	External rewards 4/35	Total per intervention Avg. 0.74
Used all three theory components				
Annesi (87)	Yes	X	X	1
Burke (88)	Yes	X	X	1
Burkhart (115)	X	X	Yes	1
Clark (116)	Yes	Yes	X	2
Collins (89)	X	X	Yes	2
Furber (81)	Yes	X	X	1
Gallagher (90)	Yes	X	X	1
Gray (80)	Yes	X	X	1
Hughes (112)	Yes	X	Yes	2
Kiernan (92)	Yes	X	X	1
Kovar (79)	Yes	X	Yes	2
Lawler (100)	Yes	Yes	X	2
Ma (93)	Yes	Yes	X	2
Manning (113)	X	Yes	X	1
McGhan (117)	Yes	X	X	1
Miller (102)	X	Yes	X	1
Moore (107)	Yes	X	X	1
Morgan (95)	X	Yes	X	1
Nansel (103)	Yes	X	X	1
Shuger (99)	Yes	X	X	1
Van Dyck (106)	Yes	X	X	1
Used two theory components				
Baptist (78)	X	X	X	0
Hollis (91)	X	X	X	0
Liebreich (101)	X	X	X	0
Mockus (94)	X	X	X	0
Morgan (96)	X	X	X	0
Padula (108)	X	X	X	0
Patrick (97)	X	X	X	0
Peterson (109)	X	X	X	0
Pinto (110)	X	X	X	0
Shao (111)	X	X	X	0
Shigaki (114)	X	X	X	0
Short (98)	X	X	X	0
Tan (104)	X	X	X	0
Tudor-Locke (105)	X	X	X	0

APPENDIX K: Semi-structured Interview Script Exploring Participant Experiences Using the Diary

- 1) Can you describe how you use the diary, explain how it works? (when did you fill in headache entries, diary entries? Did you back-log anything from previous days? Did you understand that you can set your own triggers to be tracked under settings?)
- 2) How often do you have headaches? How long do they usually last?
- 3) Did you find it difficult to keep a diary? What were the main barriers for you that got in the way of completing the diary? (Prompts: *holidays, weekends, exams, other events, not remembering; Technical difficulties: Alarms not working, cell phone/internet connection, diary not working*).
- 4) Did you find the diary useful? Why/why not. If it's not useful, what can we do to make it useful for you?
- 5) Did you have any difficulties inputting your responses into the diary(Y/N)? What difficulties did you find? (Prompts: *with the slider bars, multiple choice, scrolling lists*)
- 6) Did you ever look at the report that shows your diary entries? Did you find this useful? Why or why not? What would you change/add to the report of diary entries to improve this? (Prompts: *Are there any items that you felt should have been included in the report that weren't? Do you think there were too many items present? Did you like the layout of the report?*) Did you know that you could view reports based on the potential causes you chose to track on a daily basis?
- 7) In an attempt to improve our explanation about how WHI diary works, what would you like to see different to make the app easier to understand? (Prompts: *Illustrations, more text explaining*) – How would you like instructions to be presented?
- 8) Have you found the reminders useful? In an attempt to make the reminders much more useful, is there anything that you would change about them? (Prompts: *The noise, the wording, how often they come, the appearance*)
- 9) What did you like most about the diary? (Prompts: *Design, questions, interactivity, reminders*)
- 10) Did you feel burdened by the amount of questions? Were there any that you would take out?
- 11) Did you understand why there was a blue color along the side of each question? (Initially there is a light blue color beside all of the items. As you're answering a question, the color turns to red. Once it's been answered the color turns to dark blue indicating that the item has been answered)
- 12) What did you like the least about the diary? (Prompts: *Design, questions, interactivity, reminders*)
- 13) Is there anything that you would like to see different in the diary? YES/NO What would you like changed in the diary? (Prompts: *Interface design, Entry methods, reminders, questions asked*)
- 14) What were your goals for being in the study? To learn about your headaches, or to see how the application worked?
- 15) How did you find out about the study? What would you recommend for recruiting other participants?
- 16) Would you recommend the WHI diary to others? Why, or Why not?

APPENDIX L: Coding Guide Used to Assess the Self-monitoring Mechanisms of the Social Cognitive Theory of Self-regulation Addressed by Reported Participant Experiences

OUTCOME: Did the participant find the diary useful/helpful? Yes/No/Mixed/Unclear /Not mentioned		
Behaviour: all items on the electronic headache diary, including triggers, headaches, symptoms, coping and preventive strategies		
Self-monitoring mechanisms		
104	<p>Feedback Self-monitoring enhances performance when there is clear evidence of progress on the monitored behaviour. Knowledge of how one is doing, influences behaviour change, setting goals, and positive self-evaluation</p>	<p>Did the participants perceive that using the diary provided them with information to clearly examine their progress on the monitored behaviour?</p> <ul style="list-style-type: none"> - Can come from reports or the triggers list - Can come from the act of using the diary - Clear evidence of progress about behaviour is also implied when participants identified progress about their headaches. If the participant found that the diary provided informative feedback about their headaches, feedback about the behaviour is also implied <p>Example (Consistent with theory): “<i>Did you find the reports useful?</i>” “Yeah, kind of. It was just a faster way to look at everything and compare it which was nice, instead of going through each headache separately.”</p> <p>Example (Inconsistent with theory): “<i>Did you find the reports useful?</i>” “Not really, no... The graphs that I saw were severity of pain. So most days it was negligible, negligible, and then it would go up to 3 or 4. So measuring my pain wasn’t really applicable to me.”</p>
	<p>Temporal proximity Self-directed change is easier for behaviours monitored as they occur, in real-time. Immediate self-monitoring gives continuing information. Attention to ‘distal’ behaviours through recall is less likely to provide useful information</p>	<p>Did the participant monitor their behaviour as it happened, in real-time?</p> <ul style="list-style-type: none"> - Because the diary had capabilities of monitoring both in real-time and by recall, unless a participant stated that they ALWAYS or NEVER monitored their behaviour in real-time, temporal proximity should be coded as ‘Mixed’ - Monitoring in real-time will only be coded when a participant reports monitoring a specifically behaviour, and found that monitoring it in real-time was useful <p>Example (Consistent with theory): I found it really helpful to always enter my medication in as I took it. This gave me a clear understanding of how long it takes for my medication to start working.</p> <p>Example (Inconsistent with theory): Sometimes I would input the time that my headache started right away, but then I would go back at the end of the day and fill in the rest</p>

Consistency	Regular self-monitoring of behaviour is more informative than intermittent self-monitoring, by providing continuous attention to performance	<p>Did the participant regularly monitor their behaviour?</p> <ul style="list-style-type: none"> - A participant regularly monitored if they: <ul style="list-style-type: none"> o Kept track of their behaviour at the same time each day o Kept track of every headache episode - A participant is inconsistent with their monitoring if they: <ul style="list-style-type: none"> o Only monitored when they remembered or felt like it without any regular pattern - Participants may report occasionally forgetting days to complete the dairy, however, if overall they seemed to use the diary at the same time for most days, it can be considered regular <p>Example (Consistent with theory): I always do the daily diary at the end of the day</p> <p>Example (Inconsistent with theory): I had trouble keeping track of the diary because I would forget and not see the reminder until the morning</p>
Focus on success	Attending to behavioural accomplishments is more encouraging for behaviour change than attending to failures, which can lower subsequent performances and accomplishments	<p>Did the participant focus positively on progress/achievements/accomplishments of the monitored behaviour?</p> <ul style="list-style-type: none"> - Statements associated with a positive connotation (e.g., It was great, I really liked it) can be coded to focus on success - Statements in which participants report pleasure/satisfaction with their progress - Statements focusing on negative connotations (e.g., It was boring) focus on failure <p>Example (Consistent with theory): I have learned a lot about my headaches from using the diary, it's really great</p> <p>Example (Inconsistent with theory): It was too boring to actually enter everything in every day.</p>

Value of behaviour	Behaviours with perceived importance are likely to receive more attention when self-monitoring, than behaviours of no perceived importance.	<p>Did the participant monitor behaviour they perceived as important?</p> <ul style="list-style-type: none"> - Most behaviour tracked can be considered important. Participants were not required to track everything in the diary. We can infer that participants would skip what was unimportant to them, and only fill in the behaviours they considered as valuable - Tracking invaluable behaviours would be coded when participants explicitly stated that they tracked behaviours that they did not care about, or want to track <p>Example (Consistent with theory): I kept track of the trigger defaults that were in the diary, and also added in caffeine to see if that had an effect on my headaches</p> <p>Example (Inconsistent with theory): I kept track of the trigger defaults that were in the diary only because I thought I had to. I didn't care about whether stress or sleep impacted my headaches.</p>
Control	Self-monitoring is more capable of producing lasting effects in behaviours that are relatively easy to modify by deliberate effort. Self-monitoring only has minor effects on behaviours that are resistant to change.	<p>Did the participant monitor behaviour that they felt they could easily change?</p> <ul style="list-style-type: none"> - Explicit statements about whether the participant thought they could modify a specific behaviour or not <p>Example (Consistent with theory): I found out that using my computer without my glasses causes headaches. I'm going to try wearing my glasses from now on to try and change my headaches.</p> <p>Example (Inconsistent with theory): I know that my work triggers my headaches, but there's nothing that I can do about having to work night shifts.</p>
Motivation	People who desire to change the behaviour they are monitoring are more likely to set goals and react positively toward the progress they are making.	<p>Did the participant monitor behaviours that they desired to change?</p> <ul style="list-style-type: none"> - Wanting to cope with triggers - Desire to learn or understand the behaviour - Wanting to change behaviour to improve an outcome <p>Example (Consistent with theory): I want to be able to change my behaviour</p> <p>Example (Inconsistent with theory): I don't plan on making any change to my headaches, they don't bother me that much anyway.</p>

Self-diagnosis	Self-monitoring behaviour can identify new patterns or insights between situations, thoughts, and actions. Self-insights related to behaviour can set in motion behaviour change.	<p>Did the participant gain new insight about their behaviour?</p> <ul style="list-style-type: none"> - If the participant found that the diary provided insight about a link between their behaviour and their headaches. - If the participant identified new patterns about their headaches <p>Example (Consistent with theory): I was able to see that lack of sleep usually coincided with a headache</p> <p>Example (Inconsistent with theory): I didn't learn anything new about my headaches. found out that I get headaches more often than I realized.</p>
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