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Investigating the effectiveness of theory-based interventions for improving treatment adherence of patients with type 2 Diabetes Mellitus: A systematic review of Randomised Controlled Clinical Trials

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Abstract

Introduction: Theory can enhance the effectiveness of interventions designed to change health-related behaviours, however, there is a significant lack of such interventions to improve treatment adherence of Type 2 Diabetes Mellitus (T2DM) patients. This systematic review aims at examining the effectiveness of theory-based interventions on improving adherence of T2DM patients, also examining their methodological quality.
Methods: An electronic search was conducted, including only Randomised Controlled Trials published in English and Greek from 2004 to 2016. Databases searched included PubMed/Medline, Science Direct, Wiley Online Library, Oxford Journals and PsychInfo. The review protocol was designed and performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.
Results: The review included reports of 11 interventions, using the Health Belief Model (n = 3), Social Cognitive Theory (SCT) (n = 2), Theory of Planned Behaviour (n = 2), Transtheoretical Model (n = 2), Information-Motivation-Behavioural skills model (n = 1) and Motivational Interviewing (n = 1). Nine interventions improved adherence of T2DM patients; the mean quality of the studies was 6.6, out of 10.
Discussion and Conclusion: Most theory-based interventions were effective in improving adherence of T2DM patients, especially SCT, which successfully improved all three aspects of treatment (i.e., medication taking, diet and physical exercise). Self-efficacy is included in most of the theories and was the most effective element, especially when combined with goal setting practices, another common, effective element across interventions. However, the wide heterogeneity in the methodology of the studies impeded comparison and synthesis of findings. Common limitations were the use of self-reports, short follow-up periods and insufficient information on how theoretical constructs were used to design the intervention.

KEY WORDS: RCTs; theory-based interventions; type 2, diabetes mellitus; systematic review; treatment adherence.

Riassunto

Introduzione: La teoria può rinforzare l'efficacia degli interventi progettati per modificare i comportamenti correlati alla salute, tuttavia, c'è una significativa mancanza di interventi tali da migliorare la compliance terapeutica dei pazienti affetti da diabete mellito tipo 2. Questa revisione sistematica è stata finalizzata ad esaminare l'efficacia degli interventi basati sulla teoria per il miglioramento dell'aderenza terapeutica di questi pazienti, anche attraverso l'analisi della qualità metodologica degli studi.
Metodi: È stata condotta una ricerca elettronica, includendo soltanto trial clinici randomizzati pubblicati in inglese e greco dal 2004 al 2016. I database esaminati includevano Pubmed, Science Direct, Wiley Online Library, Oxford Journals and PsychInfo. Il protocollo della review è stato progettato ed effettuato secondo il PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.
Risultati: La revisione ha incluso i report di 11 interventi, usando il modello delle credenze della salute (n = 3), la teoria cognitiva sociale (n = 2), la teoria del comportamento pianificato (n = 2), il modello transterico (n = 2), il modello delle abilità informativo-motivazionali-comportamentali (n = 1) e l'intervista motivazionale (n = 1). Nove interventi hanno migliorato l'aderenza dei pazienti affetti da diabete mellito tipo 2; la qualità media degli studi è risultati pari a 6.6 su di un massimo di 10.
Discussione e Conclusioni: Molti interventi basati sulla teoria sono stati efficaci nel migliorare l'aderenza dei pazienti affetti da diabete mellito tipo 2, specialmente quelli derivanti dalla teoria socio-cognitiva, che hanno migliorato tutti e tre tipi di trattamento (ovvero terapia farmacologica, dieta ed esercizio fisico). Il senso di auto-efficacia fa parte della maggior parte delle teorie ed è stato l'elemento più efficace, specialmente quando combinato con le pratiche di goal-setting, un altro elemento efficace commune tra gli interventi. Tuttavia, l'ampia eterogeità nella metodologia degli studi ha impedito il confronto e la sintesi dei risultati. Comuni limitazioni sono state l'uso del self-report, brevi periodi di follow-up ed insufficienti informazioni su come i costrutti teorici sono usati per progettare l'intervento.

TAKE-HOME MESSAGE

Based on this systematic review's findings, health professionals can improve the effectiveness of adherence-enhancing interventions targeting Type 2 Diabetes Mellitus patients through adopting a holistic approach to treatment, implementing goal setting practices in the intervention design and using elements from Bandura's Social Cognitive Theory, especially self-efficacy through its four sources.

Competing interests - none declared.

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INTRODUCTION

Type 2 Diabetes Mellitus overview

Type 2 Diabetes Mellitus 'T2DM' is an increasingly prevalent chronic illness, characterized by the lack of insulin production in the body; even when insulin is being produced, it does not have its usual effects, failing to control blood glucose levels [1]. There are, approximately, 415 million T2DM patients worldwide [2]. Its main symptoms are excessive thirst, need to eat, weight loss, blurry vision and slow wound healing [1]. If left untreated, it can be life-threatening [2]. T2DM is caused by a complex interaction of biopsychosocial factors [3, 4], while its treatment involves taking medications, engaging in moderate exercise of at least 150 minutes per week, and adopting a healthy diet [5]. To optimize T2DM management, good adherence to all three aspects of treatment is required [2].

Treatment adherence and T2DM

Treatment adherence is the extent to which the patient follows the recommendations of the health care provider, regarding medication taking and lifestyle modifications [1]. Adherence of over 80% is considered to be adequate [1]. Poor adherence is prevalent in all chronic illnesses, due to the lifelong nature of their treatment, with non-adherence to medications reaching an estimated 50%, especially in developing countries, where health inequities are prevalent [1, 6]. T2DM patients are especially vulnerable to non-adherence, due to the high prevalence of comorbidities and the invasive, complex nature of diabetes treatment [7].

Importance of using theory-based interventions to improve adherence

Theory-based interventions are more successful in bringing about the desired behavioural changes compared to interventions that have no theoretical basis [8, 9]. Many researchers have highlighted the importance of integrating research and practice, using theoretical models of behaviour change to guide interventions [8, 10]. Using a theoretical framework to develop an adherence-enhancing intervention provides structure [9], allowing researchers to describe and evaluate the separate constructs of an intervention more clearly [11]. Moreover, theory-based interventions help identify which constructs are causally related to a behaviour, how the behaviour change occurred, facilitates the intervention's replicability and boosts its effectiveness [9, 12].

Theoretical models of health behaviour change

Social Cognitive Theory

Bandura's Social Cognitive Theory (SCT) supports that a dynamic interaction exists between personal, behavioural and environmental determinants and that people learn through observation [13, 14]. Its main elements are knowledge, social support, outcome expectancy, self-regulation and, especially, self-efficacy [14]. The SCT is very effective in predicting and explaining diabetes treatment adherence [14], whilst, self-efficacy has been strongly associated with various behaviours, such as exercise, where it can explain up to 40% of the variance [15]. However, most researchers focused only on a few constructs of SCT, such as self-efficacy and self-regulation, ignoring the rest [14].

Theory of Reasoned Action/Planned Behaviour

The Theory of Planned Behaviour (TPB) has been developed from the Theory of Reasoned Action (TRA) and focuses on how attitudes, subjective norms, perceived behavioural control and intentions interact to affect behaviour [16]. Behavioural intention, which is predicted by the individual's attitudes and subjective norms, immediately precedes and predicts behaviour [17]. Attitudes refer to how an individual perceives and values the outcomes of a behaviour, whilst, subjective norms are beliefs the individual holds regarding how significant others would like them to behave and the value placed on their opi-

nion [16]. Ajzen later added the construct of perceived behavioural control (PBC), which is very similar to self-efficacy and reflects the individual's belief of his/her ability to perform a behaviour and developed the TPB model [18]. PBC predicts behaviour indirectly, through intentions, similarly to attitudes and subjective norms, but also directly [16]. The TPB has successfully predicted adherence of chronically ill patients [19, 20], with the elements of attitudes and PBC being the strongest determinants [21]. However, more research is needed as other studies found no such associations [22].

Health Belief Model

The Health Belief Model (HBM) supports that people engage in preventative behaviours to respond to health threats [23]. Its main elements are: (i) The individual's perceived susceptibility to the threat; (ii) perceived severity of the threat and its consequences; (iii) benefits of behaviour change; and, (iv) related barriers. These elements affect the individual's readiness to act, whilst, self-efficacy was later added to the model [16, 23]. The model also includes the need of a cue to action, a trigger motivating individuals towards behaviour change [16]. Empirical evidence supports HBM's effectiveness on explaining health-related behaviours, and many researchers suggest that it has a strong predictive utility in accordance to adherence patterns [16, 24, 25]. However, there is still inconsistency regarding the manner in which the HBM's variables are associated with adherence.

Transtheoretical Model

The Transtheoretical Model (TTM) is a stage-based model of health behaviour change, developed by Prochaska & DiClemente in 1983 [26]. The TTM argues that individuals achieve behavioural change by moving through five adjacent stages: (i) Pre-contemplation, where individuals do not yet think about behaviour change; (ii) contemplation, where they start thinking about behavioural change; (iii) preparation, where they are preparing to take action; (iv) action, where they actually engage in behaviour change; (v) maintenance, where they have achieved behaviour change and maintained it for over 6 months [16]. There is also the likelihood of relapse to a previous stage [16]. Processes of change affect transition from one stage to another [16], with decisional balance, which reflects the individual's evaluation of the positive and negative aspects of behaviour change, and self-efficacy, being considered as causes of transition between stages [26]. Empirical evidence strongly supports the TTM's effectiveness on behaviour change [27, 28]. However, there are mixed results regarding its application on adherence behaviour [28, 29].

Information-Motivation-Behavioural Skills Model

The Information-Motivation-Behavioural (IMB) skills model has three main constructs; information, motivation and behavioural skills. Information reflects the patient's knowledge regarding the medical condition, its prognosis and management practices [30, 31]. Motivation reflects the patient's attitudes towards the behaviour, the perceived social support and subjective norms [1]. Lastly, behavioural skills refer to ensuring that patients have the required skills to adopt the behaviour [1]. The IBM has been used to develop adherence-enhancing interventions among HIV patients with success, explaining up to 40% of the variance among T2DM patients [31]. The association between information and motivation has been shown to be weak, which is to be expected considering the constructs within the model are independent [1].

Motivational Interviewing (MI)

MI is a collaborative approach to enhancing the patients' motivation for behavioural change, by eliciting from them reasons for this change [32]. The practitioner then reinforces the patients' motivation for behavioural modifications through reflective listening [32]. MI is very effective in enhancing motivation and improving adherence among chronically ill patients [32]. However, according to many

researchers, MI is a type of therapist-patient communication approach and should not be considered a theoretical model of behaviour change [32].

Summary of theoretical models

Theoretical models mainly focus on the interplay of behavioural, cognitive and environmental influences to explain and predict health-related behaviours [16]. There are common themes across most models, with the most important one being self-efficacy [18]. A main reason behind self-efficacy's frequent inclusion in these theories is its effectiveness in facilitating behaviour change [13, 14]. All of the aforementioned models have been used to examine and predict adherence of chronically ill patients, although there is a significant lack of interventions for T2DM. The TPB and the HBM seemed to be effective in predicting adherence, although with significant inconsistency [19, 26]. On the other hand, the SCT has been consistently effective in predicting adherence among chronically ill patients [14], whilst the IBM has also been effective in predicting adherence of T2DM patients, although there is still a lack of studies which impedes reliable conclusions [31]. Despite the empirical support these models have received over the years, their actual predictive power is still somewhat small, with the most effective models being able to predict approximately 30-40% of behaviour [15]. Many researchers have suggested that, to improve the predictive utility of these models, different models and elements may need to be combined [8, 26].

Rationale and significance of current systematic review

T2DM prevalence is increasing every year, having a dramatic impact on both the individuals' health and the costs of the health care system [1, 3, 4]. Improving adherence enhances patients' glycaemic control, lowers risk of complications, optimises health outcomes and reduces costs [1, 4]. A significant lack of well-designed interventions to improve adherence of T2DM patients has been reported [11]. According to previous findings, theory-based interventions are very effective in improving adherence, especially when they are also evidence informed [12, 33]. However, there is still a lack of such interventions, especially among T2DM patients and, even interventions using a theoretical framework, often have many methodological differences that do not allow for conclusive results [11, 34]. This inconsistency in findings raises the need to systematically review the relevant literature and compare the effectiveness of similar interventions, to explore which theoretical model and/ or elements have been shown to be the most effective one(s) in improving adherence. This could facilitate the development of more effective interventions which could also be holistic, targeting all three aspects of T2DM treatment, as diet and exercise, together with medications, are essential components of T2DM treatment [1]. It could also provide information to inform the design of future research to enhance the evidence base. Additionally, there is a need to examine the methodological quality of adherence-enhancing interventions targeting T2DM patients, to identify common weaknesses and improve the quality of future interventions. It is important to note that, even though there are already a few systematic reviews on this topic, they have not focused only on Randomized Controlled Trials (RCTs), which are considered the gold standard in intervention research as they use control groups to accurately estimate the intervention's effectiveness in addition to their overall robust design. Previous systematic reviews have also focused more on different aspects of self-care in T2DM, rather than treatment adherence behaviour itself.

Objectives of the current systematic review

This systematic review aims at exploring the effectiveness of theory-based interventions and identifying the most effective theoretical models and/or elements on improving adherence of DM patients. It also aims at examining the methodological quality of these interventions. Table 1 depicts the PICO of the research question.

Table 1. Systematic Review Research Question P.I.C.O

P	I	C	O
Patients with Diabetes Mellitus (type 1; type 2)	Intervention based on theoretical model of health behaviour change	Control group/ usual care	Adherence behaviour (measured by self-report and/or objective measures)

METHODS

Databases search

The review protocol was designed and performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. An electronic search was independently conducted by two authors (D.M. and G.L.) on the PubMed/Medline, Science Direct, Wiley Online Library, Oxford Journals and PsychInfo databases, using various combinations of the following keywords: Diabetes AND/OR DM AND/OR type 1 diabetes AND/OR T1DM AND/OR type 2 diabetes AND/OR T2DM AND/OR adherence AND/OR compliance AND/OR concordance AND/OR theory-based interventions AND/OR theoretical interventions AND/OR interventions AND/OR programme AND/OR theory-based programme. Only Randomised Controlled Trials published in English and Greek from 2004 to 2016 were included. A search within the Cochrane Library confirmed that there were no similar systematic reviews. After excluding the duplicates, there were 1,129 identified papers.

Selection criteria

Interventions were eligible for inclusion if they: (i) Targeted patients who had been diagnosed with Diabetes Mellitus (T1DM or T2DM); (ii) specified adherence as the targeted behaviour; (iii) were theory-based; (iv) had RCTs, and; (v) had full-text available, to allow for quality evaluation. Interventions targeting adherence in other chronic illnesses, lacking a theoretical basis and an RCT design, were excluded. Also, papers which only described a protocol, which were not in the English/ Greek language and/or for which only the abstract was available, were also excluded. T1DM patients were not excluded from the review as their treatment is highly similar to T2DM.

Quality evaluation

The quality criteria, against which the included papers have been evaluated, were derived from the Consort [35] and Re-aim [36] checklists. We applied the following criteria: a) Author(s) have described participants' demographic characteristics; b) power calculations have been carried out; c) the author(s) have clearly described the outcome measures they used; e) the author(s) used Cronbach's alpha to examine internal reliability of questionnaires, if applicable; f) the author(s) have examined the effect size; g) the author(s) have described the attrition rates; h) the author(s) have conducted Intention-to-Treat analysis; i) the author(s) have reported all outcomes of the intervention clearly; l) baseline and follow up data have been reported by the author(s); m) the author(s) have provided sufficient information to allow for replicability.
This set of quality criteria has been selected to examine the validity and reliability of the included studies. Studies were given a score based on whether they fulfilled each criterion: 'Y' for 'Yes', 'N' for 'No', 'I' for when information was incomplete, with scores ranging from 0-10. Table A, in the Appendix, depicts the scoring.

RESULTS

Eligible studies

Overall, the initial search resulted in 1,129 papers, with 273 relevant to the research question. After the screening process, based on the eligibility criteria, there were 11 papers eligible for inclusion (please see Figure 1 'Flow Diagram'). A reviewer inter-rater reliability check was completed, regarding the re-

trieval and appraisal processes, to reduce bias and evaluate the rigour of the research design and implementation. The second reviewer evaluated 50% of the studies considered for inclusion and the inter-rater agreement was 100%. To develop adherence enhancing interventions, 3 studies were based on the Health Belief Model 'HBM', 2 on Social Cognitive Theory 'SCT', 2 on the Theory of Planned Behaviour 'TPB', 2 on the Transtheoretical Model 'TTM', 1 on the Information-Motivation-Behavioural Skills model 'IMB', and, 1 on Motivational Interviewing 'MI'. Table 2 depicts the PICO.

Studies quality evaluation

Almost all of the studies (10/11) described the participants' demographic characteristics, with the exception of one [37]. Five studies did not conduct any power calculations to determine the required sample size [37–41]. All studies used self-reports, with two also using objective measures, measuring medication adherence with Medication Event Monitoring System [42], and, dietary adherence, indirectly, using electronic weighing scales [37]. Internal reliability, using Cronbach's alpha, was explored in only five studies [37, 39, 43–45]. The rest did not examine any type of reliability, also not reporting reliability from

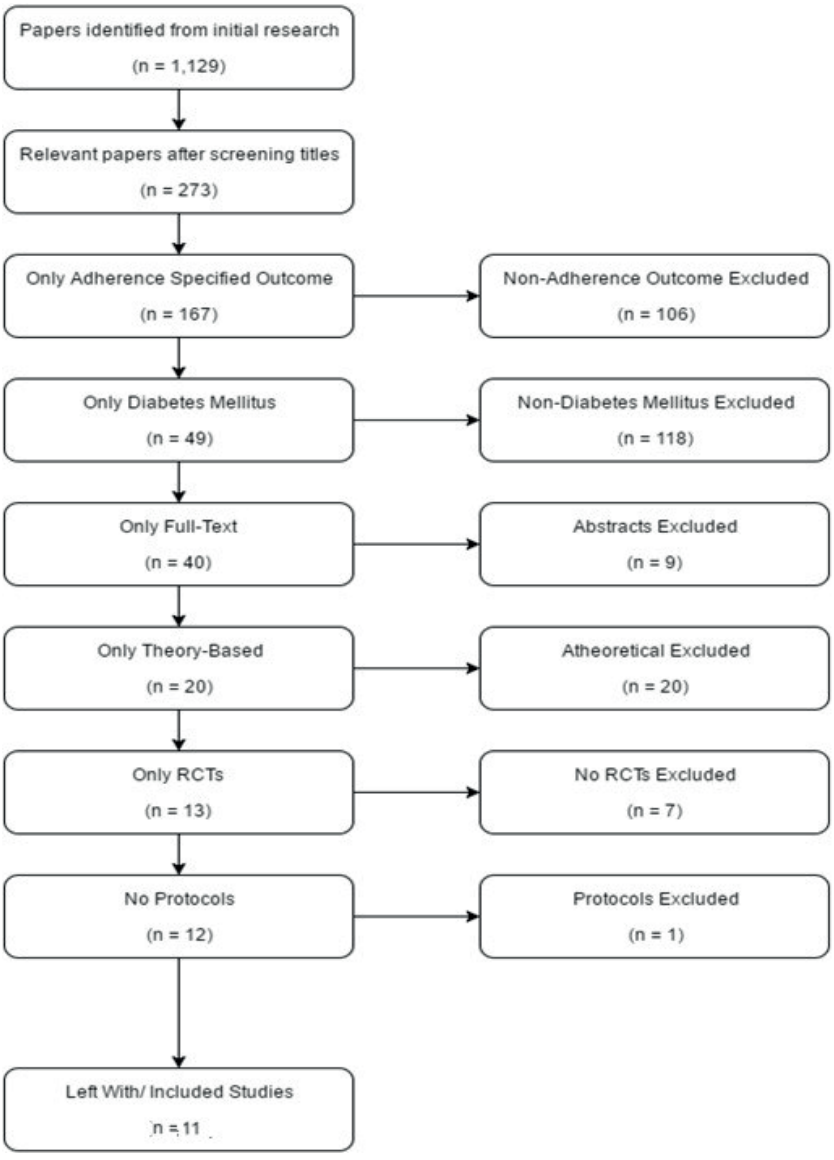

Figure 1. Flow Diagram.

Table 2. Included studies PICO.

Authors	Population	Intervention	Comparison	Outcome	Qualit Score
Albikawi et al, 2015	Patients diagnosed with T2DM, under oral medication and being > 20 years old (n = 168)	A SCT-based self-efficacy enhancing intervention package. The intervention aimed at enhancing self-efficacy of intervention group, through elements such as educational training, efficacy enhancing counselling session and skills training, also incorporating goal setting. Data were collected on baseline, at 2 weeks and 3 months follow-up.	Routine diabetic educational program (control group)	Improved adherence to diet, exercise and medication; improved adherence to foot care and blood glucose testing practices (measured by questionnaires)	8/10
Beiranvand et al, 2015	Patients with T2DM, 30-60 years old, who were referred to the Diabetes Clinic at Ahvaz Golestan Hospital, Iran (n = 80)	A TPB-based, 4-week educational program	Diabetes routine training; series of educational leaflets and booklets on diabetes management and foot care (control group)	Improved adherence to foot care behaviour (measured by questionnaires)	7.5/10
Clark et al, 2004	Patients with T2DM, 40-70 years old, with BMI>25 (n = 100)	A TTM-based brief, tailored lifestyle self-management intervention including telephone call follow up; main elements used in the intervention were self-efficacy and goal setting	Usual care (control group)	Significant improvement in dietary adherence and, to lesser extent, physical activity (measured by questionnaires and weighing scale)	6/10
Farmer et al, 2012	Adult patients with T2DM, under oral medication treatment with HbA1c > 7.5 (n = 211)	Adult patients with T2DM, under oral medication treatment with HbA1c > 7.5 (n = 211)	Standard care (control group)	Increased medication adherence (measured by Medication Event Monitoring System and questionnaires)	9/10
Gatwood et al, 2016	Adults with DM, 21-64 years old, with HbA1c > 8.0%, taking medication for diabetes (n = 75)	A HBM-based, daily tailored text messaging for 90 days, also using elements from the Self-Determination Theory	Standard care and monthly check-in message (control group)	No improvement in medication adherence (measured by questionnaires)	8/10
Jackson et al, 2007	Patients with T2DM, 34-75 years old, attending a diabetes outpatient's clinic in London (n = 40)	A TTM-based exercise consultation one-to-one weekly interview with a dietitian which focused on goal setting	Physical activity leaflet (control group)	Improved physical activity adherence (measured by questionnaires)	4.5/10
Jalilian et al, 2014	Patients with T2DM (n = 120)	A HBM-based, health educational programme to improve self-management, consisting of 6 teaching units, also aiming at improving self-efficacy	Usual care (control group)	Improved adherence to self-management practices; i.e. foot care, diet, physical activity, smoking and measuring blood glucose (measured by questionnaires)	5/10
Mardani Hamuleh et al, 2010	Patients with T2DM, aged less than 65 years old, under treatment (n = 128)	HBM-based four 40-minutes educational classes.	Standard treatment (control group)	Improved dietary adherence (measured by questionnaires)	3.5/10
Osborn et al, 2010	Adult patients with T2DM (n = 118)	IMB-based, 90-minute session improving information, motivation and behavioural skills training, incorporating goal setting practices	Usual care (control group)	Improved dietary adherence; no differences for exercise adherence (measured by questionnaires)	6/10
Rubak et al, 2011	Patients with T2DM, 40-69 year old (n = 80)	MI-based courses consisting of a 1 ½ -day training sessions with a half-day follow-up, conducted by MI trained GPs	Standard care (control group)	No improvement in medication adherence (measured by questionnaires)	9/10
Tan et al, 2011	Adult patients with T1 or T2DM, with HbA1c >7% (n = 164)	A SCT-based brief structured education programme using principles of self-efficacy, consisting of 12 weeks monthly sessions – 2 face-to-face individual education sessions and 1 telephone follow-up, also incorporating goal setting strategy	Standard care (control group)	Improved physical activity and medication adherence but not diet (measured by questionnaires)	10/10

previous literature. The effect size was measured by only four of the studies [42, 44–46], being found to be from small to medium. Attrition rates were identified in all studies but two [39, 40]. However, intention-to-treat analysis was conducted by only three studies [37, 42, 45]. All of the studies clearly described their statistical analyses' outcomes. All studies described the baseline data and most collected follow-up data, with a few exceptions [38, 40, 43]. However, only three interventions had a follow-up of over 3 months [37, 42, 47]. Only five studies explained in detail the intervention design, allowing for future replications [41–43, 45, 46], with three providing excellent descriptions [41, 45, 46]. Overall, the methodological quality of the studies was moderate, with the lowest score, out of 10, being 3.5 [4], and the highest 10 [45]. The mean quality score was 6.6.

Effectiveness in improving adherence

Overall, seven interventions successfully improved DM patients' adherence, with two improving adherence to diabetes self-management, including diet, exercise, foot care, blood glucose monitoring, smoking [39], as well as medication [46], one study to diet and exercise [37], one to medication [42], one to diet [40], one to exercise [38], and one to foot care [43]. Two studies were partially successful in improving adherence, one aiming at diet and exercise [41], whilst, the second at medication, diet and exercise adherence [45]. Only two studies, both aiming at improving medication adherence, were unsuccessful [44, 47].

Interventions based on the TTM

Clark et al. [37] designed a brief TTM-based intervention, aiming at improving diet and exercise adherence of T2DM patients, which consisted of a tailored self-management program where participants were encouraged to engage in goal setting to improve adherence and overcome barriers. The control group undertook usual care. Questionnaires were used to collect data and an electronic weighing scale to measure weight differences. The intervention group significantly improved adherence to both diet and exercise, retaining these changes at 9 months follow-up. Self-efficacy was shown to be the best predictor and the intervention mainly used goal setting to bring about the desired changes. However, there was very little information on how the TTM was utilised in the intervention design. Jackson et al. [38], aimed to improve exercise adherence of T2DM patients through a TTM-based intervention. The control group received standard exercise leaflets, while, the intervention group was treated with an exercise consultation one-to-one interview, by a dietitian, which aimed at helping them develop goals to initiate and maintain exercise. The intervention significantly improved exercise adherence, however, there was no follow-up.

Interventions based on SCT

Albikawi et al. [46], developed an SCT-based intervention, using self-efficacy to improve TDM patients' adherence to self-management practices. The control group undertook routine diabetic training, whilst, the intervention group undertook an educational programme to enhance their self-efficacy through its four sources: Vicarious experiences, performance accomplishment, verbal persuasion and self-evaluation. The intervention consisted of 3 face-to-face meetings and 1 telephone follow-up. The 1st meeting used a DVD viewing to increase knowledge of self-care, also presenting a 'role-model', a T2DM patient who described his engagement in self-care practices, targeting vicarious experience [46]. The 2nd meeting provided participants with booklets, which emphasized daily self-management skills, also focusing on goal-setting, targeting vicarious experience and performance accomplishments. The 3rd meeting provided self-efficacy enhancing counselling sessions aiming at increasing patients' confidence in their ability to practice self-care. This meeting also focused on goal setting, training patients to use goal setting sheets. The last meeting was the follow-up. Only subjective measures were used to collect data. The intervention significantly improved adherence to diet, exercise, foot care, medications and blood glucose

monitoring, with these improvements retained at a three- month follow-up. Tan et al. [45] also developed a SCT-based intervention to improve adherence to exercise, medication, diet and blood glucose monitoring of T1DM and T2DM patients. Self-reports were used and the control group undertook usual care. The intervention group was treated with three monthly educational sessions, based on the element of self-efficacy and its four sources. During the 1st session, approaches to overcome self-care difficulties and evidence-based studies were discussed, targeting vicarious experience [45]. Three weeks were then given to the participants to practice self-management, after setting realistic goals and being encouraged to work towards them [45]. The 2nd meeting focused on praising the patients' achievements, targeting performance accomplishments, on identifying and overcoming barriers, targeting verbal persuasion, and coping with emotional problems, targeting emotional arousal. The 3rd was a follow-up, through phone calls, which aimed at reinforcing the education the participants received. The intervention improved adherence to medication, exercise and blood monitoring. The study was unsuccessful for diet adherence but was a well-designed intervention, providing clear and detailed information to facilitate replication.

Interventions based on the TPB

Beiranvand et al. [43], developed a TPB-based intervention targeting adherence to foot care practices of T2DM patients. The control group undertook routine training. The intervention group participated in a 4-week educational program, based on the TPB elements, and was informed about risk factors associated with foot care, daily foot care activities and the positive outcomes of foot-care adherence. The intervention, which was delivered through a series of lectures, workshops and practical demonstrations, significantly improved adherence to foot care and patients' attitudes. However, subjective norms, PBC and intention did not differ significantly and there was no follow-up data. Farmer et al.'s [42] TPB-based intervention aimed at improving medication adherence of T2DM patients and data were collected through objective and subjective measures. The control group received standard care. The intervention group undertook a programme delivered by nurses. The 1st part, aimed at enhancing the perceived benefits and reducing barriers of behaviour change, enhances norms and reinforces positive attitudes towards adhering. In the 2nd part, the participants were asked to develop if-then plans with regard to where, how and when they were going to take their medications. The intervention effectively improved medication adherence at post-intervention and 20 weeks follow-up.

Interventions based on the HBM

Gatwood et al. [44] developed a telephone-based intervention, using elements of the HBM in combination with self-determination theory. The intervention entailed tailored text messages, which were sent once each day, for 90 days. These messages aimed at improving patient education, reinforcing desired beliefs regarding the condition and the treatment of the disease and increasing motivation. However, it failed to improve medication adherence. Jalilian et al. [39], developed an HBM-based intervention to improve self-management of T2DM patients. The control group undertook usual treatment whilst the intervention group participated in 6 weekly teaching sessions. The results of the intervention were measured by questionnaires. The 1st session educated patients on T2DM complications, the 2nd on foot care, the 3rd on exercise to increase self-efficacy, the 4th on smoking-related complications and the 5th on the appropriate diet, aiming at increasing self-efficacy. A final assessment took place during the 6th session. The intervention improved adherence to foot care, diet, exercise, smoking and blood glucose monitoring. Self-efficacy was the most effective construct. Finally, Mardani-Hamuleh et al. [40] developed a HBM-based intervention using both subjective measures and blood tests to examine dietary adherence of T2DM patien-

ts. The control group undertook usual treatment whilst the intervention group took part in 4 weekly educational sessions. The intervention was effective in improving diet adherence, HbA1c levels, severity, susceptibility, perception of barriers and benefits. However, too little information, regarding the intervention's design, impedes replication. Also, no follow-up was examined.

Intervention based on the IMB

Osborn et al. [41] developed a brief intervention based on the IMB to improve dietary and exercise adherence. The control group undertook usual care while the intervention group participated in a programme where, initially, participants were given information on diet and exercise; afterwards, counselling techniques were used to enhance the motivation to change and overcome barriers and, finally, participants developed behavioural skills to overcome barriers and adhere better. Self-efficacy and goal setting were the main elements of the intervention. The intervention, as measured by questionnaires and blood tests, successfully improved diet but not exercise adherence.

Intervention based on MI

MI was used in an intervention developed by Rubak et al. [47], aiming at improving medication adherence of T2DM patients. Whilst the control group undertook usual care, the intervention group participated in a counselling programme, aiming at enhancing their empowerment and decision making, using the MI elements. Questionnaires were used to collect data, but, the intervention did not improve medication adherence.

DISCUSSION

Summarizing the findings

Overall, there were three HBM, two TPB, two TTM, two SCT, one IMB and one MI interventions designed to enhance adherence in diabetes patients. All targeted T2DM patients, with two additionally including a small number of T1DM patients [44, 45]. Two interventions were not effective in improving adherence, one based on MI [47], and the other on the HBM [44], both targeting medication adherence. The IMB intervention improved adherence to diet but not exercise [41], whilst two of the HBM-based interventions were successful in improving adherence to exercise, foot care, blood monitoring and diet [39, 40]. The TPB-based studies improved adherence to foot care and medications [42, 43], whilst, one SCT-based intervention improved adherence to all three aspects of DM treatment [46], and the other improved adherence to medication and exercise, but not diet [45]. Lastly, the TTM intervention was effective in improving adherence to exercise and diet [37, 38]. With respect of studies' quality, SCT-based interventions had a mean quality score of 9, TPB-based of 8.25, IMB-based of 6, MI-based of 6, HBM-based of 5.5, and, lastly, TTM-based of 5.25. Self-efficacy and goal setting practices appeared to be the most effective elements across interventions, especially within the SCT framework.

Methodological quality of theory-based interventions

The methodological quality of theory-based interventions is very important to allow for accurate assessment and evaluation of their findings and design [34]. Poorly designed methodologies impede replication and do not allow for an in depth understanding of adherence-enhancing related factors. Power calculations are important as a sample size needs to be appropriately large to allow for reliability and generalizability of the findings [48]. However, only six of the studies conducted power calculations; four, out of eight, successful interventions did not examine power. The majority of studies did not examine the measures' internal consistency, something that has major implications for their ability to collect reliable data on adherence and provide accurate assessments [49]. Many of the studies used already standardised questionnaires, however, it is considered appropriate for each study to examine the current Cronba-

ch's alpha of the questionnaires used [50]. Another important issue is the lack of effect size. Effect size assesses the magnitude of the effectiveness of a behaviour change intervention [51]. By examining the effect size, we not only know that an intervention was successful but also how successful it was, with researchers strongly supporting that the use of the p-value is not enough to assess an intervention's effectiveness [52]. However, only four of the included interventions used effect size [42, 44–46], with most of the successful interventions not examining the effect size. Even though attrition rates were reported by most studies, only 3 conducted intention-to-treat analyses, thus failing to report how missing responses and deviations from randomized allocation were handled, potentially introducing bias. Another major issue in both research and clinical practice is the replicability of an intervention, which was allowed by only five papers; there needs to be enough detail on how the intervention was developed and implemented, utilizing the theoretical elements [41–43, 45, 46].

Effectiveness of theory-based interventions

Social Cognitive Theory

SCT was shown to be an effective model, increasing adherence to most aspects of diabetes treatment, a main issue when targeting T2DM patients [45, 46]. Both studies used the theory of self-efficacy, which lies at the heart of the SCT, and its four sources [13, 53]. Previous studies also support the effectiveness of SCT on improving adherence in other illnesses, with this theory being widely considered as one of the most comprehensive models of behaviour change [14]. However, many researchers develop their interventions loosely based on SCT, targeting only self-efficacy, rather than using the model's other constructs [14]. Both SCT-based interventions in this review utilised the element of self-efficacy, but, through its four sources, clearly describing how these were utilised. Both papers described in detail the intervention's design, facilitating their replicability. Albikawi et al.'s [46] intervention entailed the use of various methods, such as DVD viewing, to improve diabetes self-care knowledge, use of role-models, educational booklets, self-efficacy enhancing counselling and problem-solving skills training, targeting the four sources of self-efficacy, also incorporating goal setting practices [46]. Tan et al.'s [45] SCT-based intervention also emphasized the elements of goal setting and enhancing self-efficacy through its four sources. More specifically, Tan et al.'s intervention entailed delivering a health education programme whereby participants were informed of strategies to overcome self-care difficulties. Afterwards they were encouraged to develop goals and stick to them, were praised for the achievements they made, received support to identify and overcome barriers and cope with emotional problems [45]. However, one of the interventions failed to improve adherence to diet [45], perhaps due to its brief nature. It should also be noted that, in Albikawi et al.'s study [46], adherence was measured as one construct, thus not allowing understanding of whether the effectiveness of the intervention varied between the different aspects of T2DM treatment [46]; this may account for the different findings with Tan et al.'s intervention [45]. Still, these were among the most effective interventions, both aiming at the main aspects of T2DM treatment, also reporting medium effect sizes.

Transtheoretical Model

Both TTM-based interventions successfully improved diet and exercise adherence, through enhancing motivation [37, 38]. This was in accordance with previous studies, which support that enhancing motivation to change, enhances adherence and prevents relapse [54]. Both interventions used goal setting, whilst, self-efficacy was shown to be a strong predictor of stage transition [37]. However, it should be noted that the interventions' methodologies were not clearly described and no effect sizes had been estimated, thus it is very difficult to accurately evaluate their findings and the magnitude of the intervention's significant effectiveness.

Theory of Planned Behaviour

The TPB improved foot care [43] and medication [42] adherence. These results agree with past research, which supports TPB as an effective model in predicting adherence [19, 20]. Farmer et al. [42], combined the TPB with the implementation-intentions technique, asking participants to form if-then plans and goals. The intervention was effective in improving medication adherence, something that is also supported by past research which suggests that using implementation-intentions bridges the gap between intention and behaviour and increases the TPB's effectiveness [55, 56]. However, there were no data regarding changes in TPB elements to be able to evaluate their effectiveness on improving medication adherence [42].

Health Belief Model

The HBM is considered an effective model, especially regarding adherence [16, 25]. This review's findings are largely in line with previous ones, with self-efficacy being, again, highlighted as the most effective element [57, 58]. Two, out of three, HBM-based interventions successfully improved patients' adherence to general self-management practices [39, 40], though not medication [44]. However, this may have been due to the use of phone-based messages, to increase knowledge and motivation, as previous studies, despite some inconsistency, have found that mobile technology-based interventions can be ineffective [44].

Information-Motivation-Behavioural Skills model

The IMB-based intervention effectively improved dietary adherence and clearly described its methodology and use of theoretical elements; however, no differences in exercise adherence were found [41]. The intervention aimed at increasing self-efficacy, through motivation-enhancing consultations, also incorporating goal setting practices. Previous studies also support the effectiveness of the IMB [59]. It would be very interesting to further examine the effectiveness of this model on improving adherence behaviour to all three aspects of T2DM, medication, diet and exercise.

Motivational Interviewing

Contrary to the findings of other studies, MI was not effective in improving medication adherence of T2DM patients, when used on its own [47]. However, this may have been due to methodological problems within the intervention design. It should also be noted that, even though the authors referred to the intervention as theory-based, MI is widely considered as a set of techniques rather than a model of behaviour change [32].

Summarizing the effectiveness of theoretical models and elements

Overall, it is difficult to compare the effectiveness of the included theory-based interventions due to the wide heterogeneity of their methodologies, however, some elements were found to be more effective than others, such as self-efficacy, goal setting, problem-solving skills training, attitudes and motivation. A main model that seemed to be effective in improving adherence holistically was SCT, through enhancing self-efficacy and using goal-setting practices. The detailed design of the SCT-based interventions [45, 46], especially the one by Tan et al. [45], allows for their replication and in-depth evaluation. The TPB and the HBM were also, generally, effective, but the former only targeted medication, while the latter only diet and exercise adherence. The TTM was also effective, but, it did not target medication adherence. Additionally, none of the interventions based on these three models had a detailed methodology, contrary to the SCT studies, impeding the assessment of their effectiveness on improving adherence and not allowing for replication. The most effective elements, as identified by this current systematic review, were self-efficacy, through its four sources, and goal setting. Both were used within different interventions to effectively improve adherence of DM patients, whilst their combination se-

emed to be very effective. Both elements were prevalent across intervention based on the TPB [42, 43], the TTM [37], the IMB [41], and the HBM [39], although only SCT-based interventions described in detail how they enhanced self-efficacy, making use of its four sources, in complete accordance to Bandura's SCT [45, 46]. It is also worth mentioning that neither self-efficacy nor goal setting practices were involved in the design of the only two interventions, which did not improve adherence of diabetes patients [44, 47].

Limitation of studies

There were some common limitations across the included studies. Firstly, adherence was measured only through subjective measures, which are highly vulnerable to bias. Future studies could examine adherence using a combination of subjective and objective measures, which can provide accurate findings, reducing bias [60]. Another common limitation was the too short follow-up period, with most studies having a follow-up of < 3 months. This hinders investigation of the maintenance of adherence improvement, something essential since significant improvements in the well-being of T2DM patients become more evident after a period of adhering to treatment [1].

Limitations of the current systematic review

Firstly, grey literature was not included in our review process. Moreover, only papers published in the English language were examined. Publication bias is another main issue, which is quite common in systematic reviews [61]. As effective interventions are sometimes more likely to be published compared to those which were not successful, this may affect the results of systematic reviews synthesizing these findings.

Future directions

The current review's findings highlight the need for theory-based interventions, which are also well-designed to allow for replication and accurate evaluation and synthesis of findings, to improve T2DM adherence. There was a lack of studies investigating psychological health, to better evaluate the importance of such interventions in patients' quality of life. As psychological health has already been associated with adherence, it would be very interesting to further examine the effectiveness of adherence-enhancing interventions on mental health [62]. For future interventions to effectively improve adherence of T2DM patients, they need to use a clear theoretical framework and be tailored to the individuals' needs, targeting all three aspects of diabetes treatment [1]. The element of self-efficacy, combined with goal setting, has been highlighted as a main determinant of behaviour change, especially within the SCT framework. It is, however, important to take into account the four sources of self-efficacy as well, targeting them through an educational package that may include booklets with information on self-care practices, role-modelling, problem-solving skills training, self-efficacy enhancing consultation and goal setting strategies.

CONCLUSION

To conclude, increasing self-efficacy, through its four sources, and incorporating goal setting techniques were the most effective elements of the interventions, especially when used within the SCT framework. There is a need for future interventions to use longer follow-up periods, to examine effect sizes and the maintenance of adherence improvement, using reliable and valid measures, where appropriate. They also need to allow for replication and examine their applicability [63]. Overall, the number of high-quality, theory-based, T2DM adherence enhancing interventions is somewhat small, as shown by this review, highlighting the need for more, well-designed, interventions to improve adherence and psychophysical health of T2DM patients.

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Appendix A. Quality evaluation of included studies.

Total Score 10	8	7.5	6	9	8	4.5	5	3.5	6	6	10
Replicability	Y	Y	N	Y	N	I	N	N	Y	N	Y
Baseline/ Follow-up	YY	YN	YY	YY	YY	YI	YY	YN	YY	YY	YY
Outcomes	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Intention to Treat	N	N	Y	Y	N	N	N	N	N	N	Y
Attrition Rates	Y	Y	Y	Y	Y	Y	N	N	Y	Y	Y
Effect Size	Y	N	N	Y	Y	N	N	N	N	N	Y
Internal Reliability	N	Y	Y	N	Y	N	Y	N	N	N	Y
Outcome Measures	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Power Calculations	Y	Y	N	Y	Y	N	N	N	N	Y	Y
Demographics	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
Authors	Albikawi et al. 2015 (SCT)	Beiran-vand et al. 2015 (TPB)	Clark et al. 2004 (TTM)	Farmer et al. 2012 (TPB)	Gatwo-od et al. 2016 (HBM)	Jackson et al. 2007 (TTM)	Jalilian et al. 2014 (HBM)	Mardani Hamu-leh et al. 2010 (HBM)	Osborn et al. 2010 (IMB)	Rubak et al. 2011 (MI)	Tan et al. 2011 (SCT)