

**Translating research results into everyday healthcare practice: An empirical study
examining the influence of social-cognitive and perceived environmental factors on
physical activity and weight during early stages of a lifestyle intervention**

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Vorgelegt von
Sylvia Hansen
aus Erkelenz

Hauptberichter:	Prof. Dr. Wolfgang Schlicht
Mitberichter:	Prof. Dr. Ralf Brand
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Institut für Sport- und Bewegungswissenschaft
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List of abbreviations

ADF	Asymptotic distribution-free
ANOVA	Analysis of Variance
ANT	Actor Network Theory
AVE	Average Variance Extracted
BCT	Behaviour Change Technique
BMI	Body Mass Index
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit Index
CI	Confidence Interval
CID	Clinical Investigation Day
cov	Covariance
c.r.	Critical value
CRI	Composite Reliability Index
df	Degrees of freedom
DPP	Diabetes Prevention Program
DPS	Diabetes Prevention Study
DQS	Da Qing Diabetes Prevention Study
FIML	Full Information Maximum Likelihood
GFI	Goodness of fit index
H	Hypothesis
HAPA	Health Action Process Approach
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
LED	Low Energy Diet
M	Mean
MAR	Missing at Random
MI	Modification Index
ML	Maximum Likelihood
MRC	Medical Research Council
MVPA	Moderate-to-Vigorous Physical Activity
N	Number of participants

NCD	Non communicable diseases
NFI	Normed Fit Index
OGTT	Oral Glucose Tolerance Test
PA	Physical Activity
PREMIT	The PREview behaviour Modification Intervention Toolbox
PREVIEW	Prevention of Diabetes Through Lifestyle Intervention and Population Studies in Europe and Around the World'
RCT	Randomised Controlled Trial
RMSEA	Root Mean Square Error of Approximation
RQ	Research Question
SCT	Social-Cognitive Theory
SD	Standard Deviation
S.E.	Standard Error
SDT	Self-determination Theory
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TLI	Tucker-Lewis index
TPB	Theory of Planned Behaviour
TTM	Transtheoretical Model

Abstract

Interventions aiming at increasing physical activity (PA) carry great potential to counteract lifestyle-related diseases such as type 2 diabetes mellitus. However, many interventions are only conducted in controlled settings without or only insufficient implementation into real-world settings ('research-to-practice gap'). In order to improve public health, such interventions need to be translated into practice and therefore examined in terms of their practical effectiveness. Knowledge about the underlying mechanisms of an intervention, i.e. how an intervention affects behavioural determinants and how these affect the desired behavioural outcomes, is essential to design or replicate effective real-world interventions. The aim of this study was to explore the translation of research into practice by evaluating the effectiveness of a complex theory- and evidence-based lifestyle intervention (PREMIT) implemented in the real world. Data of 1484 participants of a behaviour change intervention were analysed.

The behaviour change intervention PREMIT (PREview behaviour Modification Intervention Toolbox) was designed to support participants to maintain their initial weight loss in their natural living environment. Whereas the intervention was designed to improve participants' healthy eating and physical activity behaviours, this study focused on PA behaviour and its determinants. Physical activity behaviour was assessed by accelerometers. During clinical investigation days (CID), participants' body weight was registered and the participants filled in a battery of questionnaires with regard to social-cognitive and perceived environmental determinants (self-efficacy, expected benefits and expected disadvantages of physical activity, social support, temptations to be active). Analysis of Variance was used to investigate behavioural determinants' change between two clinical investigation days for participants rarely and participants regularly attending PREMIT sessions in order to gain insights into the effect of the intervention on behavioural determinants. Structural equation analysis was used to examine the influence of social-cognitive and perceived environmental determinants on physical activity, and the influence of PA behaviour on weight change. Furthermore, the interrelation between determinants was investigated.

Results showed that between CID 2 and CID 3 weight decreased for high attenders and increased for low attenders, suggesting PREMIT to be effective. Examination of the intervention mechanisms showed that the intervention did not influence all behavioural determinants and that not all behavioural determinants influenced PA behaviour. High attendance was associated with a decrease in temptations to be inactive and expected disadvantages of physical activity whereas low attenders showed an increase in temptations

and expected disadvantages. There were no differences between low and high attenders with regard to benefits of physical activity, self-efficacy, and social support. Results of the structural equation model showed that expected disadvantages as well as social support significantly influenced PA behaviour (fewer expected disadvantages and more social support led to increased PA behaviour). Expected benefits, self-efficacy, and temptations were not significantly associated with PA behaviour. Increased social support and increased self-efficacy were associated with fewer temptations. Outcome expectancies (benefits and disadvantages) influenced self-efficacy. Physical activity influenced weight change.

The results demonstrate that the PREMIT intervention was effective in a real-world setting and may therefore contribute to preventing and combatting the rising burden of T2DM and its related diseases. The analysis of the underlying mechanisms showed expected outcomes of PA behaviour and the social environment to be relevant components to consider in developing effective behaviour change interventions. As the hypothesised mechanisms could only partly be confirmed, further research into the exact mechanisms of interventions is needed. Furthermore, the extent to which the underlying mechanisms of interventions may be valid and effective on a community level needs to be examined in order to design large-scale interventions for people with prediabetes to have an impact on population health.

Zusammenfassung

Interventionen zur Förderung von körperlicher Aktivität haben großes Potential, lebensstilbedingte Erkrankungen wie beispielsweise Typ 2 Diabetes Mellitus vorzubeugen. Viele Interventionen finden jedoch nur unter den kontrollierten Bedingungen einer experimentellen Anordnung statt. Deren Ergebnisse werden nur selten oder unzureichend in die Praxis, in ein naturalistisches Setting „übersetzt“. Es entsteht ein „research-to-practice gap“. Um die Gesundheit der Bevölkerung zu verbessern, ist es jedoch notwendig, Interventionen erfolgreich in die Praxis/ Settings zu implementieren und die Wirksamkeit unter den Bedingungen eines naturalistischen Settings zu überprüfen. Kenntnis über die Wirkmechanismen einer Intervention, d.h. die Art und Weise wie eine Intervention Verhaltensdeterminanten beeinflusst und wie diese wiederum verhaltensbezogenen Ergebnisse beeinflussen, ist unverzichtbar um wirksame Interventionen zu entwickeln und zu replizieren. Um zu prüfen, ob Ergebnisse aus kontrollierten Settings in der Praxis wirken, untersucht die vorliegende Studie die Effektivität und die Wirkmechanismen einer theorie- und evidenzbasierten Verhaltensänderungsintervention (PREMIT) in einem naturalistischen Setting. Dazu werden Daten von 1.484 Teilnehmer/innen einer Verhaltensinterventions-Studie analysiert.

Mit der PREview behaviour Modification Intervention Toolbox (PREMIT) wurden die Interventionsteilnehmer/innen in ihrem Alltag bei einer Lebensstiländerung (gesunde Ernährung und körperliche Aktivität) mit dem Ziel unterstützt, eine zuvor provozierte Gewichtsreduktion zu stabilisieren. Die vorliegende Studie konzentriert sich auf das körperliche Aktivitätsverhalten und dessen Determinanten. Die Messung der körperlichen Aktivität erfolgte mit Hilfe von Akzelerometern. Das Körpergewicht wurde an regelmäßig stattfindenden Untersuchungstagen erfasst, an denen die Teilnehmer/innen auch Fragebögen zu sozial-kognitiven und Umweltvariablen (Selbstwirksamkeit, Handlungsergebniserwartungen (erwarteter Nutzen und erwartete Nachteile von körperlicher Aktivität), zur sozialen Unterstützung, zu Versuchungen inaktiv zu sein) bezüglich körperlicher Aktivität beantworteten. Varianzanalytisch wurde untersucht, ob sich die Verhaltensdeterminanten zwischen zwei Untersuchungstagen und zwischen Probanden/innen, die regelmäßig an PREMIT Gruppensitzungen teilnahmen und Probanden/innen, die selten an PREMIT-Gruppensitzungen teilnahmen, unterschieden, um damit den Einfluss der Intervention auf die Verhaltensdeterminanten zu beurteilen. Mittels Strukturgleichungsanalyse wurde überprüft, ob die Determinanten das Aktivitätsverhalten, sowie ob die körperliche

Aktivität das Körpergewicht beeinflusste. Außerdem wurden die Wechselbeziehungen zwischen den Verhaltensdeterminanten analysiert.

Die Ergebnisse zeigen, dass sich das Körpergewicht derjenigen, die oft an den PREMIT Gruppensitzungen teilnahmen, verringerte, während sich das Körpergewicht derjenigen, die selten an Gruppensitzungen teilnahmen, zunahm. Dies lässt eine wirksame Intervention vermuten. Die Untersuchung möglicher Wirkmechanismen zeigte, dass die Intervention nicht alle potentiellen Determinanten beeinflusste und dass nicht alle Determinanten das körperliche Aktivitätsverhalten beeinflussten. Eine regelmäßige Teilnahme an Interventionssitzungen war für „Verführungen inaktiv zu sein“ und „erwartete Nachteile körperlicher Aktivität“ mit einer positiven Veränderung zwischen beiden Untersuchungstagen assoziiert, d.h. diese verringerten sich, wohingegen sich die Ausprägung in beiden Determinanten bei denjenigen, die selten teilnahmen, erhöhten. Es gab keine Unterschiede in der „körperlichen Aktivität“, der „Selbstwirksamkeit“ und der „sozialen Unterstützung“ zwischen beiden Gruppen. Die Ergebnisse des Strukturgleichungsmodells zeigten einen signifikanten Einfluss der „erwarteten Nachteile von körperlicher Aktivität“ (je niedriger desto aktiver) und der „sozialen Unterstützung“ (je mehr Unterstützung desto aktiver) auf das Aktivitätsverhalten. Der „erwartete Nutzen von körperlicher Aktivität“, die „Verführung inaktiv zu sein“ und die „Selbstwirksamkeit“ waren nicht signifikant mit dem körperlichem Aktivitätsverhalten assoziiert. Mehr soziale Unterstützung und erhöhte Selbstwirksamkeit waren mit weniger „Verführung inaktiv zu sein“ assoziiert und „Handlungsergebniserwartungen (Nutzen und Nachteile)“ beeinflussten die Selbstwirksamkeit. Das Volumen der körperlichen Aktivität hatte Einfluss auf die Gewichtsveränderung.

PREMIT war in der Praxis/ im naturalistischen Setting effektiv und könnte damit einen Beitrag zur Prävention und Bekämpfung von Typ 2 Diabetes Mellitus und den Folgeerkrankungen auf Populationsebene leisten. Die Intervention zeigte, dass bei der Entwicklung effektiver Verhaltensinterventionen Handlungsergebniserwartungen und das soziale Umfeld als relevante Bausteine berücksichtigt werden sollten. Da die vorliegende Studie die der Intervention zugrunde gelegten Wirkmechanismen nur teilweise bestätigt, sollten detaillierte Wirkmechanismen von Interventionen in realen Lebenswelten weiter untersucht werden. Außerdem sollte untersucht werden, ob Lebensstilinterventionen auch in der täglichen Versorgungspraxis wirken. Wirksame Interventionen könnten großflächig für die Gruppe der Prä-Diabetiker umgesetzt werden, um deren Risiko für den T2DM zu minimieren (indizierte Prävention).

1 Short overview - Research topic and aim of this study

Due to the high and increasing global prevalence, its complications, and associated healthcare cost, type 2 diabetes mellitus (T2DM) constitutes a considerable public health burden (da Rocha Fernandes et al., 2016; N.C.D. Risk Factor Collaboration, 2016). Not only is type 2 diabetes associated with microvascular complications such as blindness, diabetes increases the risk for cardiovascular diseases and all-cause mortality. The most important risk factors for T2DM are behavioural: physical inactivity and an unhealthy diet. Although extensive efforts have been devoted to the prevention of T2DM by changing risk behaviour (Uusitupa et al., 2019), its incidence continues to increase (Guariguata et al., 2014). Why have these efforts failed to produce positive results in terms of constant or decreasing incidence rates?

There is evidence that behavioural interventions aiming to promote physical activity and a healthy diet leading to body weight loss and weight maintenance were both clinically effective and cost-effective in reducing the incidence of T2DM (Alouki, Delisle, Bermudez-Tamayo, & Johri, 2016; Diabetes Prevention Program Research Group, 2002; Gillett et al., 2012; Lindstrom et al., 2003; Png & Yoong, 2014). However, systematic reviews and meta-analyses evaluating the effectiveness of lifestyle interventions on weight loss and weight maintenance have shown heterogeneous results and often only modest success (e.g. Conn, Hafdahl, & Mehr, 2011; Dombrowski, Knittle, Avenell, Araujo-Soares, & Sniehotta, 2014; Terranova, Brakenridge, Lawler, Eakin, & Reeves, 2015).

Designing or replicating effective intervention requires the understanding of intervention mechanisms, i.e. how an intervention works to achieve its goals. Evaluating interventions, however, can be challenging, as many lifestyle interventions are considered complex, integrating a number of interacting intervention components regarding intervention planning, implementation, investment in resources and the target group (Campbell et al., 2000; Craig et al., 2008; Moore et al., 2015). Therefore, insufficient knowledge about intervention mechanisms may be a barrier for designing effective interventions to combat diseases associated with behavioural risk factors. Furthermore, in general, poor description of interventions makes it difficult to not only know what components and behavioural strategies were addressed as part of the intervention, but also to understand intervention mechanisms and design effective interventions. This may be a reason why efforts to combat the rising number of diabetes cases have not been fruitful.

Furthermore, even though behaviour change interventions in type 2 diabetes prevention such as the US Diabetes Prevention Study (DPP) (Diabetes Prevention Program Research Group, 2002), the Finnish Diabetes Prevention Study (Lindstrom et al., 2003) and the China Diabetes Prevention Study (Pan et al., 1997) have shown beneficial changes in diet and physical activity, concerns have been raised that evidence-based interventions are poorly implemented into clinical practice, especially after an intensive research phase to examine their efficacy (Glasgow, Lichtenstein, & Marcus, 2003). Translating research into practice is assumed to happen along a research-to practice continuum, which describes how a scientific endeavour has an impact on public health. Whereas efficacy trials are conducted under controlled conditions, effectiveness studies move from the controlled conditions further along the research-to-practice continuum into a real-world environment (Gitlin & Czaja, 2015). This translation of evidence-based interventions into real-world settings still remains a challenge.

In the context of T2DM prevention, the results of efficacy trials need to be translated into the real world in order to decrease the increasing number of people with T2DM cases worldwide. The PREview behaviour Modification Intervention Toolbox (PREMIT) was developed as part of an T2DM prevention trial (PREVIEW - Prevention of Diabetes Through Lifestyle Intervention and Population Studies in Europe and Around the World) to support participants through physical activity and diet behaviour changes in their natural environment in order to maintain an initially required weight loss. The main aim of the PREVIEW randomised controlled trial was to identify the most efficient dietary and exercise strategy for the prevention of diabetes in participants with prediabetes in eight different centres around the world. As a theory-and evidence-based behaviour modification program the PREMIT intervention used a stage-based approach to support the participants with their lifestyle changes. The challenge of the PREMIT behaviour modification intervention was to offer flexible support for participants in a real-world setting while ensuring that new health behaviours become self-regulating. The main mechanism of supporting behaviour change within the PREMIT intervention was by influencing behavioural determinants or mechanisms. As these terms (determinants and mechanisms) are used differently, they are defined for purposes of this study in later sections (see chapter 3 and 4.1). PREMIT could be adapted to different situations and target populations (for detailed information about PREMIT see Kahlert et al., 2016).

Although PREMIT addresses dietary and physical activity behaviour and their determinants, this study concentrates on the role of behavioural determinants, i.e. self-efficacy, outcome expectancies (expected benefits and disadvantages), social support, and temptations,

and their influence on PA behaviour and weight regulation. The focus on physical activity was chosen because physical activity has been found to be important during weight maintenance (cf. Fogelholm & Kukkonen-Harjula, 2000).

Nevertheless, evidence related to PA determinants of weight control is inconsistent (Teixeira et al., 2015; Teixeira, Going, Sardinha, & Lohman, 2005) and less studied than the influence of dietary factors on weight. In this study, data from two stages – the preparation and action stages of the PREMIT intervention – were used. During these stages, participants were expected to actively change their PA behaviour.

Due to the high and increasing number of people with T2DM and the considerable potential for prevention of T2DM through lifestyle changes (Lean et al., 2019), the focus of this study was the prevention of T2DM among high-risk individuals with prediabetes, a condition preceding T2DM.

Being theory- and evidence-based and implemented into the real world, the PREMIT intervention was suitable to describe and later test underlying intervention mechanisms in the real world (e.g. Campbell et al., 2000; Moore et al., 2015). Thus, this study aims to support the translation of an intervention from a research setting into real-world clinical practice; PREMIT's effectiveness was examined. Firstly, it was examined whether theory- and evidence-based determinants were associated with physical activity behaviour change. Secondly, this study evaluated whether adherence to the PREMIT intervention was associated with changes in behavioural determinants as expected. It must be noted that the term PREMIT's 'effectiveness' in this study only applies to the preparation and action stages of PREMIT, i.e. the stages that are analysed here.

This study adds to the research on translating research into practice (often called translational or implementation research) and may encourage stakeholders to implement interventions on community level to improve population health.

2 Diabetes mellitus

Diabetes mellitus is one of the four main non-communicable diseases and a leading cause of mortality and disability worldwide. Globally, the number of people with type 2 diabetes mellitus has more than doubled over the past three decades and still continues to increase (L. Chen, Magliano, & Zimmet, 2011; N.C.D. Risk Factor Collaboration, 2016). Whereas in 2017 approximately 425 million adults worldwide suffered from diabetes, this number is expected to increase to 629 million adults by the year 2045 (International Diabetes Federation, 2017). The number of people with prediabetes, a pre-cursor of T2DM characterised by impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT), has also shown an increasing trend (Mainous, Tanner, Baker, Zayas, & Harle, 2014), and the number of people with impaired glucose tolerance (over 350 million in 2017) is projected to increase to 587 million by 2045 (International Diabetes Federation, 2017). People with prediabetes have a higher risk of developing diabetes – per year, 5-10% of people with prediabetes develop diabetes (Tabak, Herder, Rathmann, Brunner, & Kivimäki, 2012). In Germany, the lifetime prevalence of diabetes is 7.2% in the adult population (18-79 years) (Heidemann, Du, Schubert, Rathmann, & Scheidt-Nave, 2013), whereas it is higher among older age groups with about 22% of those 70 years or older and below 5% in younger age groups. The prevalence of prediabetes among the German population is about 20% and another 2% of the population are estimated to have undetected diabetes (Heidemann et al., 2015).

Two main types of diabetes mellitus exist, type 1 diabetes mellitus (T1DM) and T2DM. Another type worth mentioning is gestational diabetes, a glucose intolerance first diagnosed during pregnancy and not reaching the cut-off values for manifest diabetes (American Diabetes Association, 2016). Gestational diabetes usually disappears after pregnancy, but should still be treated because it is associated with an increased risk for complication during pregnancy and childbirth (Crowther et al., 2005; The Hapo Study Cooperative Research Group, 2008), and increases the chances of getting T2DM. The prevalence of other specific types is rather low (1-3%) (International Diabetes Federation, 2017).

Type 1 diabetes mellitus is usually caused by autoimmune reactions that destroy the insulin-producing cells (β -cells) of the pancreas (Todd, 2010). Therefore, people with type 1 diabetes secrete only little or no insulin and need to rely on insulin injections. Research has shown that heredity is associated with increased risk to develop T1DM (Hämäläinen & Knip, 2002), but more detailed research into how genetic variations and other risk factors affect disease progression is needed.

The majority of people with diabetes (about 90 - 95%), however, suffer from T2DM. The exact aetiology of T2DM is not known, but defective insulin secretion by the β -cells of the pancreas usually related to insulin resistance is at the core of T2DM development (Skyler et al., 2017). T2DM usually develops slowly over time, starts with decreased insulin sensitivity, and may often go unnoticed. Although genetic factors have a role in the development of the T2DM, the most important risk factors for developing T2DM are overweight/obesity, physical inactivity and an unhealthy diet (Hill et al., 2013; F. B. Hu, 2011) whereas the latter two are also the most proximal behavioural determinants of weight control. Furthermore, the risk for developing diabetes increases with age and diabetes occurs more frequently in women who have suffered from gestational diabetes previously and in certain ethnic groups such as those of south Asian descent (Kanaya et al., 2014) or African American blacks (Holmes, Hossain, Ward, & Opara, 2012). Whereas the highest prevalence of T2DM is among older people, the age of onset has been decreasing (Koopman, Mainous, Diaz, & Geesey, 2005).

Diabetes is associated with an increased risk of a variety of macrovascular and microvascular complications. The risk for a cardiovascular disease such as coronary heart disease or cerebrovascular disease is two to three times higher in diabetes patients (International Diabetes Federation, 2017). Furthermore, microvascular complications such as nephropathy, retinopathy and neuropathy are common among diabetes patients, causing end-stage renal disease, blindness and amputations. Furthermore, diabetes has been associated with increased risk for depression (S. Chen et al., 2016; Roy & Lloyd, 2012). Mortality due to diabetes accounted for approximately 11% of global all-cause mortality in 2017 (International Diabetes Federation, 2017). Consequences of prediabetes (macrovascular and microvascular) appear to be similar to these of diabetes itself (Bansal, 2015). People with prediabetes have an increased risk for cardiovascular events and all-cause mortality (Huang, Cai, Mai, Li, & Hu, 2016).

Not only due to the treatment of T2DM itself, but also due its co-morbidities, diabetes is associated with increased healthcare costs and therefore constitutes an important public health challenge worldwide. Globally, healthcare expenditure on diabetes was 727 billion USD in 2017, an increase of 8% from the year 2015, expecting to rise to 776 billion USD by 2045 (International Diabetes Federation, 2017). Additionally, a great amount of healthcare costs arises for diabetes-related complications, i.e. indirect costs (cf. Alva, Gray, Mihaylova, Leal, & Holman, 2015). Globally, direct and indirect costs were estimated to 1.3 trillion USD in 2015 (Bommer et al., 2017). Healthcare costs directly related to T2DM in Germany were approximately 28.4 billion euros (Jacobs et al., 2017), and are the second highest costs related

to diabetes in Europe (International Diabetes Federation, 2017). Indirect costs are estimated to be even higher than direct costs of T2DM (Ulrich et al., 2016). There is also evidence that people with diabetes who do not engage in physical activity have higher healthcare cost than those being physically active (Codogno, Fernandes, Sarti, Freitas Júnior, & Monteiro, 2011).

Diabetes risk can be reduced by lifestyle interventions and other preventive measures such as medication. A healthy lifestyle (including a healthy diet and regular physical activity) not only helps to prevent diabetes but also is important for those who already suffer from diabetes as it positively influences blood glucose regulation and therewith helps to prevent concomitant diseases and complications. Among adults, weight loss has been shown to be a successful strategy in diabetes prevention (Feldman et al., 2017). Research has indicated that individuals with diabetes and prediabetes can reduce the risk or delay the onset of T2DM by changing their lifestyle and reducing their body weight (Walker, O’Dea, Gomez, Girgis, & Colagiuri, 2010). Whereas physical activity supports weight loss, physical activity is associated with benefits such as improved insulin sensitivity (e.g. Johnson & George, 2010; Knowler et al., 2002; Laaksonen et al., 2005) independent of weight loss. It also has positive effects on cardiovascular fitness and on blood lipid profiles, protecting against cardiovascular disease. It has been shown that regular physical activity of all types reduces the risk of T2DM (Aune, Norat, Leitzmann, Tonstad, & Vatten, 2015). Furthermore, diets high in protein and with low glycaemic index seem beneficial for the prevention of T2DM (Ajala, English, & Pinkney, 2013; Buyken, Mitchell, Ceriello, & Brand-Miller, 2010).

Even though studies show positive outcomes of successful behavioural interventions, changing one’s lifestyle is complex and challenging and systematic reviews about lifestyle interventions among adults with diabetes have shown only modest success (Terranova et al., 2015). Most people trying to lose weight do not lose more than 5% of their body weight in a period of 12 months or more (Franz, Boucher, Rutten-Ramos, & VanWormer, 2015). Especially weight loss maintenance (MacLean et al., 2015), i.e. achieving permanent lifestyle changes can be challenging (Conner & Norman, 2017) and relapses to old behaviours are common (Avenell et al., 2004; Song, Huttunen-Lenz, & Holland, 2010; Wing & Phelan, 2005). Research has identified different barriers and facilitators of behaviour change (S. Kelly et al., 2016).

3 Barriers and facilitators in achieving lifestyle changes

Health behaviour change and especially health behaviour maintenance is difficult to achieve. Many people struggle to stop smoking or lose weight even though they want to change their behaviour. Kelly et al. (M. P. Kelly & Barker, 2016) have summarised six reasons related to the difficulty of behaviour change. Challenges relate to both individuals trying to change their behaviours as well those encouraging others to change their behaviours.

Two of the reasons Kelly & Barker (2016) name as difficulties in behaviour change are that people act neither (1) rationally nor (2) irrationally. First, it has been assumed by theories such as the expected utility theory (Edwards, 1954) that behaviour is driven by rational decisions and by purposeful actions to maximise utility. However, people may not always act in favour of their own maximised utility. This may be caused by emotions such as fear or anger. Indeed, especially eating behaviour and PA behaviour may be influenced by emotions or other affective states and – on the other hand – may contribute to the regulation of emotions or coping with stress (cf. Adam & Epel, 2007). For example, negative emotions may lead to increased eating, called ‘emotional eating’ (Newman, O'Connor, & Conner, 2007). Stress may constitute both as a barrier or facilitator of physical activity, depending whether the individual perceives it as a coping mechanism with stress or as an extra task to be done increasing stress (Stults-Kolehmainen & Sinha, 2014). Positive emotions associated with being physically active may constitute a facilitator to behaviour change (cf. Liao, Shonkoff, & Dunton, 2015).

Furthermore, in everyday life, habitual behaviour is common (Wood, Quinn, & Kashy, 2002). Habitual behaviour as well as previous life experiences has been identified as a barrier to behaviour change (Følling, Solbjør, & Helvik, 2015). Thurn (2014) has defined habitual PA behaviour as a learned disposition to repeat physical activity due to certain situational context-specific stimuli, meaning that it can be initiated without conscious planning or intention. Physical activity can be initiated automatically. The fact that habitual behaviour is deeply implemented into day-to-day routines makes behaviour change especially difficult, because automatic reaction to cues usually overrules conscious motivation (Gardner, 2015). Brand & Ekkekakis (2018) in their Affective-Reflective Theory also emphasise the role of automatic associations of a stimulus and the affective evaluation thereof in explaining why people initiate behaviour change or not.

The fact that habits are initiated by situational or environmental cues shows that behaviour is determined by a variety and interplay of different personal and environmental factors. People live and behave in a complex environment and their behaviour is not only determined by personal factors. Moreover, it is impacted by the broader social, cultural and policy context in

which a person lives. Thus, even when people are highly motivated to change certain behaviour such as physical activity, environmental pressures, time constraints or financial constraints for example may pose barriers to behaviour change (S. Kelly et al., 2016). Likewise, a lack of social support is often seen as a barrier to behaviour change (Murray, Craigs, Hill, Honey, & House, 2012). Thus, behaviour change is a complex endeavour in a complex environment.

Second, the same way that people do not act rationally, their behaviour is not completely irrational. The same behaviour may seem rational to some people but irrational to others. Kelly and Barker (M. P. Kelly & Barker, 2016) refer to an example: smoking is an irrational behaviour from a health promotion point of view as it is associated with severe health consequences. However, even people with little financial resources still somehow find money to buy cigarettes and smoke. When they were asked for the reason, they responded that this behaviour was something that they could do completely for themselves. Hence, from a different point of view, i.e. following the person's own reasoning, this behaviour would make sense as such behaviour may fulfil a function for the actor. This is often not obvious for external parties. Therefore, interventions designed by external parties may not take into account what role certain behaviour plays for individuals in their daily lives, thus rendering interventions ineffective (a similar debate can be found in Kühn in the context of healthism).

Third, the failure to see behaviour as a complex endeavour while assuming that behaviour follows a linear process that does not need to be studied thoroughly is another common error in science. This misunderstanding leads to assumptions that behaviour can be influenced by common sense interventions. The results lead to development of ineffective interventions (M. P. Kelly & Barker, 2016). Behaviours happen in the real world, i.e. an environment in which behaviour is influenced by an interplay of multiple personal, interpersonal and environmental factors that often cannot be controlled.

Fourth, it is often falsely assumed that knowledge itself may cause behaviour change. Fifth, it is often likewise assumed that messages just need to be shaped correctly, thus implying that individuals who have understood the message would consequently successfully change their behaviour (M. P. Kelly & Barker, 2016). There is much more to changing behaviour than just knowledge transfer and choosing appropriate communication with the target population. The success of health campaigns such as for reducing tobacco use is not based solely on information about the toxic effects of nicotine made available to the individuals. The most successful campaigns include intervention components on different levels with different features, such as school programs, price policy, or control over advertising; all of these contributed to this success (Lee, 2011).

The last common error listed by Kelly & Barker (2016) states that behaviour can be predicted accurately. If that was the case, the obesity epidemic for example, caused by behavioural risk factors, would have already been stopped. Rather, the complexity and exact behavioural determination has not been identified yet. How to design effective interventions is not fully understood.

When barriers and facilitators of behaviour are understood, such as what motivates people and how external pressures can be addressed, interventions can be designed accordingly. How can this information be retrieved? A promising way could be to look at theories. In order to understand different behaviours and behavioural change, research has used theories to identify determinants of behaviour and behaviour change and to specify the pathways by which behaviours could be successfully influenced (cf. Michie, West, Campbell, Brown, & Gainforth, 2014). Behavioural determinants refer to the underlying factors (barriers and facilitators) that affect behaviour and behaviour change, i.e. determinants that influence the probability of performing specific behaviours.

Within the frame of behavioural research the term ‘determinant’ is often used interchangeably with terms such as ‘correlates’, ‘factors’, ‘predictors’, ‘associates’, ‘underlying behavioural processes’, ‘antecedents of behaviour’, ‘theoretical mechanisms of change’, ‘causal mechanisms’ (Michie, 2008; Michie, Johnston, Francis, Hardeman, & Eccles, 2008), or ‘theoretical mechanisms of action’ (Carey et al., 2018; Davis, Campbell, Hildon, Hobbs, & Michie, 2015; Michie, West, Sheals, & Godinho, 2018). Whereas some of these terms imply causality, others do not (cf. Bauman, Sallis, Dzewaltowski, & Owen, 2002). It is presumed that most studies using the term ‘determinant’ have not fulfilled all criteria of causality and may therefore often misuse the term ‘determinant’ in its original sense. Being aware of this misuse, in this study, the term ‘determinant’ or ‘behavioural determinant’ is used and is defined as factors influencing behaviour. i.e. processes through which certain activities/ behaviour change techniques (BCT) influence behaviour. It relates to associations rather than to causality. Behavioural determinants and their interrelations are addressed in detail in the following.

3.1 Health-specific determinants of behaviour

Behavioural scientists have developed theories to understand behaviour and behaviour change. In health psychology, two major types of theory to explain health behaviour have developed. Continuum theories such as the social-cognitive theory (SCT) or the theory of planned behaviour (TPB), and stage theories such as the transtheoretical model (TTM) or the

health action process approach (HAPA). Continuum theories explain how behaviour is the result of what motivates people to perform a certain behaviour, how intentions are built and how behaviour is regulated towards maintaining the behaviour. Stage models differentiate between qualitatively different stages that people pass through from recognising a risky behaviour to having made the new behaviour a habit (Schlicht & Zinsmeister, 2015).

Theories suggest a variety of determinants to explain behaviour change. There are certain determinants that are relevant in both continuum and stage theories, such as self-efficacy or outcome expectancies. However, whereas continuum theories often mainly address intention, post-intentional, volitional processes should also be taken into account when looking at behavioural determination. Such processes include self-control and self-regulatory processes. ‘Self-control or self-regulation is defined as the capacity to override natural and automatic tendencies, desires, or behaviours; to pursue long-term goals, even at the expense of short-term attractions...’ (Vohs & Baumeister, 2013, p. 65). Thus, self-regulatory activities help to adhere to set goals and resist temptations. Temptations represent a motivational state, i.e. the immediate pleasurable desire or impulse to engage in a specific behaviour (that is seen as beneficial in the short-term) and can be distinguished from goals, which are higher-order motives and important in the long run (cf. Fishbach & Converse, 2010). Temptations often disrupt an individual’s ability to pursue more valued but temporally delayed goals. For example, being tempted to sit down and watch television disrupts the higher-order goal of weight loss by meeting the physical activity recommendations.

In order to understand behaviour and design effective interventions for complex behaviours, there is a need to look beyond current social-cognitive theories and include environmental factors such as the social, built or natural environment (cf. Buchan, Ollis, Thomas, & Baker, 2012; Cortis et al., 2017). Physical activity levels have been associated with different environmental factors, such as aesthetics, safety, or perceived availability of physical activity facilities (Humpel, Owen, & Leslie, 2002; Trost, Owen, Bauman, Sallis, & Brown, 2002). Furthermore, social support for physical activity has been associated with PA behaviour (Wendel-Vos, Droomers, Kremers, Brug, & van Lenthe, 2007). Social support can influence individuals’ health behaviour in a way that other people’s goals or habits can influence one’s own behaviour in different ways. Meeting friends after work may foster activities such as drinking alcohol, smoking cigarettes, and sitting that negatively influence our health. On the other hand, social support from doctors, friends and family has shown to positively influence health behaviour. Intervention studies show promising results with regard to social support for

increasing physical activity (cf. Knoll, Scholz, & Rieckmann, 2017). Still, more evidence is needed on how social environmental factors influence physical activity (cf. Prince et al., 2016).

As interventions targeting individuals have not been able to control the obesity epidemic and its consequences such as T2DM, socio-ecological approaches are more and more emphasised and commonly applied to guide the research into behavioural determination and intervention design. According to socio-ecological models (cf. Bronfenbrenner, 1977; Glass & McAtee, 2006; Stokols, 1992), behaviour is determined by a reciprocal interaction of the person and the environment integrating multiple factors on different levels, e.g. psychological, social, policy and environmental (Davis et al., 2015). Health supportive environments combined with strategies to motivate the individual to adopt a healthy behaviour are likely to be most effective in achieving healthy behaviours (Ottawa Charter for Health Promotion, 1986). Especially physical activity and dietary behaviour is affected by a system of interrelating social, political, economic and individual factors, such as the food and drink environment and opportunities for physical activity (e.g. Butland et al.). In order to design effective interventions, using behaviour-specific ecological models is proposed to be most effective (Sallis, Owen, & Fisher, 2015). For example, Sallis et al. (2006) have developed an ecological model with four domains of physical activity, structured as an onion. The domains represent different levels of influences such as intrapersonal factors, the perceived environment, behavioural settings and access characteristics, the sociocultural environment (cutting across the other levels), the policy environment, the natural environment, and the information environment.

Within this context, the question arises how the environment may influence behaviour. The actor network theory (ANT), primarily developed by Latour (2007), denotes things as well as humans as actants (Kneer & Schroer, 2009). Within the actor network theory, actions are the results of the interaction between actants, i.e. between the environment and humans (Schlicht, 2017). Therewith, this view rejects the belief that an action is solely controlled by the consciousness and intention of a human being (Kneer & Schroer, 2009). Gibson (2015) suggest a reciprocal, functional relationship between environment and behaviour. He introduced the concept of 'affordances'. Affordances are action opportunities with an inviting character that emanate from objects or environments. For example, a chair *affords* sitting. Such affordances are always present but are not always utilised. As affordances represent the functional relationship between an individual and the environment, the same object can afford different behaviour in different people or different behaviour of the same individual at different times. When an observer has a certain need, he '...may attend to the affordance...' (Gibson,

2015, p. 130) whereas when this need is not present, the affordance is not followed by an action. It has been proposed that affordances can invite behaviour if an affordance is perceived (Withagen, de Poel, Araújo, & Pepping, 2012). Withagen et al. (2012) suggest that the perceived inviting character of an affordance depends on the individual-environment relationship. Whereas much research remains to be done in this field, the authors suggest a variety of factors that may determine whether or not an affordance invites or repels behaviour, such as an individual's capabilities (cf. Rietveld & Kiverstein, 2014). For example, urban environments (high buildings, fences, stairs etc.) may hinder most people from being physically active, while such urban environments may afford others, specifically parkour practitioners to be physically active. Thus, affordances may help to change PA behaviour (Davids, Araújo, & Brymer, 2016).

Sometimes the exact differentiation between social-cognitive and perceived environmental components in behavioural determination is challenging. Some variables may easily be classified into social-cognitive or environmental; for example, the existence of cycling paths is clearly an environmental variable. However, other variables may not be as easily classified, as they may not always be measured as purely social-cognitive or environmental. Rather, in their assessment they may include a social-cognitive and an environmental 'component'. For example, the construct of temptation/s may be assessed by asking how tempted someone is to eat unhealthily when passing a fast-food restaurant, or, how tempted someone is to be inactive, when in employment and having less time at their disposal. The answer given to such questions may result from a person-environment (person x environment) interaction itself. The perception of being tempted by the environment (fast-food restaurant) may already be influenced by personal self-regulatory strategies and preferences. Someone who is able to apply self-regulatory strategies in such situations may not be as tempted as someone who has not learnt/ does not apply self-regulatory strategies. However, the actual pure environmental temptation (i.e. existence of the fast food restaurant) may have been the same for both before person x environment interaction took place. Similar assumptions can be made for other 'traditional' social-cognitive variables such as self-efficacy. Self-efficacy feeds on the environment through environmental sources that enhance or impede self-efficacy. This shows that a person x environment interaction can be represented in a measured variable itself and therefore the prerequisite of person x environment interaction of ecological models may be met on variable level already.

In this study, there is no explicit differentiation between pure environmental and pure social-cognitive determinants, but rather some investigated constructs may represent the person

x environment interaction. To be in line with common scientific language, this study refers to self-efficacy and outcome expectancies as social-cognitive variables and to social support and temptations as perceived environmental variables.

3.2 *Determinants of physical activity*

Physical activity behaviour is an important factor during weight maintenance (Jakicic, 2002) and in terms of positively influencing glycaemic control (Seib et al., 2018). As with general health behaviour, the SCT, the TPB, the SDT and the TTM have frequently been applied to understand the determinants of PA behaviour and to design effective interventions (cf. Buchan et al., 2012). Comparing the utility of these theories in predicting physical activity in adults with type 2 diabetes, Plotnikoff, Lubans, Penfold and Courneya (Plotnikoff, Lubans, Penfold, & Courneya, 2014) have found no predictive advantage of one over the other, but rather recommend the integration of theory across social-cognitive models.

In scientific literature, commonly cited determinants of physical activity are among others: self-efficacy, social support, intention and outcome expectancy (Bauman et al., 2012; Choi, Lee, Lee, Kang, & Choi, 2017; Delahanty et al., 2013; Koeneman, Verheijden, Chinapaw, & Hopman-Rock, 2011; Prince et al., 2016; Trost et al., 2002; van Stralen, De Vries, Mudde, Bolman, & Lechner, 2009). Evidence is inconclusive, often due to insufficiently detailed definitions of the determinants and/or the lack of integrating such determinants into a larger framework (cf. Cortis et al., 2017). However, self-efficacy (Bandura, 1977, 1986, 1996) defined as an individual's belief to be able to perform a certain behaviour seems to be the most influential determinant of physical activity (Choi et al., 2017). The relationship between physical activity and outcome expectancies, and social support has been shown to be probable (Bauman et al., 2012; Choi et al., 2017).

Self-efficacy and outcome expectancies can be found as constructs in different theories, such as the TPB (Ajzen, 1991), the SCT (Bandura, 1998) or the transtheoretical model (Prochaska & Velicer, 1997), but their causal interrelation has recently been discussed differently (see chapter 3.2.5). Outcome expectancies in the SCT match the cognitive dimension of attitude in the TPB and the decisional balance in the TTM (D. M. Williams, Anderson, & Winett, 2005). Furthermore, subjective norm (TPB) can be referred to as '...expected social outcomes for given styles of behaviour' (Bandura, 1998). Perceived behavioural control (TPB) is compatible with self-efficacy in the SCT or TTM (cf. Noar & Zimmerman, 2005). Most social-cognitive theories also include some component of environmental influences such as social support, which have been found to be of great influence

in predicting and changing behaviour (Glanz, 2015; Kwasnicka, Dombrowski, White, & Sniehotta, 2016; McNeill, Kreuter, & Subramanian, 2006), especially in the area of physical activity (Bauman et al., 2012). The SCT states that self-efficacy stems not only from personal but also from environmental factors such as social support. In the TPB, subjective norm includes a social component as it has usually been referred to as ‘perceived social pressure to perform or not perform...’ (Ajzen, 1991, p. 188) certain behaviours. However, there may be other types of social influences such as the behaviour of others that affect individuals’ own behaviours. Many studies have also found social support to positively influence PA behaviour (Cradock et al., 2017; N. Hankonen et al., 2015; Wendel-Vos et al., 2007).

As can be seen, different models include essentially similar or the same determinants with different names (cf. Bandura, 2004). It may therefore not be desirable to include as many determinants as possible, but rather to integrate evidence-based determinants for a specific behaviour into a general model and to examine their relative importance for a specific health behaviour and target group (cf. Maddux, Brawley, & Boykin, 1995). For PA behaviour, the exact mechanisms leading to regular physical activity are not known and more research is needed on how social-cognitive variables interrelate with each other and how they act together with perceived environmental variables to enhance regular PA behaviour.

3.2.1 Self-efficacy

The concept of self-efficacy was introduced in Banduras SCT (Bandura, 1977, 1986). Bandura hypothesised that self-efficacy influences the initiation of action towards certain behaviour and determines how much effort and time will be invested in case barriers/obstacles are encountered. The higher someone’s perceived self-efficacy, the higher his/her confidence in successfully achieving a task and resisting temptations, and using skills and resources to meet the situational demands (Conner & Norman, 2005).

Bandura (1977) defines four sources of self-efficacy that can enhance or impede self-efficacy. First, mastery experience: self-efficacy beliefs can be enhanced by feelings of accomplishment and reduced by feelings of failure, as far as success or failure is attributed internally. Second, experiencing another person, someone who the individual feels is similar to him/herself, accomplishing certain behaviour or mastering a difficult situation may enhance one’s own self-efficacy through social comparison processes. Likewise, seeing someone similar to fail at a task may decrease self-efficacy (vicarious experience). Third, behaviour can directly be encouraged or discouraged by verbal persuasion. Fourth, emotional arousal influences self-efficacy: when emotionally aroused, an individual may feel either less or more

capable of accomplishing a certain behaviour. Positive emotions may cause higher performance whereas negative emotions may lead to failure. Warner et al. (2014) have examined the sources of self-efficacy for physical activity in community-dwelling older adults in Germany and found that especially mastery, self-persuasion and reduction in negative affective states were the most important predictors for physical activity. Numerous studies (Choi et al., 2017; McAuley & Blissmer, 2000) found self-efficacy to be the strongest correlate of physical activity. However, inconsistent findings exist (Choi et al., 2017; Cortis et al., 2017) and it is necessary to investigate the influence of self-efficacy on physical activity in a framework with other social-cognitive and perceived environmental determinants.

3.2.2 *Outcome expectancies*

Outcome expectancy is a central determinant of Bandura's SCT and represents the outcomes that an individual expects when a specific behaviour has been performed (Bandura, 1986); for example, someone expecting to no longer have weight problems as a result of being physically active on a regular basis. Such expectancies (positive or negative ones) may hinder or facilitate certain behaviour. Expected consequences of a behaviour can be categorised into three domains: physical outcome expectancies, social outcome expectancies, and evaluative outcome expectancies. Furthermore, they can be categorised into short-/ long-term outcome expectancies and positive/negative outcome expectancies (Conner & Norman, 2015). Physical outcome expectancies refer to physical symptoms as a consequence of performing behaviour, such as knee pain from running (negative outcome expectancies – short-term) or weight loss (positive outcome expectancies – long-term). Social outcome expectancies deal with social responses evoked by a specific behaviour such as approval or disapproval (Kelder, Hoelscher, & Perry, 2015). Engaging in physical activity for example may be approved by family and friends for being healthier and looking fitter (Kelder et al., 2015). Evaluative outcome expectancies take into account an individual's internal standards. In evaluative outcome expectancies feelings are anticipated that arise from comparing the behaviour to internal standards, e.g. a student may anticipate a feeling of joy when receiving a good grade. Students with different internal standards, such as those whose peer group devaluates academic achievement, may anticipate negative feelings when receiving a good grade (Kelder et al., 2015).

Outcome expectancies have shown to influence physical activity in various studies (Choi et al., 2017) and seem to be especially important in the first stages of behaviour initiation (van Stralen et al., 2009). Different studies (Anderson-Bill, Winett, & Wojcik, 2011; K. E. Williams & Bond, 2002) found a relation between positive outcome expectancies and physical

activity while negative outcome expectancies seemed to be less predictive behaviour. Other studies examining the influence of self-efficacy, outcome expectancies, self-regulation and social support did not find a direct influence of outcome expectancies on physical activity (E. S. Anderson, Winett, Wojcik, & Williams, 2010; E. S. Anderson, Wojcik, Winett, & Williams, 2006; Young, Plotnikoff, Collins, Callister, & Morgan, 2014, 2016). Contradictive findings show the need to further study outcome expectancies for explaining and predicting physical activity especially in a framework including self-efficacy and environmental factors (cf. D. M. Williams et al., 2005).

3.2.3 *Temptations*

Temptation is a construct within the Transtheoretical Model (Prochaska & Velicer, 1997). The TTM has been applied to physical activity and exercise research (Marshall & Biddle, 2001) and hypothesises that individuals move through different stages: pre-contemplation, contemplation, preparation, action, and maintenance, which represent sequential stages of behaviour change. Some TTM versions include a termination stage where the individual has permanently adopted the new behaviour. However, this stage has received little empirical attention (Conner & Norman, 2015). At the beginning, there is no intention for behaviour change (pre-contemplation), followed by deciding upon a behavioural change (contemplation), i.e. having the intention to regularly engage in a behaviour. In the preparation stage, individuals have started the behaviour, but their behaviour is not consistent while during the action stage, individuals regularly perform the behaviour. When such changes continue for six or more consecutive months, a person is classified to be in the maintenance stage. Finally, individuals are said to be in the termination stage when they have maintained their behaviour for more than 5 years and have no temptation to engage in the undesired behaviour and have full self-efficacy to engage in the desired behaviour (Prochaska & Velicer, 1997). However, within the framework of the TTM it is assumed that in the maintenance stage, people experience full self-efficacy and zero temptations. This cut-off value (100% self-efficacy versus 0% temptation) had been developed for the cessation of negative health behaviours such as to stop smoking, and may need to be modified for positive behaviours such as engaging in physical activity (Fallon & Hausenblas, 2003). Not to have any temptations not to exercise may not be realistic and temptations may remain even in individuals maintaining behaviour.

In TTM people are thought to move forwards through the stages, but they may relapse to earlier stages (Prochaska & Velicer, 1997). The following constructs are used to move between the stages of behavioural change: temptations, self-efficacy, decisional balance, and

processes of change. Within the area of physical activity, temptation not to exercise refers the urge or desire to not engage in physical activity across different challenging situations. The degree and frequency of temptations is associated with higher likelihood to fall back into old behaviour (Hausenblas et al., 2001). Furthermore, temptation is found to be inversely associated with self-efficacy (the situation-specific confidence to be able to handle difficult situations without falling back into old habits, see chapter 3.2.1) across the stages of change (Hausenblas et al., 2001). Temptation is highest in the earlier stages and lowest in the later stages with equal levels of temptation and self-efficacy in the preparation or action stages (Hausenblas et al., 2001; Prochaska & Velicer, 1997). Even though the TTM has been applied to study PA behaviour, temptations have rarely been studied within the context of physical activity and only in 2001 Hausenblas et al. (2001) developed a scale to measure temptations not to exercise. Furthermore, temptation has mostly been studied in later stages of behaviour change (Fallon, Hausenblas, & Nigg, 2005). ‘Decisional balance’ refers to evaluating the behaviour in terms of pros and cons of the behaviour and can be compared to outcome expectancies (Noar & Zimmerman, 2005). The dimension ‘processes of change’ helps to understand how shifts in behaviour occur. Ten processes, i.e. activities and experiences that people engage in to modify behaviour, are defined and each includes different methods and techniques (Fallon et al., 2005; Romain et al., 2014). Even though self-efficacy in terms of resisting temptations has been analysed comprehensively in physical activity research, temptations not to be active (as a counterpart to self-efficacy) have been studied only rarely.

3.2.4 Social support

Social support refers to ‘the perception of encouragement and support a person receives from his or her social network’ (Kelder et al., 2015, p. 161) and can be categorised into instrumental, emotional, informational or esteem support. Instrumental support means providing materials or measures for tasks that need to be done such as cooking, while emotional support means expressing positive affect, such as caring or comfort. Informational support is the provision of information from the supportive person. This could be advising someone on behaviour change (Knoll et al., 2017). Esteem support is defined as providing support with the intent of enhancing someone’s feelings about himself/herself as well as their abilities and accomplishments. Besides this functional categorisation, it is possible to differentiate between ‘received’ and ‘perceived’ social support. Perceived social support refers to the support that an individual perceives from his/her social network to be accessible in general, i.e. the potential availability of social support, and is relatively stable (Wills & Shinar, 2000). Received support

refers to actual support transaction from another person (e.g. by a friend or family member) that the recipient retrospectively reports. The actual support provided by others such as by family is better reflected when using received social support measures as used in this study (Barrera, 1986).

Research has shown that social support has a strong positive impact on different health-related behaviours (and the change in these behaviours) such as physical activity (Greaney et al., 2017; Greaves et al., 2011). A review by Smith Banting, Eime, O’Sullivan and van Uffelen (2017) found that social support for physical activity by family suggested that older adults are more likely to carry out leisure time physical activity if they receive family social support for being physically active. Furthermore, social support was also associated with positive lifestyle changes in adults with diabetes (Strom & Egede, 2012) and has been shown to play an important role in weight loss and weight loss maintenance (Verheijden, Bakx, van Weel, Koelen, & van Staveren, 2005; Wing & Jeffery, 1999). Just like outcome expectancies, social support seems to be especially important during early stages of behaviour change (van Stralen et al., 2009). The strengths and direction of social support as a determinant of physical activity in prospective studies is inconsistent (Prince et al., 2016; Scarapicchia, Amireault, Faulkner, & Sabiston, 2017). Most of the evidence is based on cross-sectional research and prospective studies looking at social environmental factors are mostly lacking (Prince et al., 2016).

3.2.5 The interrelation between determinants of physical activity

Most reviews about determinants of physical activity are interested in the influence of a specific determinant on physical activity whereas the interrelation among determinants is studied less frequently. Only limited amount of research has investigated how self-efficacy and outcome expectancies act together to understand PA behaviour (D. M. Williams et al., 2005). Self-efficacy has been found to be the most robust determinant of physical activity. Its relevance in explaining physical activity especially in relation to outcome expectancies, however, has been discussed from different points of views. Williams and colleagues (D. M. Williams, 2010; D. M. Williams et al., 2005; D. M. Williams & Rhodes, 2016) reviewed the outcome expectancy construct in physical activity research with regard to its interrelation with self-efficacy and discussed the contradictory points of view. According to SCT, self-efficacy is directly related to behaviour, but also influences behaviour through outcome expectancies (Bandura, 2000). Bandura (1997) states: ‘The outcomes people anticipate depend largely on their judgments of how well they will be able to perform’ and not vice versa, i.e. as self-efficacy increases, positive outcome expectancies increase as well. Bandura (2004) emphasised the

primacy of self-efficacy in causal structures.

In contrast to SCT, others assume that outcome expectancies can influence self-efficacy, especially self-regulatory behaviour such as exercising (Maddux, 1993, 1999), i.e. positive outcome expectancies may lead to higher self-efficacy, which in turn leads to improved behavioural outcomes. For example, when incentives were offered for performing certain behaviour, it has been shown that self-efficacy increased (cf. Corcoran & Rutledge, 1989), i.e. the anticipated outcome influenced people's self-efficacy. Williams (2010, p. 419) described '[self-efficacy as] a function of expected outcomes of exercising when one expects that exercise will result in falling further behind at work [...], or missing an opportunity to do something more interesting.' This means that self-efficacy is not solely understood as an individuals' perceived capability as suggested by self-efficacy theory, but reflects a concept of motivation. This may often be the case for behaviours that participants assume that they are capable of anyways, such as for self-regulatory efficacy, i.e. being able to perform a behaviour in the context of potential barriers. Knowing that one is able to be active, such items reflect the broader motivation of participants. How self-efficacy is conceptualised and assessed is therefore crucial. Rhodes and Blanchard (2007) found that expected outcomes are usually considered in rating self-efficacy even though the responder is not specifically asked to consider these. Therefore, outcome expectancies might have been underestimated in their explanatory power in relation to self-efficacy (D. M. Williams, 2010).

Williams (2010) in his debate about this issue suggests to either modify the operational definition of self-efficacy or adjust self-efficacy theory (Bandura, 1977) so that outcome expectancies can influence self-efficacy as has been empirically shown. Items asking about self-efficacy could be accompanied by e.g. 'if I wanted to' so that outcome expectancies could be held constant. The option of modifying self-efficacy theory involves some difficulties as self-efficacy and outcome expectancies may be difficult to '...conceptually and empirically disentangle' (D. M. Williams, 2010, p. 421). Furthermore, the definition of capability can differ between individuals, so that even when outcome expectancies are held constant, self-efficacy may differ due to different understandings of capabilities.

According to former work of Bandura (1997, p. 416), social support acts primarily through self-efficacy, i.e. an increase in social support increases self-efficacy leading to greater change in PA behaviour (E. S. Anderson et al., 2010; E. S. Anderson et al., 2006; Rovniak, Anderson, Winett, & Stephens, 2002). However, the study by Anderson-Bill et al. (2011) found both a direct effect as well as an indirect effect through self-efficacy. Furthermore, a study by Oyibo, Adaji and Vassileva (2018) also found social support to directly influence bodyweight

exercise behaviours whereas social support had the same effect strengths on exercise behaviour as self-efficacy. In a study of 110 African American adults, social support did not influence physical activity (Gothe, 2018).

Few studies included other environmental determinants such as perceived barriers or temptations in one framework with social-cognitive determinants explaining PA behaviour, especially not longitudinal studies. Temptations as such have rarely been studied. Only one study looked at the influence of temptation on physical activity beyond self-efficacy (Nigg et al., 2009) and found that temptations did not account for explaining physical activity beyond self-efficacy. In general, temptations as assessed here are often included in a category such as 'barriers to physical activity', including among others: lack of time or other competing choices. These barriers have consistently been associated with less physical activity (Prince et al., 2016; Trost et al., 2002). However, self-regulatory strategies may help to resist temptations and adhere to set goals and have been found to be related to PA behaviour (E. S. Anderson et al., 2006).

Considering the findings with regard to physical activity determination, it is crucial to not only consider the individual factors influencing physical activity, but also to always examine their interrelationships. Some determinants may not be directly associated with PA behaviour, but have an indirect relationship through strengthening another important determinant.

4 Complex behaviour change interventions and current challenges

Due to the contemporary health challenges of non-communicable diseases (NCDs) such as T2DM, whose developments are influenced by lifestyle choices, interest and research in behavioural interventions has increased. As behavioural and lifestyle factors play a major role in the development of T2DM as well as in the development of other NCDs such as cardiovascular diseases, prevention through behaviour change is promising and contributes to improving population health (Mehta & Myrskylä, 2017). Lifestyle interventions in people with prediabetes have shown, for example, that successful behaviour change leads to a lower rate of progression to diabetes (Glechner et al., 2018). Research has, however, indicated that lifestyle interventions vary widely in their effectiveness. The US Diabetes Prevention Study has shown that diabetes incidence reduced by 58% among participants with impaired glucose tolerance who participated in a lifestyle intervention group (Diabetes Prevention Program Research Group, 2002). Likewise, the Finnish Diabetes Prevention Study (DPS) has shown that an intensive lifestyle intervention led to long-term beneficial changes in weight, diet, physical activity and clinical parameters, and reduced diabetes risk (Li et al., 2008; Lindstrom et al., 2003). The China Da Qing Diabetes Prevention Study (DQS) also showed reduced diabetes incidence, but reported a reduction of 38%. The same variety of effectiveness is seen in interventions to reduce incidence of diabetes in the real world (Dunkley et al., 2014) as well as change PA behaviour (Rhodes, Janssen, Bredin, Warburton, & Bauman, 2017). A randomised controlled trial by Yates, Davies, Gorely, Bull, and Khunti (2009) for example showed only a mean weight change of 0.49 kg while Katula et al. (2011) showed a mean weight change of 6.97 kg in their RCT. After the trial phase when lifestyle interventions are translated into routine practice, they usually have less effect on diabetes risk reduction (Cardona-Morrell, Rychetnik, Morrell, Espinel, & Bauman, 2010).

Often, the causes for success or failure of an intervention are difficult to identify, mostly due to the complexity of the interventions. In the context of behaviour change, the Medical Research Council (MRC; Craig et al., 2008) defines complex interventions as interventions that are characterised by a combination of different interacting components (Craig et al., 2013). The MRC refers to components as ‘behaviours, parameters of behaviours (e.g. frequency, timing), and methods of organising and delivering those behaviours (e.g. type(s) of practitioner, setting and location)’ (Medical Research Council, 2000). Lewin et al. (2017) describes an intervention component as ‘a discrete, active element of the intervention that could be implemented independently of other elements’.

Guise, Chang, Butler, Viswanathan, and Tugwell (2017) summarise prior literature defining complexity and group characteristics of complexity such as an intervention's causal pathways, mediators or moderators, or the interaction with contextual factors into the following clusters: 'intervention complexity', 'pathway complexity', 'population complexity', 'implementation complexity', and 'contextual complexity'. Therewith, Guise et al. (2017) take into account not only the intervention content (intervention complexity), but also how the intervention is supposed to work in terms of proposed pathways. Furthermore, the target population may be diverse and needs to be addressed on different organisational levels (population complexity) and with different implementation strategies (implementation complexity). In addition to complexity, an intervention may be implemented in a multidimensional environment, as is common with behavioural interventions.

Another common challenge for developing/replicating effective interventions has been encountered: interventions are often poorly described (Aagaard-Hansen et al., 2014; Michie, Fixsen, Grimshaw, & Eccles, 2009). This makes it difficult to identify the exact components used in an intervention and whether a structured program was used, which in turn hinders the identification of intervention components leading to either intervention success or failure. Sometimes, with great effort and personal commitment the components used in different studies can be discovered by contacting authors, for example. Baker, Simpson, Lloyd, Bauman, and Singh (2011) have made an effort to do this for RCT studies (including, the DPP, DPS, DQS) aiming at diabetes prevention. They examined the additional information besides the published papers. In the DPP and DPS the intervention group received group counselling as well as individual counselling and supervised exercise sessions. Furthermore, participants used goal setting and kept record of their diet and physical activity and weight. Participants of the DQS study did not keep record of either diet or physical activity or weight and had less total contact during the study period (Baker et al., 2011). Studies differed in using behavioural strategies such as self-monitoring, goal-setting or problem-solving (American Diabetes Association, 1999; Baker et al., 2011). Furthermore, while in the DPP and DPS a structured core curriculum was used, this was not the case in the DQS. These findings may contribute to explaining the 20% difference in effectiveness. However, the exact reasons cannot be identified, and often even intensive research may not reveal these. Therefore, the MRC has suggested a framework to ensure robust methodology for developing, implementing and evaluating complex behaviour change interventions as methodological differences may influence intervention effectiveness, which will briefly be explained in the following.

4.1 Development, implementation, and assessment of complex interventions

Sound methodology in developing, implementing and evaluating complex interventions can enhance intervention effectiveness as it allows understanding for how an intervention works. Knowledge about the intervention mechanism, context and outcomes can thus be used to either replicate an effective intervention or improve an intervention that showed insufficient results (c.f. Moore et al., 2015).

How exactly is the term ‘mechanism’ defined? Within the field of behavioural sciences, Michie et al. (2017) refer to ‘the processes through which a behaviour change technique affects behaviour’, which resembles the definition of a determinant. Within evaluation sciences, the term ‘mechanism’ is used more broadly. The intervening mechanisms evaluation approach by Chen (1990), evaluates both, i.e. how intervention activities influence determinants as well as how determinants influence behaviour. In this study, the term ‘mechanism’ is used to refer to the whole range of underlying processes to generate behavioural outcomes. This includes the mechanisms of how a determinant is influenced and, in turn, influences behaviour as well as how multiple determinants relate to each other in changing behaviour. Even though ‘mechanisms’ are often referred to as something abstract and not measurable (c.f. Astbury & Leeuw, 2010), in this study, the term ‘mechanism’ is operationalised in terms of measured intervention activities and determinants.

The MRC guidance calls for a systematic approach to the intervention development and evaluation process and suggests a four-phase cyclical framework. The new MRC guidance, however, emphasises that the phases may not be linear or follow a cyclical sequence in practice. This may be due to the fact that when carrying out interventions in practice, it may be necessary to jump back and forth between phases. Evaluation for example may not necessarily take place before, but in parallel to the implementation phase (e.g. utilisation-focused evaluation).

The first phase of the framework includes intervention development, and includes identifying existing evidence and theory and understanding the mechanisms as to how behavioural change may be achieved (Craig et al., 2013). To begin with, carrying out a systematic review, identifying a systematic review or performing a realist synthesis that shows evidence with regard to the planned intervention is necessary in order to create an evidence base. Likewise, a theory should be identified or developed in order to outline the change mechanisms. Modelling intervention processes and outcomes, i.e. how intervention components (inputs and outputs) relate to outcomes (Hardeman et al., 2005) is recommended. The second phase of the development and evaluation process is to assess its feasibility including its acceptability, recruitment and retention rates, and to determine sample size (Craig

et al., 2013). This way, potential problems can be identified and anticipated in the main study. In the evaluation phase, the third phase, intervention effectiveness is assessed. To evaluate the effect of the study, an appropriate study design should be chosen, and important primary and secondary outcomes identified. By analysing the outcomes, effects can be identified. Evaluating the change processes through which an intervention works gives useful insights into why an intervention works or not and can be used to improve the effectiveness of future interventions.

Therefore, a key question in evaluating complex interventions is: ‘...how [does] the intervention work[s] and what are the active ingredients and how are they exerting their effect?’ (Craig et al., 2013, p. 588). In this phase, the mechanisms hypothesised in phase 1 can be evaluated. If possible, a cost-effectiveness evaluation should be included in this phase as well. This way, the health benefits can be contrasted with the estimated costs. The last phase is implementation into routine practice including dissemination, monitoring and follow-up (Craig et al., 2013). These phases strengthen the theory- and evidence base of complex interventions aiming to assure that outcomes can be replicated in real-world settings.

The MRC advocates that behaviour change interventions should be grounded on theory (Craig et al., 2013; Horodyska et al., 2015). ‘A theory is a set of interrelated concepts, definitions, and propositions that present a systematic view of events or situations by specifying relations among variables, in order to explain and predict events or situations’ (Glanz & Bishop, 2010, p. 26). Theory enables definition of expected intervention mechanism, i.e. the pathways by which the intervention expects to influence behaviour/s. Theory helps to understand processes that underlie and determine the success or failure of lifestyle interventions as theories contribute to understanding of the antecedents of behaviour, i.e. the understanding of what works and why. Knowing this, interventions can be better adapted to different contexts and can be more efficient (Michie et al., 2008).

While some reviews have found theory-based interventions to be more effective for changing health behaviour than those without explicit theoretical considerations (Prestwich, Webb, & Conner, 2015; Webb, Joseph, Yardley, & Michie, 2010), other reviews have not found added effect of using theory (McEwan et al., 2018; Prestwich et al., 2014). This however may be due to interventions being described as theory-based, but may only have been theory-inspired, or interventions being described as not theory-based but still having implicitly used some kind of pre-defined theoretical assumptions (cf. Baker et al., 2011). Furthermore, theory may have been poorly applied, or theory may not have been chosen appropriately (Prestwich et al., 2015). Moreover, theory might be understood differently.

Even though guidance on the design and evaluation of complex lifestyle interventions' is available, there continues to be considerable variation in intervention effectiveness as mentioned previously (cf. Dunkley et al., 2014). Besides the complexity and poor description of interventions, this may be due to methodological differences in intervention development, evaluation and implementation into practice (cf. Craig et al., 2008; Rychetnik, Frommer, Hawe, & Shiell, 2002; A. B. Steckler, Linnan, & Israel, 2002; Wilshire, 2017). Many interventions are developed intuitively rather than systematically (cf. Michie, Fixsen, et al., 2009). An intuitive approach is not based on scientific knowledge or evidence. Instead, intervention developers or stakeholders act according to their unsubstantiated assertions and beliefs and use components that they are familiar with or that seem to work irrespective of the scientific state of knowledge. Often, they choose a specific format instead of concentrating on the content. Outcomes (or the change in outcomes) are not measured, objectives are chosen that are not appropriate for reaching the desired aims, the specific intervention context or needs are ignored, and the mechanism through which interventions have an effect is not disclosed (Schlicht, 2018). Furthermore, efficacy research may not be translated well into clinical practice (Glasgow et al., 2003), leading to limited effectiveness or the variation in effectiveness of interventions. Evaluating interventions will improve understanding into how an intervention works and whether it is effective in the real world.

4.2 Theory-driven evaluation

To evaluate whether and how an intervention works, theory-driven evaluation can be used. The term 'theory-driven evaluation' has often been used interchangeably with terms such as 'program theory evaluation' (Rogers, Petrosino, Huebner, & Hacsí, 2000), 'program theory-driven evaluation science' (Donaldson, 2007), or 'theory-based evaluation' (Weiss, 1997). Here, according to Chen (1990, 2005), the term theory-driven evaluation is used. A central element of theory-driven evaluation is the program theory. A program theory does not only help with systematically planning an intervention, but is especially useful to evaluate an intervention (Schlicht & Zinsmeister, 2015). A program theory describes why and how a certain goal is achieved. It enables intervention planners to perform an evaluation on what exactly might have caused the intervention's success or failure, so that an intervention can be reproduced when successful, or adapted when unsuccessful. Chen defines a program theory as '...a set of stakeholders' implicit and explicit assumptions on what actions are required to solve a problem and why the problem will respond to the actions' (H. T. Chen, 2005, p. 16).

This definition is stakeholder-orientated. Program theories developed based on stakeholders' beliefs, ideas and experiences, although only rarely evaluated, hold promise in their effectiveness (cf. H. T. Chen & Turner, 2012). Often, stakeholders' assumptions about how change will occur are implicit. These implicit assumptions need to be made explicit in order to develop a program theory. This way, intervention planners' and stakeholders' assumptions about how the intervention will work are clearly stated and can be negotiated and possibly modified before implementation. Collaboratively stating the underlying program theory of an intervention may prevent false expectations from stakeholders' perspective and allows joint agreement upon evaluation design and priorities.

However, theory-driven evaluations have been predominantly based on formal behavioural theories (Christie, 2003), which have often been valued as superior to stakeholder theories (Berwick, 2008) and therefore also tend to be more frequently funded (H. T. Chen & Turner, 2012). In this study, theory-driven evaluation is referred to as an evaluation based on '...an explicit theory or model of how the program causes the intended or observed outcomes and an evaluation that is [...] guided by this model' (Rogers et al., 2000, p. 5). This study evaluates whether assumptions defined in the program theory also function in the real world. The purpose of theory-driven evaluation is to detect the underlying mechanism through which an intervention achieves its outcomes.

A program theory includes two components: a set of descriptive assumptions about causal processes of a problem, also called 'causative theory or change model' as well as prescriptive assumptions about what actions are needed to activate these causal processes, called the 'normative theory or action model' (H. T. Chen, 1990). The change model is purely descriptive in nature and makes assumptions about how an intervention works with regards to goals, outcomes, determinants, and the contextual factors through which a desired outcome may be reached (H. T. Chen, 2014). It usually includes an analysis of a problem, such as a certain health problem and asks what the problem is, for whom the problem exists, and what future projections are. Furthermore, it includes analysing its causes and contributing factors, its consequences, and related evidence. The change model defines goals and outcomes as well as determinants and intervention activities and assumes a causal chain between these components, i.e. intervention activities will influence determinants, which will in turn change outcomes to achieve the intervention's goal. Well-established social science theories can be used to identify determinants of health behaviour and intervention activities can be chosen accordingly. The action model 'switches on' the causal processes of the change model. 'An action model is a systematic plan for arranging staff, resources, settings, and support

organisations in order to reach a target population and deliver intervention services' (H. T. Chen, 2005, p. 23). The action model can be seen as the supporting unit for implementation of the intervention and is concerned with what 'ought to be', i.e. what and how activities of an intervention ought to be done (H. T. Chen, 1990).

Both models and their hypothesised activities and causal pathways need to function by themselves, but also need to work in tandem for an intervention to be successful. Although it is useful to differentiate between action and change model when designing a program theory, in practice, developing the change and the action model usually go hand in hand and may take place at the same time.

While many scientists and practitioners have supported the use of theory-driven forms of evaluations and appreciated its advantages such as knowing the exact intervention mechanisms (H. T. Chen, 1990, 2005; Donaldson, 2003, 2007), theory-driven evaluation has been criticised by others. Scriven (1998) expressed criticism with regard to the evaluator's task in saying that understanding why a program works is not necessary for program evaluators to know. Rather, knowing whether an intervention is effective or not may be sufficient. Stufflebeam (2001) doubted that well-articulated program theories exist and therefore concluded that investing in an evaluation that is based on unfound program theory would be counterproductive. This is also one issue that was raised by Weiss (1997). She expressed concerns that program theories often do not exactly state how change is caused, use theory poorly or do not use it to guide the evaluation (Rogers, 2000). Still, Stufflebeam (2001) acknowledges the use of theories to enhance an intervention's effectiveness when sound theories such as the transtheoretical model or the SCT are used. Especially when an intervention is complex, it is necessary to know the exact part of the programme that works and not just that 'it works' (Rogers, 2000).

Coryn, Noakes, Westine, and Schröter (2011) performed a systematic review of theory-driven evaluations in order to investigate if theoretical prescriptions of theory-driven evaluations match with real-world practices. They did not find evidence to substantiate arguments that either advocates or critics of theory-driven evaluations made. It could be concluded, however, that theory-driven evaluations were not used in a meaningful way in practice (Coryn et al., 2011). In practice, the concept of theory-driven evaluations may have been interpreted in different ways. Such different interpretations, operationalisation and even misconceptions of the fundamental idea of theory-driven evaluation may have obscured the original concept and aim of theory-driven evaluations (Davidson, 2006). However, Donaldson (2003) reviews practical examples of theory-driven evaluations and shows the benefits of these,

for example that knowledge of the exact intervention mechanisms helps to identify important intervention components that can be focused on when scaling up interventions and identifying unnecessary components that can be deleted. Furthermore, De Silva et al. (2014) have recommended including a theory-driven approach, i.e. theory of change, into the MRC council's framework for complex interventions as this would improve the evaluation of complex interventions and eventually increase effectiveness. Besides, a committee of the board of the Society of Prevention Research, chaired by Denise Gottfredson, released updated standards for evidence with regard to research on prevention interventions. They defined the inclusion of a clear theory of causal mechanisms as a standard for both efficacy and effectiveness (Gottfredson et al., 2015).

4.3 *Intervening mechanism evaluation*

'Intervening mechanism evaluation' is one type of theory-driven evaluation that is often applied (Donaldson, 2003). In order to understand not only if but also how an intervention works, it is necessary to understand the causal processes that are assumed to cause the effectiveness of an intervention (cf. H. T. Chen, 1990, p. 44). Therefore, the intervening mechanism evaluation evaluates the causative theory and aims to uncover underlying processes so that the success or failure of an intervention can be understood. Once these processes are understood, interventions can be altered and improved. For evaluating the intervention mechanisms, two theories can be tested: a) the action theory, assessing if the treatment variable influences the intervening variable(s) and b) the conceptual theory, testing whether the intervening variable(s) successfully influences the outcome variable (H. T. Chen, 1990, 2005). This way, one will be able to differentiate between the inability of an intervention to change behavioural determinants (action theory) and the inability of the behavioural determinants to bring about behavioural change (conceptual theory) as causes of intervention failure (cf. Davis et al., 2015) (Figure 1).

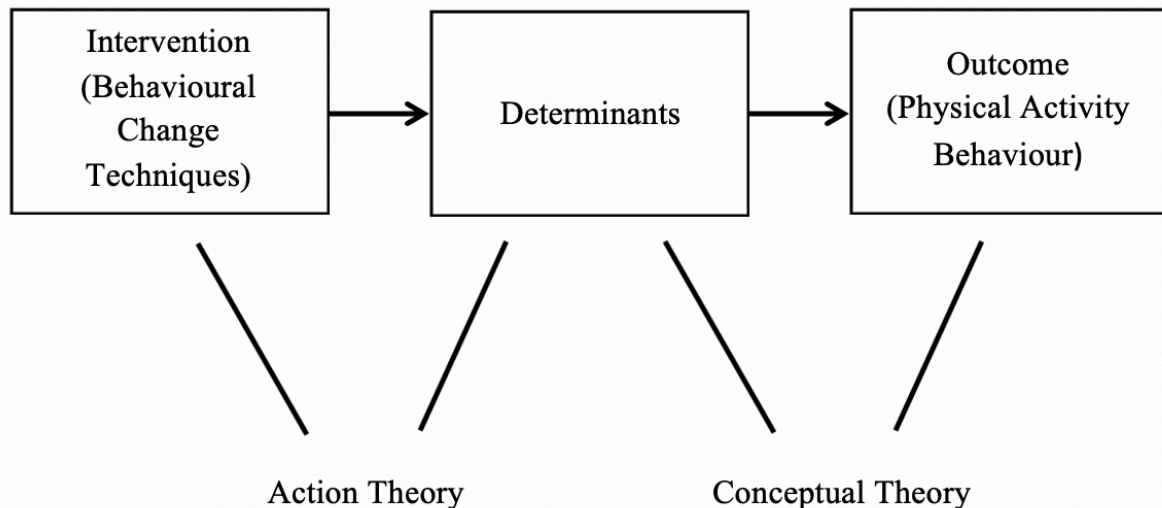


Figure 1: The basic model of intervening mechanism evaluation (adapted from H. T. Chen, 1990, p. 200).

Behavioural determinants and their influence on behaviour (conceptual theory) have already been discussed above. These behavioural determinants can be influenced with BCTs. A BCT is defined as ‘an active component of an intervention designed to change behaviour’ (Michie, Atkins, & West, 2014). A BCT is the smallest identifiable active component; it needs to be observable, replicable and irreducible and can have a measured effect on behaviour (Michie et al., 2013). ‘Prompting self-monitoring behaviour’ or ‘providing feedback on performance’ are examples of BCTs. Susan Michie et al. (2013) have developed a taxonomy of BCTs to facilitate a common understanding of the different techniques and therewith help with increasing effectiveness and replication of complex interventions. Furthermore, Michie et al. (2008) have linked BCTs to behavioural determinants. Specific techniques have been found to be especially important in changing different behavioural determinants and behaviours. In healthy eating and physical activity interventions for example, especially self-monitoring has been found to be an effective technique (Michie, Abraham, Whittington, McAteer, & Gupta, 2009). In general, for developing interventions, not only do evidence-based determinants need to be chosen, but also the BCTs must be appropriate to change the determinants. Linking BCTs to determinants reflects the ‘action theory’ (cf. Figure 1).

In order to replicate effective interventions or refine interventions, the entire behavioural change mechanism must be understood. An intervening mechanism evaluation helps to investigate whether the intervention influences the behavioural determinants and if these in turn influence behaviour as hypothesised. Hence, the advantage of using a theory-driven approach is that knowledge about the exact mechanisms of how the intervention affects the

outcome can be generated, possible breaks in the pathways can be detected, and therewith recommendations about the replication of interventions and how they can be improved can be provided (Rogers, 2000).

Many interventions have been carried out in controlled settings whereas there is a need to examine if theory- and evidence-based intervention mechanisms also work in a natural, real-world setting. Implementing interventions in the real world is a key requirement for reaching people and therewith influencing population health.

5 Translating behaviour change intervention into clinical practice

In general, evidence-based interventions are often (<10 % ; Green, Ottoson, Garcia, & Hiatt, 2009) not translated to and used in health promotion practice (Cilenti, Brownson, Umble, Erwin, & Summers, 2012; Glasgow et al., 2003), or they take about 17 years to be incorporated into practice to improve population health (Morris, Wooding, & Grant, 2011). There is an obvious research-to-practice gap.

To solve this problem, i.e. to translate research into practice, different research translation frameworks or models have been described (cf. Milat & Li, 2017). The research translation continuum or T-models, originally developed by Zerhouni (2003) have been widely applied. The original T1 (from bench to bedside) and T2 (from bedside to practice/community) steps have been used to build upon and include further steps. Khoury, Gwinn and Ionnidis (2010) have defined four translational steps (T1, T2, T3, T4), where T1 and T2 research concerns the generation of scientific discoveries out of the laboratory, i.e. from basic science to human studies. Within steps T3 and T4 research moves away from the controlled environment into the real world, i.e. the translation into clinical practices and the community (T3) and into policy and public health strategies (T4). T1 and T2 research is done under strictly controlled and artificial conditions with highly-selected participants (efficacy studies) whereas T3 and T4 research is concerned with moving from the controlled environment into the real world, i.e. focusing on intervention effectiveness and implementation (effectiveness studies).

Thus, efficacy studies differ from effectiveness studies *inter alia* in their controllability of confounding factors and the control a researcher has over the study (Flay et al., 2005). Efficacy studies focus on controlling external factors and restricting settings, populations and conditions while effectiveness studies aim to ‘produce robust effects’ (Glasgow et al., 2003, p. 1263) throughout different populations, settings, and conditions. An intervention that is efficacious under controlled conditions is not automatically effective in practice, under real-world conditions.

Efficacy studies mainly focus on internal validity, i.e. whether a suggested causal relationship between intervention and outcome exists under optimal, highly-controlled conditions. External or ecological validity becomes more important in effectiveness studies and is concerned with generalisability and contextual factors, i.e. whether an intervention works in a real-world setting. Some authors (cf. Andrade, 2018) view ecological validity as a subtype of external validity, with external validity referring to generalisability with regard to different participant characteristics, and ecological validity referring to generalisability with regard to setting characteristics, such as generalisability to naturalistic settings. This study does

not specifically differentiate between external and ecological validity and uses the term 'external validity' to refer to generalisability with regard to populations and settings. Although external validity is important to implement interventions in practice settings, research has tended to prioritise efficacy studies above effectiveness for a long time (Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004) and the number of small-scale efficacy studies exceeds the few successful effectiveness trials (Glasgow et al., 2003). The preferred design of efficacy studies (and often also effectiveness studies) is the randomised controlled trial. However, such designs are characterised by low external validity, meaning that results from an RCT, i.e. outcomes obtained from a study that strictly controls the environment, are hardly generalisable to different populations and settings and not easily transferable to a natural, everyday setting. This makes it difficult for stakeholders and decision makers to judge an intervention's applicability and relevance to practice, constituting one reason for the poor translation of research into public health practice (Glasgow et al., 2004). It has been recognised that the methodology of RCTs may not be appropriate to improve population's health as people live in a real-world setting. Therefore, research designs maximising external validity and increasing ecological validity have been gaining greater attention recently and are recommended to be used more frequently (cf. Mazzucca et al., 2018).

Interventions translated into clinical practice or the community often turn out to be less effective, because the optimal conditions, under which efficacy trials were implemented, are not generalisable to real-world settings. Interventions implemented in the real world are often more complex as they are implemented in less controlled and different settings, delivered by non-experts and usually address a more heterogeneous group of people (cf. Marchand, Stice, Rohde, & Becker, 2011). Besides, evidence-based interventions are often insufficiently described (Aagaard-Hansen et al., 2014; Michie, Fixsen, et al., 2009; Olswang & Prelock, 2015; Proctor, Powell, & McMillen, 2013), thus making it difficult for practitioners to implement them with fidelity. The decrease in effectiveness of real-world interventions compared to efficacy studies was reported earlier. Still, a systematic review by Luoma et al. (2017) found a few physical activity interventions for patients with type 2 diabetes that were both effective and pragmatic for clinical implementation. In order for interventions to be effective, implementation barriers, i.e. factors that influence the adoption and successful implementation of interventions, need to be overcome.

Glasgow and Emmons (2007) summarised barriers to intervention translation into four categories: characteristics with regard to the research design, the intended target setting, intervention characteristics, and the interactions among these three categories. Research design

can determine if contextual factors will be considered or not (cf. efficacy vs. effectiveness studies). Research design not representative of the sample of patients, settings or clinicians hinders the translation of research evidence into the practice settings (cf. external validity). Besides, the failure to evaluate the intervention in terms of e.g. cost, reach, implementation or sustainability may also lead to insufficient adoption of interventions in the real world. Regarding the intended target setting, in the real world, insufficient organisational support or competing demands, i.e. the existence of more pressing issues as well as limited resources or time may impede implementation of an intervention, i.e. the translational process. With regard to intervention characteristics, different barriers can be encountered. Staff expertise and skills as well as intervention costs pose barriers to effective implementation (Bauer, Damschroder, Hagedorn, Smith, & Kilbourne, 2015; Glasgow & Emmons, 2007, p. 415). To implement interventions in the real world, staff with sufficient expertise and skills needs to be available to implement the intervention. Efficacious interventions are often labour- and time- intensive (Knowler et al., 2002; Wing & Phelan, 2005). Another barrier mentioned by Glasgow and Emmons (Glasgow & Emmons, 2007, p. 415) concerning intervention characteristics is that interventions are often not manualised, not customisable (e.g. tailored to a specific population and setting) and do not consider user needs.

The interplay between the three categories of barriers represents the fourth barrier type, and possibly the most important one. Intervention characteristics, the practice situation and the research design can often not be aligned (cf. Glasgow & Emmons, 2007). A lifestyle intervention aiming at weight reduction may be designed as very labour- and time intensive, i.e. having many face-to-face meetings to increase intervention efficacy whereas in a practice setting, resources and time are usually scarce and cost reduction a priority, thus hindering implementation of such interventions. Furthermore, interventions are often not straightforward and not easily understandable for implementers who do, however, not have the time or organisational support to intensively become acquainted with the intervention's content and mechanisms. Therefore, intervention designers need to provide them with helpful and time-saving tools (cf. Hansen, Kanning, Lauer, Steinacker, & Schlicht, 2017). Other important barriers that reflect the interplay of different barrier categories are the lack of flexibility of the intervention and – mostly due to organisational issues – lack of adequate implementation. Obviously, such misfit and disagreement between intervention characteristics, the target setting and research design makes it challenging to translate interventions into practice, resulting in low adoption and implementation rates. In general, research priorities with regard to

intervention design and methods do not match requirements and the infrastructure of the service delivery system that is in place in practice settings.

To close the research-to-practice gap, different approaches have been suggested. First, it is of uttermost importance that interventions focus more on external validity (Garfield et al., 2003; Glasgow et al., 2006; Glasgow et al., 2004; A. Steckler & McLeroy, 2008), i.e. whether interventions work under real-world conditions. Kessler and Glasgow (2011) and others (Green, 2008, 2014) call for trials that focus on answering practice-relevant questions and are real-world compatible. External criteria are mostly not reported (Partridge, Juan, McGeechan, Bauman, & Allman-Farinelli, 2015). Kessler and Glasgow (2011) suggest a ten-year moratorium of efficacy studies, because these do not contribute to public health due to their long study duration. Furthermore, he states that efficacy studies do not fit with the priorities and processes of practical settings.

To better understand practicabilities in order to improve the translation of evidence-based interventions into practice, i.e. bridging the research-to-practice gap, the field of implementation sciences has emerged. Implementation sciences have been defined as: ‘the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services’ (Eccles & Mittman, 2006, p. 1) encompassing implementation research and dissemination research (Schillinger, 2010). Implementation research is concerned with the implementation processes of an evidence-based intervention in order to advance knowledge about integrating evidence-based interventions into practice settings and improving population health. It supports the collaboration between researchers and practitioners (Feuerstein et al., 2018) in order to identify possible implementation barriers early and aims to solve problems encountered by practitioners.

Second, the collaboration between researchers and practitioners can help closing the gap as ‘the practitioner’s practical knowledge about the service delivery system, facilitators and barriers to implementation, and the realities of bringing about change [...] complement the researcher’s scientific expertise’ (Feuerstein et al., 2018, p. 646). Stakeholders’ knowledge of the real-world practices can be valuable to intervention effectiveness (cf. H. T. Chen & Turner, 2012). Cooperation between researchers and practitioners/stakeholders will increase the focus on external validity, but not at the expense of scientific rigor (Geng, Peiris, & Kruk, 2017). Involving practitioners in early stages of research may facilitate the successful implementation of interventions into practice settings and therewith lead to public health benefits.

Identifying implementation problems and addressing these collaboratively has been shown to be successful. It has been shown that, for example, resource and cost barriers experienced by practitioners can be overcome. Becker and Stice (2017), for example, have engaged lay people to execute an intervention task. This way, it was possible to reach a higher number of people with the intervention and improve implementation cost-effectively. This task shifting in combination with train the trainer workshops (the trainer, a subject-matter expert, trains others in/about a certain subject while simultaneously teaching them how to train others) has been successful and intervention effects equal those of experts performing the task (Becker & Stice, 2017). Likewise, Ali, Echouffo-Tcheugui, and Williamson (2012) have concluded from their review that when medical personnel implements diabetes prevention interventions, the same effectiveness can be reached at lower costs.

However, it is necessary to differentiate between intervention outcomes, i.e. the effect of the intervention on health or other outcomes, and implementation outcomes, i.e. factors with regard to the adoption and implementation of the study such as the proportion of people delivering the intervention or patients receiving it (cf. Bauer et al., 2015; Fixsen, Naoom, Blase, & Friedman, 2005). Research questions for implementation studies are distinct from efficacy and effectiveness research questions and can be categorised into the last stage of the research-to-practice continuum following efficacy and effectiveness (Landsverk et al., 2012).

The third approach to close the gap – besides better focusing on external validity (1) and research-practitioner collaboration (2) – concerns the process of translating interventions into practice. Some authors argue that the process of translating interventions into practice by linearly passing through each step of the research-to-practice continuum as well as the strict difference between the steps (in terms of related research questions and research designs) needs to be re-thought to prevent the slow translation of evidence-based interventions (Glanz, 2015; Gottfredson et al., 2015; Green, 2014; Green & Glasgow, 2006; Onken, Carroll, Shoham, Cuthbert, & Riddle, 2014).

Cardona-Morell et al. (2010) for example investigated the feasibility of physical activity and dietary intervention on diabetes risk in routine clinical practice as well as the replicability of outcomes from randomised controlled trials and found that adaptations need to be made to the original trials for these interventions to be feasibly implemented into clinical practice.

These adjustments for implementing in the real world are another step to be made before implementation, thus slowing down the translational process. Therefore, Green et al (2014), while acknowledging the value of RCTs, suggest also considering other, more practice-based research such as from surveillance, monitoring or evaluation studies. Recent literature also

suggests that there has been a shift away from linear processes of integrating interventions into practice towards a more flexible methodology (Gottfredson et al., 2015; Spoth et al., 2013).

Taking into account features of the implementation context during earlier stages (cf. Koorts et al., 2018) of the translational process can speed up the translational process. To do this, features of the implementation context should be taken into account during the intervention development process. Context should be considered before research is initiated (Olswang & Prelock, 2015). There are also calls for practice-based research and increased external validity (Glasgow & Emmons, 2007; Green, 2008; Green, Glasgow, Atkins, & Stange, 2009).

Hybrid designs linking effectiveness and implementation studies are one way to speed up the translation process (G. M. Curran, Bauer, Mittman, Pyne, & Stetler, 2012). One type of hybrid design focuses on ‘testing a clinical intervention while gathering information on its delivery during the effectiveness trial and/or on its potential for implementation in a real-world situation’ (G. M. Curran et al., 2012, p. 220). This way, implementation issues are already considered during earlier stages of the translational process, i.e. during effectiveness studies. This makes later implementation into real-world settings more likely as evaluating implementation data provides possibilities for improvement. Furthermore, having data on implementation allows realistical judgement of an intervention’s effectiveness, as poor implementation can lead to poor intervention results just as easily as an ineffective intervention itself.

Furthermore, Onken et al. (2014) list similar possible solutions for bridging the gap. They propose changing the intervention (rather than the practical settings) to take account of practical issues as this prevents reduction of effectiveness that may be caused by implementers making adjustments to the intervention in order to make it suitable for the practical setting. In fact, an evidence-based intervention that is not implemented as such into practice but modified to fit practicabilities is not evidence-based anymore and may not produce the expected effects (Onken et al., 2014). Thus, researchers and practitioners need to collaborate. This way, the practitioners can ask questions about how the intervention is supposed to work and judge if this may hold in the practical setting. During collaboration, first, it is important for researcher to understand practical issues. This way, an intervention may be adjusted, e.g. slimmed or simplified in order to meet e.g. practical time- and resource limits without deleting components that are crucial to intervention effectiveness (cf. Damschroder et al., 2009).

Second, Onken et al. (2014) recommend that implementers also have a basic understanding of behaviour change mechanisms. This allows them to better implement interventions with

fidelity compared to those who do not understand mechanisms and only adhere to the manual. Besides, training materials should be available to help implementers administer the intervention with fidelity. Understanding mechanisms will also ensure that interventions can be flexibly adapted to the target population and setting. There are different views on either implementing an intervention with complete fidelity or adapting to local circumstances (Cohen et al., 2008). Maximising fidelity while adapting to the target population and setting (Glasgow et al., 2004) as well as finding the balance between intervention fidelity and necessary adaptation to ensure a good fit with the target population and setting will lead to the most benefits (Chambers, Glasgow, & Stange, 2013), but is a challenge (Perrin et al., 2006). However, often, the intervention mechanisms are not thoroughly understood in the first place (e.g. Murphy, Cooper, Hollon, & Fairburn, 2009). Without knowing how an intervention works, many questions will arise when an intervention fails, and it may not be possible to find out the exact reason.

Therefore, it is suggested here that the appropriate research design combined with suitable methods used during intervention design, such as collaborating with practitioners during the development stage and using a hybrid effectiveness-implementation study, may support a bridging of the research-to-practice gap. In this way, the intervention can be designed under consideration of practical issues relevant for implementation.

6 Aim and research questions

As per state of research, there is a need to translate intervention studies from the controlled environment into real-world settings, i.e. closing the research-to-practice gap. Reaching people in their natural setting and supporting them with lifestyle changes in their familiar environment is needed to improve their health in the long term. Lifestyle changes are indispensable in combating the increase of lifestyle-related diseases such as diabetes and their consequences.

Furthermore, it is necessary to understand the causes of intervention success or failure, i.e. the underlying mechanisms of how behaviour change is reached or not. Only this way can effective interventions be replicated and ineffective interventions improved. As many interventions have not been implemented in the real world or not been evaluated in detail, research is needed to examine whether hypothesised pathways of theory- and evidence-based interventions work in a natural setting.

Therefore, the aim of this study was to explore the translation of research into practice by evaluating the effectiveness of a complex theory- and evidence-based lifestyle intervention (PREMIT) implemented in the real world. PREMIT was part of the PREVIEW study, which can be categorised into translational step T3, because PREVIEW participants were supported in changing their lifestyle towards a certain diet and volume of physical activity as part of their regular life in their familiar environment and not in a controlled setting, i.e. the intervention is integrated into participants' natural environments.

This study used a theory-driven evaluation, more specifically the intervening mechanism approach, to investigate the underlying intervention mechanisms, i.e. to test if the hypothesised theory- and evidence-based behavioural determinants with regard to physical activity (self-efficacy, outcome expectancies (benefits and disadvantages), temptations, social support) influenced physical activity and weight (cf. conceptual theory) in the preparation and action stages of behavioural change in a sample of adults with prediabetes. A theoretical model based on SCT, but adjusted according to the current state of research in the field of physical activity, was used to identify social-cognitive and perceived environmental determinants and their interrelation in explaining physical activity. Here, outcome expectancies were hypothesised to be influencing self-efficacy supporting Williams' self-efficacy-as-motivation argument (D. M. Williams & Rhodes, 2016), because the way that self-efficacy was operationalised in this study, self-efficacy and outcome expectancies may be challenging to differentiate and self-efficacy may rather be understood as a broader motivation. This study therefore adds to the small number of studies investigating this relationship. The suggested model is graphically displayed in Figure 2.

Furthermore, this study evaluates the effect of the lifestyle intervention by evaluating if theory- and evidence-based determinants are influenced by behavioural change techniques (cf. action theory) that are taught and addressed during group counselling sessions (measured in terms of group session attendance). Here, both pathways shown in Figure 1 were examined whereas the focus lied on the conceptual theory and how the different determinants are associated with each other and the outcome variable. Assessing if mechanisms and pathways of the PREMIT intervention work in a real-world setting will help to promote the translation of evidence into clinical practice. Identifying which pathways function for the PREVIEW population and having a detailed description of the intervention helps stakeholders to decide if this intervention may work in their clinical or community setting and population. Knowing the exact component that made the intervention work may help to adopt the intervention if necessary.

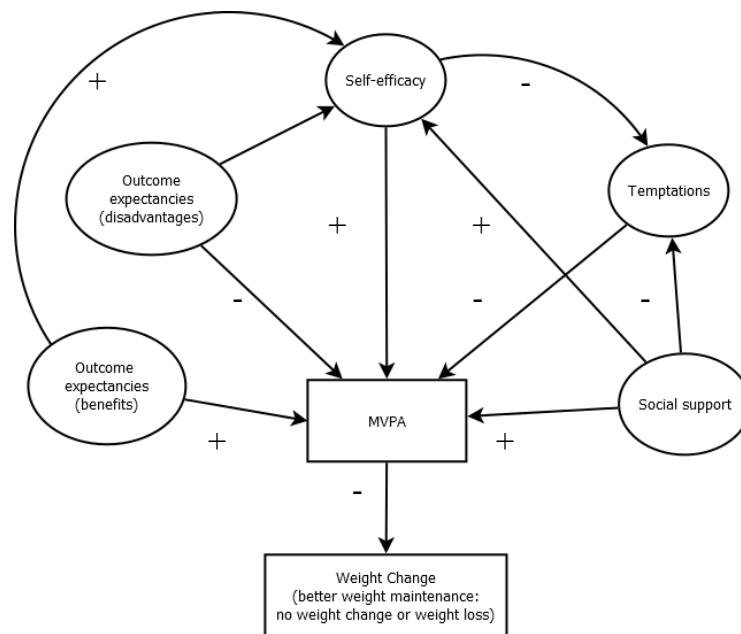


Figure 2: Underlying theoretical model of the investigated relationship between behavioural determinants and physical activity and weight, based on SCT.

The following research questions (RQ) are posed and hypotheses (H) derived:

RQ 1: How do social-cognitive and perceived environmental behavioural determinants influence the volume of physical activity (measured as moderate-to-vigorous physical activity; MVPA) and does MVPA influence weight?

H1.1: A model as depicted with sufficient model fit can be found.

H1.2: All social-cognitive and perceived environmental determinants depicted in the model directly influence MVPA. This hypothesis is proposed because in scientific literature these determinants have been found to be related to physical activity.

RQ 2: How are social-cognitive and perceived environmental behavioural determinants interrelated in influencing the volume of physical activity (MVPA)?

H2.1: Self-efficacy mediates the relation between outcome expectancies (benefits and disadvantages) and MVPA.

H2.2: Self-efficacy mediates the relation between social support and MVPA.

H2.3: Temptations mediate the relation between social support and MVPA.

H2.4: Temptations mediate the relation between self-efficacy and MVPA.

RQ3: Is there a difference in the change in all social-cognitive and perceived environmental determinants (self-efficacy, outcome expectancies (benefits and disadvantages), social support, temptations) as well as weight change between participants who attended the PREMIT counselling sessions rarely/less frequently (low attendance) and frequently/always (high attendance)?

H3.1: There is a difference in the change of social-cognitive and environmental variables and weight between participants with high group attendance in comparison to those with low attendance. An increase in self-efficacy as well as in advantages of physical activity and social support is expected whereas disadvantages of physical activity and temptations to be inactive are hypothesised to decrease in high attenders. There may be no change or a change in the opposite direction for low attenders.

The research questions will be answered using participants' data from the start of the PREMIT intervention, i.e. the preparation and action stages of PREMIT. Data collected at CID 2 and CID 3 from the PREVIEW project will be used. During this time (weeks 8-26), six group counselling sessions took place. PREMIT is well suited for the research aim as it is evidence- and theory-based (making detailed evaluation of intervention mechanisms possible) and

implemented in participants' natural, real-world environment. PREMIT was designed considering practical implementation issues aiming to facilitate implementation and increase effectiveness. While evaluation of implementation outcomes should not be ignored, the focus of this study is to explore if PREMIT's underlying intervention mechanisms function in the real world.

7 PREview behaviour Modification Intervention Toolbox (PREMIT)

The lifestyle intervention PREMIT has been systematically developed to support participants with overweight and prediabetes of the PREVIEW project with changing and maintaining their lifestyle (Kahlert et al., 2016). PREVIEW was an international randomised controlled trial aiming to reduce the incidence of diabetes among participants with prediabetes. The key components of the trial were reducing and maintaining weight through changing the physical activity and dietary behaviour of the study participants. Participants of the PREVIEW study were required to follow one of two diets (either a moderate or a high protein diet) and physical activity recommendations (either moderate or vigorous physical activity) for a period of three years in order to maintain an initial weight loss of 8% of their body weight.

Participant's lifestyle change was supported by a behaviour modification intervention – PREMIT – attended at regular intervals during the three-year-intervention. PREMIT was developed to be implemented into the real world, i.e. translating research into practice, and can be categorised into T3 translational step. The PREMIT intervention supported all participants with their behavioural changes in their familiar, real-world environment. Through taking into account methodological challenges for translating research into practice in order to set the stage for the intervention to be successful, PREMIT was developed systematically, based on behavioural change theory disclosing the proposed behavioural pathway leading to the desired outcome. As suggested by Onken et al. (2014) practical issues of intervention implementation were considered during intervention development and the implementation of PREMIT was designed in such a way that implementers had a basic understanding of behavioural change mechanisms, so that they could flexibly adapt the intervention to participant needs.

In order to comply with requirements for practical implementation, PREMIT has been conceptualised in a flexible manner aiming to address external validity. PREMIT was delivered within group counselling sessions and designed to support all PREVIEW participants in maintaining their weight during the three-year weight maintenance phase by living a healthy lifestyle. Delivering an intervention via group sessions to minimise costs has been recommended as an important component to increase effectiveness (Greaves et al., 2011). The instructors were not behavioural experts themselves, but participated in a workshop that imparted knowledge about behaviour change mechanisms and about how to support people in changing and maintaining their behaviour. Instructing lay people also saves costs and resources in terms of hiring behavioural experts. This workshop was given to all group instructors either in person or via online meetings/teleconferences. Instructors were provided with a manual that defined the content of each group session according to PREMIT. However, the instructors were

encouraged to tailor support to the participants as the intervention took place in different countries and therefore addressed a heterogeneous group of people. This was possible because the instructors gained basic understanding about behavioural change mechanisms and the intervention design itself.

To sum up, the complex lifestyle intervention PREMIT responds to the current methodological challenges with regard to designing effective interventions: PREMIT has been developed systematically and based on well-established psychological theories of behaviour. It uses standardised, well-described BCTs to address evidence-based behavioural determinants that are hypothesised to influence behaviour and describes the intervention in detail. Furthermore, PREMIT has been designed to be applicable in the real world. Therewith PREMIT follows the new MRC guidance (Craig et al., 2013) and allows for a useful evaluation. Evaluating PREMIT will give insights into whether the first stages of the PREMIT lifestyle intervention were effective in changing behaviour in a real-world setting and whether the underlying behavioural change mechanisms (action and conceptual theory) worked as hypothesised. This will contribute to the refinement of interventions and therewith to intervention effectiveness and will add to the evidence base of health behaviour change.

8 Methods

8.1 Recruitment of participants and eligibility criteria

The PREVIEW study was conducted at eight different study sites: University of Copenhagen (Denmark), University of Helsinki (Finland), University of Maastricht (the Netherlands), University of Nottingham (United Kingdom), University of Navarra (Spain), Sofia University (Bulgaria), University of Sydney (Australia), and University of Auckland (New Zealand). Participants were recruited between June 2013 and February 2015 by radio, television, newspaper advertisement, newsletter or by primary and occupational health care providers, depending on the study site. Participants eligible for the study were overweight (BMI > 25 kg/m²), had prediabetes and were between 25 and 70 years old. Prediabetes was diagnosed by an oral glucose tolerance test (OGTT) according to the American Diabetes Association criteria: (i) impaired fasting glucose (IFG) with venous plasma glucose concentration of 5.6 – 6.9 mmol/l after fasting, and/or (ii) IGT, with venous plasma glucose concentration of 7.8 – 11.0 mmol/l 2 hours after oral administration of a standard 75 g glucose dose, and fasting plasma glucose < 7.0 mmol/l. Individuals diagnosed with diabetes were excluded. Individuals with cardiovascular diseases including angina, myocardial infarction or stroke within 6 months prior to the screening procedure, heart failure or peripheral vascular disease were also excluded from the study. Further exclusion criteria were: chronic renal impairment, liver disease, active inflammatory bowel disease, celiac disease, chronic pancreatitis, or other disorders potentially causing malabsorption, transmissible blood-borne disease, malignancy currently active or in remission, and psychiatric illness. People with previous bariatric surgery or a recent surgical procedure not fully convalescent were excluded. People with systolic blood pressure above 160 mmHg and/or diastolic blood pressure above 100 mmHg whether on or off treatment for hypertension were excluded. If treated for high blood pressure, no change in drug treatment within the last three months was allowed. Those with chronic respiratory, neurological, musculoskeletal or other disorders were excluded if the investigator thought there was an unacceptable risk or difficulty in complying with the protocol (e.g. physical activity). Likewise, those with a self-reported weight change of > 5% or those following special diets within two months prior to the screening procedure were excluded. Additionally, those with severe food intolerances were not allowed to participate. People abusing drugs or regular drinking were excluded as well as those with self-reported eating disorders. Pregnant women were excluded as well as those who had a blood donation/transfusion one month prior to the first clinical investigation day; those not understanding the national language or those without phone or

internet access. Finally, engagement in competitive sport was not allowed and those with psychological or behavioural problems that could lead to difficulty complying with the protocol were excluded. The list of inclusion and exclusion criteria can be found elsewhere (Fogelholm et al., 2017).

8.2 *Intervention procedure*

PREVIEW consists of two phases: (1) an 8-week weight reduction phase (preparation phase) and (2) a 34-months lifestyle intervention phase, thus totalling a study duration of three years. During the weight reduction phase participants were instructed to follow the Cambridge Weight Plan – a commercial low-energy diet (LED) – in order to achieve 8% weight loss. Those participants who achieved the 8% weight loss were eligible to enter the randomised controlled trial aiming at weight maintenance over 34 months. The RCT compared two different diets and two different intensities of physical activity and participants were randomised into one of four intervention arms: high intensity physical activity/high protein diet; high intensity physical activity/moderate protein diet; moderate intensity physical activity/high protein diet; moderate intensity physical activity/moderate protein diet.

Data collection was carried out during Clinical Investigation Days (see Figure 3). Data collection included both physiological and socio-cognitive measurements. Physiological measurements included participants' anthropometric metrics, haemodynamic (e.g. blood pressure) and metabolic (e.g. HbA1c) values. Social-cognitive and perceived environmental variables were collected by having participants fill out a battery of questionnaires (e.g. self-efficacy, outcome expectancies) using an online platform.

8.3 *PREMIT*

PREMIT is part of the PREVIEW study supporting participants to achieve and maintain behavioural change with regard to physical activity and dietary behaviour. In developing PREMIT, behavioural determinants for the specific target group and target behaviour were identified using scientific evidence and a number of health behaviour theories: the TPB (Ajzen, 1991), the SCT (Bandura, 1996), SDT (Deci & Ryan, 2008) and others, according to the principles of ecological models. The PREMIT intervention assumes that people pass through different stages during the behavioural change process, following a stage-based approach. PREMIT differentiates between four stages: a preliminary stage (LED phase of PREVIEW), a preparation stage, an action stage and a maintenance stage. During the PREMIT preliminary stage, participants were prepared to be mentally ready for behaviour change. During the preparation stage, PREMIT's overall objective was to begin, follow and train the new

behaviour (healthy diet and physical activity). During the action stage, participants were encouraged to adhere to the new behaviour autonomously whereas the last stage (the maintenance stage) focused on preventing lapses and relapses and help participants cope with difficult situations (Kahlert et al., 2016).

PREMIT addresses different behavioural determinants according to the different stages of change. In the preparation and action stage sessions, which are the focus of this study, the behavioural determinants such as outcome expectancies (benefits and disadvantages of PA behaviour), self-efficacy, temptations, and social support were addressed, focussing on enhancing self-efficacy, fostering positive outcome expectancies, enabling participants to overcome barriers, promoting self-regulation to perform the recommended behaviour and helping participants to find social support.

Second, well-described BCTs were chosen to influence behavioural determinants in order to influence behaviour (physical activity and dietary behaviour) and finally weight loss and weight maintenance. Therefore, evidence was collected on the link between BCTs and determinants in general and the effectiveness of BCTs for physical activity and dietary behaviour, specifically. The specific determinants were influenced by appropriate BCTs such as ‘provision of feedback on performance’ to enhance self-efficacy, ‘information on individual consequences’ to influence outcome expectancies, ‘barrier identification/problem solving’ or ‘environmental restructuring’ to influence temptations, or ‘plan social support’ to increase social support.

During the counselling sessions, participants were taught and practised BCTs addressing different behavioural determinants in order to achieve a behavioural change towards a healthy lifestyle. The PREMIT group sessions took place in regular intervals during the PREVIEW study (see Figure 3). Usually ten to twenty participants attended one group, which was led by an instructor who had previously received special training with regard to behaviour change and appropriate methods. PREMIT was applied in the same way to all participants, not tailored to intervention arms. Even though participants were randomised in two different exercise groups, there was no differences in the volume of physical activity between participants of the different intervention arms, i.e. moderate and high intensity-physical activity (independent sample t-test with original dataset: $t(1228) = .166, p = .868$). Therefore, this study does not differentiate between the two groups but considers all participants as one group.

In total, 18 groups counselling sessions took place during the three-year intervention. Four of the sessions took place during the PREMIT preliminary stage, i.e. the eight-week weight reduction phase of PREVIEW. Six of the counselling sessions were scheduled during

the PREMIT preparation and action stages. The interval between the group counselling sessions decreased over time, i.e. at the beginning of the intervention the group counselling sessions took place more frequently; towards the end of the intervention the group counselling sessions took place less frequently. Figure 3 shows the alignment of the PREVIEW RCT and the PREMIT group counselling sessions.

PREVIEW RCT	8-week Low-Energy Diet (Phase I)								Weight maintenance (Phase II)											
PREMIT intervention	Preliminary stage (Stage 1)				Preparation (Stage 2)				Action (Stage 3)				Adherence (Stage 4)							
PREMIT session	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18		
Data collection	CID 1				CID 2				CID 3				CID 4		CID 5	CID 6	CID 7			
Time in weeks	0	2	4	6	8	10	12	16	20	26	32	44	52	64	78	104	130	156		

Figure 3: Timeline of the PREVIEW phases and the corresponding PREMIT stages.

8.4 *Measurements*

Participants' data were collected at so-called Clinical Investigation days (CID), on which participants visited the centres. Anthropometrics, hemodynamic (e.g. blood pressure) and metabolic (e.g. Hb_{A1c}) values were measured at the CIDs (see Figure 3). Social-cognitive and perceived environmental variables were measured using validated questionnaires. Questionnaires were translated from English into different languages (Finnish, Danish, Dutch, Spanish, Bulgarian) and back-translated to English by authorised translators. Any translational difficulties were discussed and resolved. Participants answered the questions in their mother tongue. Data from CID 2 and CID 3 were used for the analysis. Scale reliability was tested for CID 2 and CID 3 values.

8.4.1 *Physical activity*

Participants wore an Actigraph LLC (ActiSleep +) accelerometer for seven consecutive days, 24 hours/day. The accelerometer was attached to an elastic waist belt, worn over the right mid-axillary line. The accelerometer was only removed during contact sports or activities in water/showering/bathing. Data were downloaded in 1-second epochs and aggregated to 60-second epochs (Gabriel et al., 2010; Troiano et al., 2008). Accelerometer sampling rate was 100 Hz (100 times per second). Nocturnal sleep periods were removed. Non-wear time was defined as 60 minutes of consecutive zero allowing for interruptions of up to two minutes. Large studies using these cut-offs have shown to minimise misclassification of sedentary time as non-wear time (Oliver, Badland, Schofield, & Shepherd, 2011). Participants' data were included in the analysis if valid data (≥ 10 hours/day of waking wear time) were provided for at least 4 days including one weekend day (G. D. Miller et al., 2013). Time (minutes/day) spent at different intensities was determined using Troiano cut-points (Sedentary < 100 , moderate < 2.020 and vigorous < 5.999 counts per minute). MVPA at CID 3 (Troiano et al., 2008) was calculated by summing up moderate and vigorous activity minutes and using average MVPA minutes/day for the analysis.

8.4.2 *Weight and weight change*

A study nurse measured participants' body weight while participants wore light clothing. Weight change was calculated by subtracting weight at CID 2 from weight at CID 3.

8.4.3 *Physical Activity Self-efficacy*

The *Physical Exercise Self-efficacy Scale* (Schwarzer & Renner, 2005) consisting of five items ('I can manage to carry out my exercise intentions' ... '... even when I have worries

and problems'; '...even if I feel depressed'; '...even when I feel tense' '...even when I am tired', '...even when I am busy') was used to examine participants' self-efficacy to carry out their exercise intentions. Participants rated their self-efficacy on a scale from '1' (*very uncertain*) to '4' (*very certain*). The mean value was computed. Low scores stand for low self-efficacy and high scores for high self-efficacy. The scale showed good reliability for CID 2 and CID 3 (Cronbachs $\alpha = 0.89$ and Cronbachs $\alpha = 0.91$, respectively).

8.4.4 Outcome expectancies

Outcome expectancy of changing PA behaviour was assessed with 13 items: three items reflecting disadvantages ('If I exercise regularly' ... '... I'll have to make a great effort each time'; '... it will take a lot of time'; '... that will be a burden for my financial situation') and ten items reflecting benefits ('If I exercise regularly' ... '... I will simply feel better afterwards'; '... I won't have weight problems anymore'; '... other people will appreciate my willpower'; '... my cholesterol level will improve'; '... I'll look more attractive'; '... I'll be more balanced in my daily life'; '... it will increase my quality of life'; '... I will be appreciated by others for that'; '... I will prevent a heart attack'; '... that will be good for my blood pressure') using a subscale from Renner & Schwarzer (2005). Participants rated expected benefits and disadvantages from '1' (*not at all true*) to '4' (*exactly true*) with low scores reflecting fewer expected benefits/disadvantages and high scores reflecting many expected benefits/disadvantages. A mean value was computed. Cronbach's α were 0.75/ 0.78 (CID 2/ CID 3) for physical activity benefit and 0.65/ 0.63 (CID 2/ CID 3) for physical activity disadvantage.

8.4.5 Temptations to be inactive

To measure physical inactivity temptations, participants were asked about their temptations not to exercise using the subscale *competing demands* from the *Temptation to not Exercise Scale* (Hausenblas et al., 2001) with 5 items: 'How tempted are you not to exercise and be sedentary in the following situations'... '... when/while family events/situations interfere'; '... I feel that I don't have the time'; '... I feel lazy'; '... I am busy'; '... I have work to do'. These five items were supplemented by the item ('when/while being on a business trip'). A mean value was computed ranging from 1 to 5, with low scores reflecting few temptations and high scores reflecting many temptations. Cronbach's α was 0.88 and 0.87 (CID 2 and CID 3) for temptations not to exercise.

8.4.6 *Social support for exercising*

The *Social Support for Diet and Exercise Behaviour Scale* (Sallis, Grossman, Pinski, Patterson, & Nader, 1987) including 10 items (e.g. ‘During the past two months, my family’ ... ‘...exercised with me’; ‘... offered to exercise with me’, ‘... gave me helpful reminders to exercise (Are you going to exercise tonight?’; ‘... gave me encouragement to stick to my exercise program’; ‘... changed their schedule so we could exercise together’; ‘... discussed exercise with me’; ‘... planned for exercise on recreational outings’; ‘... helped plan activities around my exercise’; ‘... asked me for ideas on how they can get more exercise’; ‘... talked about how much they like to exercise’) assessed participants’ social support from family to exercise regularly. The items were rated on a scale from ‘1’ (*none*) to ‘5’ (*very often*). In case the question did not apply to the participant, an additional response option was given (*does not apply*). The *Social Support for Diet and Exercise Behaviour Scale* has been used by several studies to measure ‘perceived’ social support (Kiernan et al., 2012; Wang, Pbert, & Lemon, 2014). However, the scale measures the actual received support (Knoll et al., 2017; Wills & Shinar, 2000) as can be seen by the individual scale items. Here, the term ‘perceived’ social support is used (meaning perceived by the participants themselves), i.e. the actual received social support that is perceived by the participants. Received social support measures ‘[...] are thought to more accurately reflect actual support provided by the environment than other types of social support’ (Barrera, 1986). Mean values for social support were computed. Low scores represent little encouragement to participate in physical activity by family and high scores represent high encouragement to participate in physical activity. Cronbach’s α for physical activity participation from family was 0.85 and 0.87 (CID 2 and CID 3).

8.5 *Statistical methods*

Data were requested from the datahub in Copenhagen, received as a cvs. file, and converted to SPSS 24. Data were cleaned, i.e. outliers identified and excluded, missing values imputed, and statistical distribution tested. Analyses were performed with SPSS 24 and AMOS 24.

8.5.1 *Data preparation*

Only participants eligible for the intervention and with recorded weight data at CID 3 were included in the analysis (N = 1569). Participants with extreme univariate and multivariate outliers (± 3.29 SD) (Tabachnick & Fidell, 2006, p. 73) for the measured variables were removed from the dataset, resulting in N = 1484. Missing data were analysed. Missing data for all variables were below 3.4% except for outcome expectancies and MVPA. The variable

‘outcome expectancies for physical activity’ showed a higher percentage of missing values at CID 2 (benefit and disadvantage 21.2% and 21.5%, respectively) because participants from Denmark were not able to answer these questions due to a programming error. Physical activity data showed missing values of 17.1% as not each participant returned the accelerometer for data to be analysed.

Data were imputed using the multiple imputation method with the fully conditional specification model (Markov chain Monte Carlo). Multiple imputation is the recommended method for data missing at random (MAR) (Schäfer & Graham, 2002) and was used because the vast majority of data indicated randomly missing data and because it is necessary to have a complete dataset (without missing values) to perform data analysis in AMOS. Where possible, i.e. for analysis with ANOVA, sensitivity analyses were executed comparing results for imputed and not imputed data. For the multiple imputation, minimum and maximum values for the specific items were defined according to the original data. Furthermore, items to be imputed were rounded to whole numbers, as this was the case in the original items. Ten duplicate datasets were generated. One of the ten multiple datasets was randomly chosen (<https://www.random.org>) and used for analysis with AMOS, because it is not possible to use a dataset with more than one imputation iteration in AMOS. Alternatively, the Full Information Maximum Likelihood (FIML) in AMOS could have been used to impute data. However, using this method, modification indices (MI) cannot be calculated.

8.5.2 *Data analysis*

Research questions 1 and 2 were analysed using a structural equation analysis including weight change in kg (CID 3 - CID 2) as the dependent variable, physical activity at CID 3 as both the dependent variable and a mediating variable and social-cognitive and perceived environmental variables at CID 2 (outcome expectancies, self-efficacy, social support, temptations to be active) as the determinants of physical activity (see Figure 2). The arrangement of social-cognitive and perceived environmental variables in the structural equation model follows well-known theoretical assumptions, suggesting a direct association of social-cognitive and perceived environmental factors with physical activity (precursor of weight change), as well as associations between social-cognitive and perceived environmental factors themselves. Bootstrapping was performed with 2000 bootstrap samples and a bias-corrected confidence interval of 95% to test the mediation effect as suggested by the hypothesis (Arbuckle, 2016). In order to judge the effect size, the standardised regression coefficient can be used which shows ‘[...] the mean response in standard deviation units of the dependent

variable for one standard deviation change in an explanatory variable, holding constant the other variables in a model' (Bollen, 1989, p. 124/125). According to Kline (2011, p. 185) the following cut-off values were used for effect size: $|\beta| = .10 \rightarrow$ small effect; $|\beta| = .30 \rightarrow$ medium effect; $|\beta| = .50$ large effect. According to Chin (1998, p. 8) only values above 0.2 are considered meaningful.

The structural equation model assumes data to come from a multivariate normal distribution. Therefore, Mardia's test for multinormality was performed using AMOS. Mardia's test had a critical value of 40.78, which was significant, meaning that multivariate normality was not given. Therefore, using the asymptotic distribution-free (ADF) estimator within AMOS was considered, which does not assume multivariate normality. However, to use the ADF estimator, N should be large (Hoogland & Boomsma, 1998), i.e. $N \approx 5000$ for ADF to work well as Hu, Bentler & Kano (L. T. Hu, Bentler, & Kano, 1992) showed for a confirmatory factor analysis (CFA) with 15 variables and under a highly kurtotic distribution. Such a large sample size, however, '...is often unrealistic for many social and behavioral fields' (Lei & Wu, 2012). Therefore, first the skewness and kurtosis of each single construct was investigated showing values less than 0.96 for skewness and less than 0.85 for kurtosis. These values do not exceed the critical values as defined by Curran, West and Finch (1996). Therefore, and due to the fact that the Maximum Likelihood (ML) estimation method seems to be robust to moderate deviations from multivariate normality and less biased than other estimators (Arbuckle, 2016; Olsson, Foss, Troye, & Howell, 2000), the ML method was used. Use of the ML method has no consequences for the point estimates (Satorra & Bentler, 2001).

The Structural equation model was constructed and evaluated in two steps as suggested by Kline (2011). First of all, a CFA for each individual measurement model was performed to validate the measurement model of latent constructs (step 1a). Second, the pooled measurement models were assessed (all measurement models simultaneously) (step 1b). Third, the SEM was evaluated (step 2). Local fit indices (evaluating if constructs can be reliably estimated from their indicators) as well as global fit indices (evaluating if empirical associations among manifest variables are appropriately reproduced by the model) were evaluated.

There are a variety of global fit measures that test whether the model appropriately reproduces the empirical associations among the manifest variables (West, Taylor, & Wu, 2012). The following global fit statistics were assessed and reported:

- The model Chi-square test (Likelihood-Ratio-Test) (χ^2): The model chi-square should not be significant (West et al., 2012) as the Null-hypothesis assumes that the empirical covariance matrix and the covariance matrix implied by the model are

equal (Weiber & Mühlhaus, 2012). The Chi-square is very sensitive to large samples (e.g. Michael W. Browne & Cudeck, 1993) and models may be rejected even though they adequately reproduce the covariance matrix. Therefore, Browne and Mels (1992) discourage use of this test. The weaknesses and strict requirements of the Chi-square test (cf. Weiber & Mühlhaus, 2012) led to the development of other global fit measures such as the comparative fit index (CFI) and the Root Mean Square Error of Approximation (RMSEA; West et al., 2012), which will be used in here.

- The χ^2 can be evaluated in relation to the degrees of freedom (df) (χ^2/df): the threshold for acceptable and good values is ≤ 2 or ≤ 3 (Weiber & Mühlhaus, 2012, p. 222). This value is a descriptive value and there is no probability distribution involved. There are, however, other cut-off values, where the cut-off value is set to < 5 such as found in West (West et al., 2012, p. 212). As with the χ^2 , the χ^2/df is also sensitive to large samples and therefore only considered descriptively.
- The RMSEA ‘...can be interpreted as the amount of information within the empirical covariance matrix that cannot be explained by the proposed model’ (Zwingmann, Wirtz, Muller, Korber, & Murken, 2006, p. 537). A rule of thumb is: when $RMSEA \leq 0.05$ a good model fit is given, when $RMSEA \leq 0.08$ an acceptable model fit is given, and when $RMSEA \geq 0.10$ the model fit is not acceptable (Weiber & Mühlhaus, 2012, p. 205). Brown (2015, p. 74) recommends RMSEA values close to 0.06 or below.
- Goodness of fit index (GFI): The Jöreskog- Sörbom GFI ‘...estimates the proportion of covariances in the sample data matrix explained by the model’ (Kline, 2011, p. 207) and is independent of sample size (Weiber & Mühlhaus, 2012). Values ≥ 0.90 indicate a good fit according to Weiber and Mühlhaus (2012, p. 211) and will be used here; others such as Schreiber, Stage, King, Nora and Barlow (2006) recommend values of 0.95 and above.
- Incremental fit indices such as the CFI, and the normed fit index (NFI) and the Tucker-Lewis index (TLI) compare the researcher’s model with a statistical baseline model in order to evaluate the relative improvement in fit. Values ≥ 0.95 are indicative of good fit relative to the independence model, while values ≥ 0.90 may be interpreted as an acceptable fit, whereby thresholds vary in the literature (cf. Schreiber et al., 2006; Weiber & Mühlhaus, 2012).

In general, if the vast majority of the indexes indicate a good fit, then there is probably a good fit (Schreiber et al., 2006). Also, Bentler (2007) recommends looking at several fit indices to judge model fit.

Local fit indices allow judgment of whether the specific constructs can be reliably estimated from their items and assess if constructs are sufficiently distinguishable (convergent validity and discriminant validity). Each measurement model was assessed in terms of indicator reliability, factor loadings, composite reliability, and average variances extracted (AVE).

- The value for indicator reliability, which indicates the percentage of the variance of the item that is explained by the specific construct, should be equal to or above 0.4 according to Weiber and Mühlhaus (2012, p. 155) and equals the squared factor loading for standardised parameters. However, Brown (2015, p. 115) does not set such a strict cut-off value and recommends approximately .25.
- The factor loadings should significantly differ from zero and have values above 0.5 (Brown, 2015, p. 115).
- The composite reliability index (CRI) measures how well a construct is measured through all indicators¹ of this construct and should be ≥ 0.6 (Weiber & Mühlhaus, 2012, p. 155).
- AVE were also examined, which should be higher than 0.5 (Fornell & Larcker, 1981). Discriminant validity was investigated by comparing the AVE values of all constructs with the squared correlations of all other constructs; the AVE should be larger than the correlation values (Weiber & Mühlhaus, 2012).

Depending on the analysis of the goodness of fit of the measurement models, models may have been adjusted, i.e. items deleted or correlations integrated as suggested by statistical modification indices as shown by AMOS (Arbuckle, 2016). All proposed modification indices were assessed to determine if statistical suggestions could be accepted based on content evaluation; additionally, the expected parameter changes were taken into account.

Research question 3 was analysed using a mixed design analysis of variance (ANOVA) to examine differences between participants who attended the group sessions 0-3 times (low attendance) compared to those who attended group sessions 4-6 times (high attendance). According to the results of the CFA in AMOS (integrated part of the analysis of research question 1), adjustments to constructs were implemented into SPSS for analysis of research question 3.

¹ The terms 'item' and 'indicator' are used synonymously whereas 'indicator' is mostly used in the context of analyses/statistics.

First, assumptions were investigated. The ANOVA assumes data to be normally distributed for each group category and each time of measurement. Furthermore, homogeneity of variances is assumed. The Shapiro-Wilk test to test for normality was significant for all variables (self-efficacy, outcome expectancies benefits, outcome expectancies disadvantage, temptations to be inactive, social support for physical activity, weight) indicating that the assumption of normality was violated. However, a large sample size often causes this test to be significant even if data are normally distributed and therefore Q-Q plots should always be investigated (Field, 2009, p. 144). The Q-Q plots showed only slight deviations from the straight line for all variables except weight. Therefore, normality was assumed and the mixed design ANOVA executed. Levene's test was not significant for all variables, i.e. equal variances were assumed. Levene's test for weight was significant. To meet the assumption of normality and homogeneity of variances, the variable weight was transformed using reciprocal transformation (Field, 2009, p. 154). Levene's test for weight was still significant. However, a large sample size often causes this test to be significant (Field, 2009, p. 150). Therefore descriptive statistics were investigated. Standard deviations for weight did not show large differences: for weight at CID 2, standard deviations for participants with low and high attendance were 0.0119 and 0.0120 respectively, and for CID 3 0.0120 and 0.121 respectively. Therefore, equal variances were assumed and the mixed ANOVA was calculated.

The fact that the two groups were unequal in size was not problematic. Unequal group sizes do not affect the ANOVA when groups are large and equality of variances (here examined using Levene's test and by comparing the variances descriptively) is given. The results of the ANOVA are only biased when variances are heterogeneous and sample sizes small ($n < 10$) (Bortz, 2005, p. 287). Furthermore, groups do not clearly differ with regard to age and gender and were not artificially constructed and therewith represent the overall population.

9 Results

9.1 Participant characteristics

Participants (986 women and 498 men; N = 1484) were on average 53.4 ± 10.8 years old. Means and standard deviations for self-efficacy, outcome expectancies (benefits and disadvantages), social support, temptations to be inactive, MVPA, and weight are shown in Table 1.

Table 1: Mean, standard deviation and number of participants for social-cognitive, perceived environmental variables, MVPA and weight

Time Point Group Session Attendance	CID 2			CID 3		
	Low (N=401)	High (N=1083)	All (N=1484)	Low (N=401)	High (N=1083)	All (N=1484)
Social-cognitive variables						
Self-efficacy (scale 1-4)	2.89 (0.65)	2.94 (0.64)	2.92 (0.64)	2.77 (0.73)	2.87 (0.70)	2.84 (0.71)
Benefits of PA (scale 1-4)	3.29 (0.46)	3.24 (0.46)	3.26 (0.46)	3.26 (0.47)	3.23 (0.49)	3.24 (0.49)
Disadvantages of PA (scale 1-4)	2.42 (0.68)	2.45 (0.76)	2.44 (0.74)	2.47 (0.72)	2.38 (0.77)	2.40 (0.76)
Social Support (scale 1-5)	2.24 (0.96)	2.17 (0.94)	2.19 (0.95)	2.35 (0.94)	2.26 (0.96)	2.28 (0.95)
Temptations (scale 1-5)	2.92 (0.94)	2.94 (0.99)	2.94 (0.97)	3.05 (0.93)	2.88 (0.97)	2.92 (0.96)
MVPA				35.04 (21.60)	35.15 (23.07)	35.12 (22.16)
Weight (kg)	86.35 (3.60)	86.38 (17.41)	86.37 (16.83)	87.79 (15.91)	86.24 (18.07)	86.66 (27.52)
Weight change (kg)				1.43 (3.60)	-.14 (4.04)	.29 (4.00)

In order to evaluate the influence of (the interrelation of) behavioural determinants on physical activity and weight, in a first step, each individual measurement model was investigated with regard to local and global fit indices (step 1a). Following, the pooled measurement models were assessed simultaneously (step 1b). Afterwards, the full structural equation model was evaluated (step 2).

9.2 Measurement models – step 1

9.2.1 Self efficacy

The measurement model for self-efficacy includes 4 items: ‘I can manage to carry out my exercise intentions’ ... ‘even when I have worries and problems’ (var1266); ‘... even if I

feel depressed' (var1267); '... even when I feel tense' (var1268); '... even when I feel tired' (var1269); '... even when I am busy' (var1270). The model fit for this measurement model was as follows: $\chi^2 = 470.901$, $\chi^2/df = 94.180$, GFI = 0.894, CFI = 0.905, NFI = 0.904, TLI = 0.810, RMSEA = 0.251 (Table 2). Composite reliability index was 0.90 and the AVE 0.63 (Table 3). Because of a low indicator reliability and factor loading compared to the other items, the item with the lowest indicator reliability (var1270) was deleted from the model. Content-wise, the item var1270 is different from the other items, as other items cover answers with regard to mood. The fit was calculated again without this item (Table 3). The model fit improved for all fit indices (Table 2). RMSEA reduced to 0.086 with a confidence interval (CI) between 0.057 and 0.118, which is borderline, but since all other fit indices were good, this modified model was considered the final model for all analyses.

9.2.2 Outcome expectancies – disadvantage

The measurement model for temptations included 3 items: 'If I exercise regularly' '... I'll have to make a great effort each time' (var1479); '... it will take a lot of time' (var1485); '... that will be a burden for my financial situation' (var1487). Since this model was just-identified, no global fit indices were calculated. Composite reliability index was 0.62 and the AVE 0.39 (Table 3). The AVE did not reach the acceptable level. Looking at the local fit indices, a very low indicator reliability and factor loading for item var1487 was found. Therefore, this item was deleted from the model. This could be justified because the other two items cover 'effort' and 'time', and this item covers a financial situation. The model fit could not be calculated with just two items because of identification problems. Therefore, the factor loadings for both items were set to 1. Indicator reliabilities, factor loadings and the CRI (0.65) in the modified model were above the threshold (Table 3). The AVE was 0.48, which is borderline (threshold = 0.5) and was considered sufficient. Therefore, this model was used for analyses.

9.2.3 Outcome expectancies – benefits

The measurement model for temptations includes 10 items: 'If I exercise regularly' '... I will simply feel better afterwards' (var1477); '... I won't have any weight problems anymore' (var1478); '... other people will appreciate my willpower' (var1480); '... my cholesterol level will improve' (var1481); '... I'll look more attractive' (var1482); '... I'll be more balanced in my daily life' (var1483); '... it will increase my quality of life' (var1484); '... I will be appreciated by others for that' (var1486); '... I will prevent a heart attack' (var1488); '... that will be good for my blood pressure' (var1489). The model fit for this measurement model was

as follows: $\chi^2 = 1336.499$, $\chi^2/df = 38.186$, GFI = 0.848, CFI = 0.750, NFI = 0.746, TLI = 0.679, RMSEA = 0.158 (Table 2). Composite reliability index was 0.84 and the AVE 0.35 (Table 3). Because of low indicator reliability for many items (Table 3), modification indices were investigated. The following error terms were suggested to be correlated: var1480 and var1486; var1483 and var1484; var1481 and var1489; var1488 and var1489. Looking at the content of these variables, the suggested pairs (including one combination of three) were closely related. Therefore, from each pair (and one three-way correlation between items var1481, var1488, var1489) the item with the lowest indicator reliability was deleted from the model. The model was calculated again without these items. The model fit improved for all fit indices (Table 2). However, the indicator reliability was still not good (Table 3). Investigating the original model, with regard to the content/theory it seemed plausible to create a bifactor model (Brown, 2015). Var1480 and var1486 constituted the bifactor ‘appreciation’. Var1483 and var1484 contributed to the bifactor ‘quality of life’ and var1481, var1488 and var1489 contributed to the bifactor ‘medical advantages’. To avoid identification problems, the items contributing to the bifactor were set equal. This model fitted well: $\chi^2 = 315.594$, $\chi^2/df = 9.862$, GFI = 0.959, CFI = 0.946, NFI = 0.940, TLI = 0.923, RMSEA = 0.077 (Table 2). The indicator reliability of the first two items was still below the threshold of .4, but within the threshold defined by Brown (2015) of .25. Therefore, this model was considered the final model.

9.2.4 *Temptations to be inactive*

The measurement model for temptations included 6 items: ‘How tempted are you not to exercise and be sedentary in the following situations’ ... ‘being on a business trip (var2123)’, ‘... family events/situation interfere’ (var2124); ‘... I feel that I don’t have the time’ (var2125); ‘... I feel lazy’ (var2126); ‘... I am busy’ (var2127); ‘... I have to work’ (var2128). The model fit for this measurement model was as follows: $\chi^2 = 419.431$, $\chi^2/df = 46.603$, GFI = 0.915, CFI = 0.913, NFI = 0.911, TLI = 0.854, RMSEA = 0.175 (Table 2). Composite reliability index was 0.87 and the AVE 0.53 (Table 3). Because of low indicator reliability and factor loadings of the first two items (var2123 and var2124), these were deleted from the model. Content-wise, these two items did not fit in very well, because the other items all somehow consider an underlying factor representing some kind of arousal level. The model was calculated again without these items. The model fit improved for all fit indices (Table 2). RMSEA reduced to 0.118 with a confidence interval between 0.089 and 0.150. This is above the cut-off value, but since all other fit indices were good, this modified model was considered the final model for all analyses.

9.2.5 *Social support for physical activity*

The measurement model for social support included 10 items asking about family social support: ‘During the past 2 months, my family:’ ‘... exercised with me’ (var2519); ‘... offered to exercise with me’ (var2521); ‘... gave me helpful reminders to exercise’ (var2523); ‘... gave me encouragement to stick with my exercise program’ (var2525); ‘... changed their schedule so we could exercise together’ (var2527), ‘... discussed exercise with me’ (var2529); ‘... planned for exercise on recreational outings’ (var2537); ‘... helped plan activities around my exercise’ (var2539); ‘... asked me for ideas on how they can get more exercise’ (var2541); ‘... talked about how much they like to exercise’ (var2543). The model fit for this measurement model was as follows: $\chi^2 = 1200.40$, $\chi^2/df = 34.29$, GFI = 0.853, CFI = 0.852, NFI = 0.849, TLI = 0.810, RMSEA = 0.150 (Table 2). Composite reliability index was 0.91 and the AVE 0.51 (Table 3). Because of low indicator reliability and factor loadings of the last two items, these items were deleted from the model. Content-wise, these items do not fit in very well, because these items were about ‘other people’s exercise’. The model fit was calculated again without these items, but did not improve. Therefore, as none of the items had especially low indicator reliability or factor loadings, modification indices were checked. Modification indices suggested correlating error terms of items var2519 and var2521 and items var2523 and var2525. These were the ones with the highest modification indices (above 250). Analysing the content of these variables, it seems that these pairs are very similar. Therefore, it was decided to delete one of the specific items, the one with the lowest indicator reliability of the two, var2519 and var2525 (this model is not shown in the table). The model fit improved for all fit indices except RMSEA. Therefore, once again, the modification indices were checked. Here, a correlation between var2537 and var2539 was suggested, which makes sense, as the two statements seem quite similar. The model without var2537 was calculated again (Table 3). The model fit improved considerably (Table 2). Therefore, this model was considered the final model for all analyses, even though the AVE decreased slightly.

9.2.6 *The pooled measurement model*

The pooled measurement model was assessed including 8 latent constructs (including 3 bifactors) and 27 items (step1 b). The model fitted well: $\chi^2 = 1268.528$, $\chi^2/df = 4.079$, GFI = 0.939, CFI = 0.947, NFI = 0.931, TLI = 0.940, RMSEA = 0.046 (Table 2). For all items, the indicator reliability was above 0.3, whereas the indicator reliability for 5 items was between 0.3 and 0.4; for all other items factor reliability was above 0.4. All factor loadings were significant. The threshold for AVE was reached for each construct, except for outcome

expectancies benefit with a value of 0.4. The square root of the AVE was higher than the highest correlation among all latent constructs, i.e. all latent constructs are distinguishable from each other (discriminant validity).

Table 2: Measures of Global Fit for the original and modified measurement models

	χ^2	df	p	χ^2/df	GFI	CFI	NFI	TLI	RMSEA	90% CI
Threshold for acceptable fit			> 0.05	< 2	≥ 0.90	≥ 0.90	≥ 0.90	≥ 0.90	≤ 0.08	
CFA models - original										
Self-efficacy	470.901	5	0.000	94.180	0.894	0.905	0.904	0.810	0.251	
Temptation	419.431	9	0.000	46.603	0.915	0.913	0.911	0.854	0.175	
Social support	1200.4	35	0.000	34.29	0.853	0.852	0.849	0.810	0.150	
Outcome expectancies – benefit	1336.499	35	0.000	38.186	0.848	0.750	0.746	0.679	0.158	
Outcome expectancies – disadvantages^a										
CFA models - modified										
Self-efficacy	23.807	2	0.000	11.903	0.992	0.994	0.994	0.982	0.086	0.057-0.118
Temptation	43.254	2	0.000	21.627	0.985	0.988	0.987	0.964	0.118	0.089-0.150
Social support	24.43	5	0.000	4.886	0.994	0.993	0.992	0.987	0.051	0.032-0.072
Outcome expectancies – benefit	68.779	9	0.000	7.642	0.984	0.966	0.961	0.943	0.067	0.053-0.082
Outcome expectancies – disadvantages¹										
Bifactor model										
Outcome expectancies – benefits	315.594	32	0.000	9.862	0.959	0.946	0.940	0.923	0.077	0.070-0.085
Pooled measurement model including the bifactor model										
Pooled measurement model	1268.528	311	0.000	4.079	0.939	0.947	0.931	0.940	0.046	0.043-0.048

^anot calculated, because the model is just-identified

Note. GFI: goodness of fit index; CFI: comparative fit index; NFI: normed fit index; TLI: Tucker-Lewis index; RMSEA: root mean square error of approximation

Table 3: Measures of local fit for all original and modified measurement models

	Item	Indicator reliability		Factor loadings		t-value for factor loading		Composite reliability index		Average Variance Extracted	
<i>Threshold for acceptable fit</i>		≥ 0.4						≥ 0.6		≥ 0.5	
CFA models		Original	Modified	Original	Modified	Original	Modified	Original	Modified	Original	Modified
Self-efficacy								0.9	0.9	0.63	0.69
	var1266	0.72	0.73	0.85	0.85	42.09***	43.14***				
	var1267	0.77	0.79	0.88	0.89	a	a				
	var1268	0.76	0.77	0.87	0.87	44.24***	44.91***				
	var1269	0.52	0.46	0.72	0.68	32.43***	30.19***				
	var1270	0.45		0.67		29.10***					
Temptations								0.87	0.89	0.53	0.66
	var2123	0.25		0.5		20.03***					
	var2124	0.37		0.61		25.75***					
	var2125	0.62	0.59	0.79	0.77	37.66***	36.80***				
	var2126	0.51	0.50	0.72	0.71	32.58***	32.36***				
	var2127	0.80	0.85	0.90	0.92	a	a				
	var2128	0.72	0.72	0.85	0.85	42.66***	42.99***				
Outcome expectancies - disadvantages								0.62	0.65	0.39	0.48
	var1479	0.37	0.47	0.61	0.68	a	a				
	var1485	0.63	0.50	0.79	0.71	7.94***	a				
	var1487	0.1		0.31		9.24***					
Outcome expectancies - benefits								0.84	0.76	0.35	0.35
	var1477	0.29	0.32	0.53	0.57	18.89***	14.91***				
	var1478	0.27	0.28	0.52	0.53	15.61***	14.28***				
	var1480	0.29	0.27	0.54	0.52	a	a				
	var1481	0.41		0.64		17.89***					
	var1482	0.37	0.43	0.61	0.65	17.38***	16.63***				
	var1483	0.51	0.50	0.71	0.71	19.02***	17.12***				
	var1484	0.49		0.70		18.78***					

	var1486	0.26		0.51		15.27***				
	var1488	0.31		0.56		16.42***				
	var1489	0.41	0.29	0.64	0.54	17.90***	14.50***			
								0.87		0.4
	Outcome expectancies benefits – Bifactor model									
	var1477	0.32		0.56		15.16***				
	var1478	0.29		0.54		14.84***				
	var1480	0.70	B1	0.52		a				
	var1481	0.55	B3	0.57		15.31***				
	var1482	0.42		0.65		16.41***				
	var1483	0.69	B2	0.69		16.87***				
	var1484	0.65	B2	0.65		16.23***				
	var1486	0.63	B1	0.49		20.74***				
	var1488	0.41	B3	0.48		13.70***				
	var1489	0.63	B3	0.58		15.41***				
	Social support							0.91	0.85	0.51
	var2519	0.59		0.77		33.00***				0.54
	var2521	0.67	0.63	0.82	0.80	a	a			
	var2523	0.53	0.53	0.73	0.73	30.88***	27.92***			
	var2525	0.46		0.68		28.03***				
	var2527	0.58	0.59	0.76	0.77	32.63***	29.53***			
	var2529	0.49	0.47	0.70	0.68	29.13***	26.01***			
	var2537	0.40		0.63		29.19***				
	var2539	0.49	0.45	0.70	0.67	20.96***	25.52***			
	var2541	0.28		0.53		26.79***				
	var2543	0.43		0.65		25.74***				

Note. a_Unstandardised values were set to equal 1 in order to ensure identifiability. B1: bifactor 1 ‘appreciation’; b2: bifactor 2: ‘quality of life; B3: bifactor 3: ‘medical advantages’

9.3 Behavioural determinants influencing physical activity and weight – step 2

In evaluating the conceptual theory, the influence as well as the interrelation of social-cognitive and perceived environmental determinants on physical activity and weight (conceptual theory) was examined using a structural equation model. The model fitted well: $\chi^2 = 1378.382$, $df = 362$, $\chi^2/df = 3.808$, $p < 0.001$, $GFI = 0.939$, $CFI = 0.944$, $NFI = 0.925$, $TLI = 0.937$, $RMSEA = 0.044$, demonstrating that the empirical data fitted the model structure. The model explained 2.3% of the variance in physical activity and 0.8% of the variance in weight change. Figure 4 illustrates the structural model without its measurement models. Information from the full equation model was described as follows: Outcome expectancies benefits and outcome expectancies disadvantages were not significantly correlated ($cov = -0.12$; $s.e. = 0.011$; $c.r. = -1.094$; $p = .274$; $r = -.038$). Outcome expectancies benefits and disadvantages were both significantly correlated with social support; benefits were positively associated with social support ($cov = 0.085$; $s.e. = 0.016$; $c.r. = 5.369$; $p = .000$) and the corresponding correlation was $r = .175$; disadvantages were negatively associated with social support ($cov = -1.004$; $s.e. = 0.025$; $c.r. = -4.129$; $p = .000$; $r = -.14$). Social support did not significantly affect self-efficacy ($\beta^2 = 0.023$; $s.e. = 0.018$; $c.r. = 1.245$; $p = .213$; $\beta^* = .035$), but significantly affected temptations ($\beta = -.063$; $s.e. = 0.025$; $c.r. = -2.457$; $p = .014$; $\beta^* = -.066$). Also, social support significantly affected physical activity ($\beta = 1.784$; $s.e. = 0.578$; $c.r. = 3.087$; $p = .002$; $\beta^* = .088$). There was no significant indirect effect of social support on MVPA ($p = 0.097$), although the indirect effect was borderline. Temptations did not significantly affect physical activity ($\beta = -0.787$; $s.e. = 0.654$; $c.r. = -1.204$; $p = 0.2229$; $\beta^* = -.037$). Outcome expectancies benefits did not significantly affect physical activity while fewer disadvantages did significantly increase physical activity ($\beta = -.482$; $s.e. = 1.507$; $c.r. = -.320$; $p = 0.749$; $\beta^* = -.010$ and $\beta = -2.732$; $s.e. = 1.108$; $c.r. = -2.465$; $p = 0.014$; $\beta^* = -.086$, respectively). Outcome expectancies benefits and outcome expectancies disadvantages did significantly affect self-efficacy ($\beta = 0.419$; $s.e. = 0.049$; $c.r. = 8.545$; $p = .000$; $\beta^* = .274$ and $\beta = -3.17$; $s.e. = 0.041$; $c.r. = -7.718$; $p = .000$; $\beta^* = -.317$, respectively). Self-efficacy did not significantly affect physical activity ($\beta = 0.688$; $s.e. = 1.094$; $c.r. = -0.629$; $p = .529$; $\beta^* = .022$). The effect of self-efficacy as a mediator between outcome expectancies benefits and outcome expectancies disadvantage and MVPA was not significant ($p = .265$ and $p = .245$). Self-efficacy significantly affected temptations ($\beta = -0.637$; $s.e. = 0.040$; $c.r. = -15.742$; $p = .000$; $\beta^* = -.428$). The

² β : unstandardised value; β^* : standardised value

mediation effect of temptation between self-efficacy and MVPA was not significant ($p = 0.234$). Physical activity significantly affected the change in weight ($\beta = -0.017$; $s.e. = 0.005$; $c.i. = -3.528$; $p = .000$; $\beta^* = -0.091$). The explained variances for self-efficacy, temptations, MVPA and weight were 19%, 19.5%, 2.3% and 0.8%, respectively.

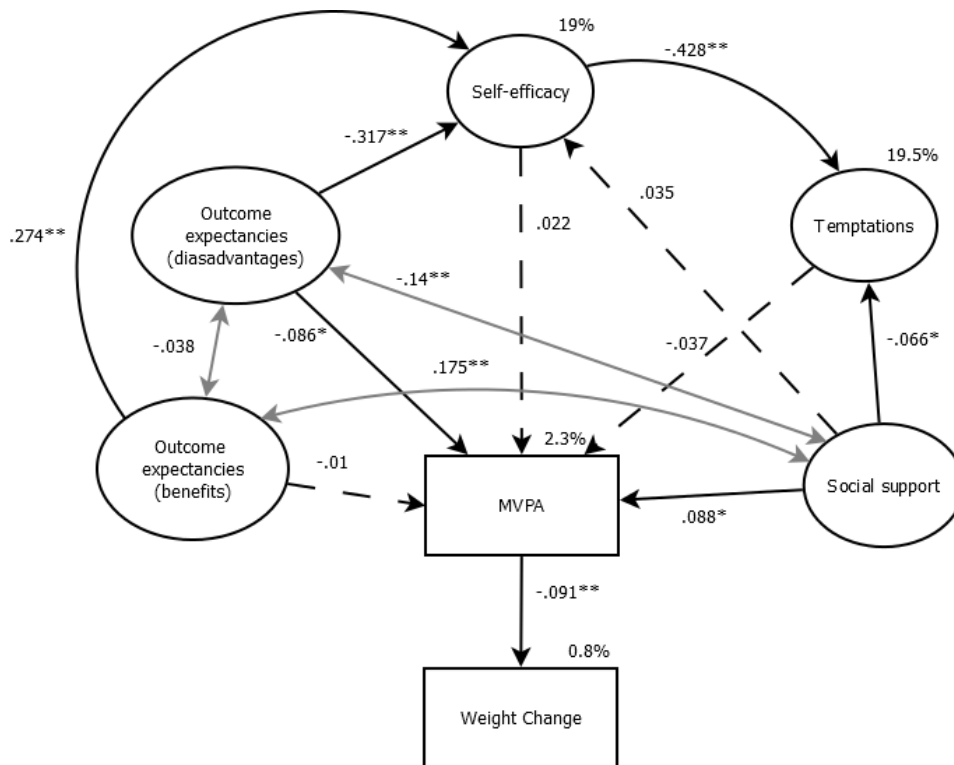


Figure 4: Full structural equation model: estimated standardised path coefficients and percentages of explained variances for the endogenous structural constructs. Non-significant paths appear dotted. Note: $^{**}p < 0.001$, $^*p < 0.05$. The association between the exogenous variables (required by AMOS) outcome expectancies (benefits and disadvantages) and social support is shown in light grey colour.

9.4 The influence of PREMIT BCTs on behavioural determinants

In evaluating the action theory the difference in change in social-cognitive and perceived environmental determinants between participants attending the PREMIT sessions rarely and frequently (action theory) were assessed with the ANOVA. The results of the ANOVA are based on the imputed dataset. Sensitivity analysis has been conducted: there were no differences in results between the imputed dataset and the original dataset. Bar charts showing the respective variable for high and low attenders over time are shown in the appendix.

9.4.1 *Self-efficacy*

There were significant main effects of measurements of time ($F(1, 1482) = 23.05$; $p < .001$; partial $\eta^2 = 0.015$) and group attendance ($F(1, 1482) = 4.12$; $p = .043$; partial $\eta^2 = 0.003$). Self-efficacy decreased from CID 2 to CID 3 in both groups from $M = 2.89$ ($SD = 0.65$) to $M = 2.77$ ($SD = 0.73$) and from $M = 2.94$ ($SD = 0.65$) to $M = 2.87$ ($SD = 0.70$) for low and high attenders, respectively. Participants with low group attendance showed lower values of self-efficacy than participants who attended the group sessions four times or more. There was no significant interaction effect between measurements of time and group session attendance ($F(1, 1482) = 1.78$; $p = .182$; $\eta^2 = 0.001$).

9.4.2 *Outcome expectancies - benefits*

There was a significant main effect of measurements of time ($F(1, 1482) = 4.16$; $p = .042$; partial $\eta^2 = 0.003$), but no significant main effect of group attendance ($F(1, 1482) = 2.13$; $p = .145$; partial $\eta^2 = 0.0031$). Outcome expectancies benefit decreased from CID 2 to CID 3 in both groups from $M = 3.29$ ($SD = 0.46$) to $M = 3.26$ ($SD = 0.47$) and from $M = 3.24$ ($SD = 0.46$) to $M = 3.23$ ($SD = 0.50$) for low and high attenders, respectively. There was no significant interaction effect between measurements of time and group session attendance ($F(1, 1482) = 1.09$; $p = .298$; partial $\eta^2 = 0.001$).

9.4.3 *Outcome expectancies- disadvantages*

There was no significant main effect of measurements of time ($F(1, 1482) = 2.81$; $p = .596$; partial $\eta^2 = 0.000$) or group attendance ($F(1, 1482) = 0.50$; $p = .48$; partial $\eta^2 = 0.000$), but a significant interaction effect between measurements of time and group session attendance ($F(1, 1482) = 7.47$; $p = .006$; partial $\eta^2 = 0.005$). Outcome expectancies disadvantages increased from $M = 2.42$ ($SD = 0.68$) to $M = 2.46$ ($SD = 0.72$) in low attenders while in high attenders outcome expectancies disadvantages decreased from $M = 2.45$ ($SD = 0.76$) to $M = 2.38$ ($SD = 0.77$).

9.4.4 *Temptations to be inactive*

There was no significant main effect of measurements of time ($F(1, 1482) = 1.25$; $p = .264$; partial $\eta^2 = 0.001$) or group attendance ($F(1, 1482) = 2.155$; $p = .142$; partial $\eta^2 = 0.001$), but a significant interaction effect between measurements of time and group session attendance ($F(1, 1482) = 12.56$; $p < .001$; partial $\eta^2 = 0.008$). Temptations to be inactive increased from $M = 2.91$ ($SD = 0.94$) to $M = 3.05$ ($SD = 0.93$) in low attenders while in high attenders temptations decreased from $M = 2.94$ ($SD = 0.99$) to $M = 2.86$ ($SD = 0.97$).

9.4.5 *Social support*

There was a significant main effect of measurements of time ($F(1, 1482) = 22.68$; $p < 0.001$; partial $\eta^2 = 0.015$). Social support increased from CID 2 to CID 3 in both groups from $M = 2.24$ ($SD = 0.96$) to $M = 2.35$ ($SD = 0.94$) and from $M = 2.17$ ($SD = 0.94$) to $M = 2.26$ ($SD = 0.96$) for low and high attenders, respectively. There was no significant effect of group attendance ($F(1, 1482) = 2.468$; $p = .116$; partial $\eta^2 = 0.002$) and no significant interaction effect between measurements of time and group session attendance ($F(1, 1482) = 0.241$; $p = .623$; partial $\eta^2 = 0.000$).

9.4.6 *Weight*

There was a significant main effect of measurements of time ($F(1, 1482) = 14.70$ ($p < 0.001$); partial $\eta^2 = 0.010$). The interaction between measurements of time and group attendance was significant ($F(1, 1482) = 48.04$ ($p < 0.001$); partial $\eta^2 = 0.031$). Weight decreased from $M = 0.0119$ to $M = 0.0118$ in the low attendance group and increased from $M = 0.0120$ to $M = 0.0121$ in high attenders, respectively. This result must be interpreted with caution. Given the fact that weight is transformed, the actual weight score increased for low attenders and decreased for high attenders. For low attenders, weight increased from $M = 86.35$ ($SD = 15.16$) (original score) to $M = 87.79$ ($SD = 15.91$) (original score). In the high attendance group weight decreased from $M = 86.38$ ($SD = 17.41$) (original score) to $M = 86.24$ ($SD = 18.07$) (original score). There was no significant main effect of group attendance ($F(1, 1482) = 2.313$; $p = .128$; partial $\eta^2 = 0.002$).

10 Discussion of findings

Within the framework of a theory-based evaluation, this study investigated the role of social-cognitive (self-efficacy, outcome expectancies) and perceived environmental determinants (social support, temptations), and their interrelation in influencing physical activity and weight in a sample of adult participants with prediabetes. Furthermore, the potential influence of evidence-based BCTs on behavioural determinants was investigated. Based on theoretical models, expected pathways were reflected against identified pathways in the empirical study in order to identify what exactly influenced participants' PA determinants, physical activity and subsequent weight change.

Evaluating complex interventions aimed at changing and maintaining behaviour is challenging due to multiple interactions between different intervention components. The exact mechanism that causes success or failure is often unclear. Effective interventions are, however, necessary to respond to the increasing prevalence and the personal as well as healthcare burden of many diseases, such as T2DM, that are largely caused by behavioural risk factors such as physical inactivity. Recent research has shown that in those with higher levels of physical activity combined with additional positive lifestyle behaviours, the risk for experiencing a cardiovascular disease event or dying from a cardiovascular disease or any other cause was reduced by half (Lacombe, Armstrong, Wright, & Foster, 2019).

Lifestyle interventions often show only modest success in changing and maintaining behaviour (e.g. Conn et al., 2011; Dombrowski et al., 2014; Terranova et al., 2015) and related health outcomes and are often not or only poorly implemented into real-world settings (cf. Glasgow et al., 2003). Therefore, evaluating the underlying intervention mechanisms of an intervention implemented in the real world can be used to understand and improve practical effectiveness. Theoretical models help to understand how interventions work by defining theory-based pathways about how changes are achieved. Knowing the mechanisms that work in a real-world setting and possible breaks in the hypothesised pathways helps to improve future intervention development or replication of an effective intervention. Furthermore, this knowledge assists in deciding if the intervention can be applied to other settings on community and population levels as well. Therefore, this study contributes to the translation of interventions from controlled settings into the real-world practice to impact public health (Glasgow & Linnan, 2008; Moore et al., 2019).

10.1 Behavioural determinants influencing physical activity and weight

The results of the SEM showed that the empirical data of participants with prediabetes of the PREVIEW study fitted well with the hypothesised model as depicted in Figure 4. (hypothesis 1.1). In contrast to the expectations, not all theory- and evidence-based social-cognitive and perceived environmental determinants were significantly associated with MVPA (hypothesis 1.2). Only disadvantages of physical activity and social support were found to significantly influence MVPA.

No significant influence of self-efficacy on physical activity was found even though self-efficacy has often been found to be the most stable factor influencing physical activity (Allen, 2004; Choi et al., 2017; Teixeira et al., 2015). However, similar to the findings of this study, another review by Cortis et al. (2017) did not find convincing evidence for self-efficacy influencing physical activity among adults. According to Bandura (1986) the influence of self-efficacy diminishes in less challenging contexts. In this study, this might be a reason why self-efficacy did not influence physical activity as expected. Participants may have experienced the actual start of the PREMIT intervention, the preparation stage, as less challenging because they were no longer required to lose weight, but ‘only’ to maintain their weight. Thus, after having lost 8% of their body weight, they might have felt confident that the actual long-term behaviour change may not be very challenging.

Furthermore, some studies have argued that self-efficacy may be more important in initiating behaviour rather than in maintaining behaviour (Baldwin et al., 2006; Linde, Rothman, Baldwin, & Jeffery, 2006). The PREVIEW participants included in these analyses had not reached the behaviour maintenance phase yet, but instead prepared and initiated behaviour change during preparation and action stages of PREMIT. Participants were not expected to change their physical activity during PREVIEW’s weight loss phase, i.e. PREMIT’s preliminary stage. However, they may have started to increase their physical activity during this phase already. Based on the available data, it was not known to what extent participants used physical activity in order to lose weight during the weight loss phase and therefore already initiated their PA behaviour.

The results of this study indicated that expected benefits of physical activities did not show a significant influence on MVPA, while expected disadvantages of PA behaviour were significantly associated with MVPA although the effect size was small. This was contrary to previous findings in literature suggesting that positive outcome expectancies are usually more predictive of behaviour than negative outcome expectancies (Choi et al., 2017; Vaughan, Ghosh-Dastidar, & Dubowitz, 2017; K. E. Williams & Bond, 2002). In fact, PREVIEW

participants may be conscious of their own vulnerability, as they know about their prediabetic status and the associated risk of developing T2DM. Therefore, they may be more motivated to be physically active in order to prevent negative outcomes (avoidance motivation), i.e. avoiding development of T2DM and its associated diseases, rather than to increase expected positive outcomes (approach motivation) (cf. N. E. Miller, 1944).

In general, older individuals may be more driven to pursue goals pertaining to avoidance orientation while younger adults may pursue more approach-orientated goals (Freund & Ebner, 2005). While younger individuals in general may focus on goals such as achievements and gains, older individuals may be confronted with more losses than gains, for example in cognitive and physical functioning (Baltes, Lindenberger, & Staudinger, 2006). A study by Freund (2006) found that older adults were more persistent in pursuing a goal to counteract losses and younger adults were more persistent pursuing goals towards achieving gains. Even middle-aged individuals showed a tendency towards loss-avoidance goals (Heckhausen, 1997). This argument is supported by, for example, a study by Anderson, Winett, and Wojcik (2007) who found that negative outcome expectancies, rather than positive outcome expectancies, influenced healthy food intake in middle-aged adults (mean age 53 years). PREVIEW participants were approximately the same age, and it may be concluded that avoidance-oriented goals may be a stronger driver for behaviour in this sample as well.

Moreover, the expected desired benefits of physical activity (desired outcomes such as lowering the risk of T2DM) may be more distal in comparison to the expected undesired disadvantages of physical activity, such as the time and effort that is involved in being physically active, as it is the case for most health promotion behaviours (Maddux, 1995). The proximity of expected outcomes usually influences behavioural motivation and finally behaviour. Proximal outcomes generally exert greater control over behaviour (Maddux et al., 1995). A study by Evans, Cooke, Murray, and Wilson (2014) found that intrinsic motivation was higher when expecting proximal positive outcomes than when expecting distal positive outcomes among participants with low levels of past exercise behaviour. In the present study, desired benefits could not be categorised into either distal or proximal, because the subscale from Renner & Schwarzer (2005) includes both proximal and distal expected benefits such as 'simply feeling better afterwards' or 'improved cholesterol level'. However, disadvantages of physical activity could be generally seen as more proximal (i.e. the effort it takes to be physically active) than benefits of physical activity reflected by many items representing distal expected benefits.

In line with previous research (Greaney et al., 2017; Smith et al., 2017), results from

the analyses indicated that higher social support from family members significantly positively influenced MVPA. Many studies have emphasised the influence of social support on health behaviours and promote social support as an important intervention component (Greaves et al., 2011). This has been shown especially for lifestyle interventions focusing on weight management (Verheijden et al., 2005). Results from the present study emphasise the relevance of social support in changing behaviour and its inclusion in physical activity interventions, even though the reported effect size was small. Furthermore, prospective studies investigating the association of social support with physical activity have found varying results regarding the type of social support as well as the strengths and direction of association (Scarapicchia et al., 2017). A study by Karfopoulou, Anastasiou, Avgeraki, Kosmidis, and Yannakoulia (2016), for example, found that positive social support was beneficial whereas social support in terms of giving instructions to be active did not appear to be beneficial in weight loss maintenance. The Social Support Scale used in the present study builds a sum score and therewith includes multiple forms of social support as many other social support studies do (cf. Natalie & John, 2019). Future research may investigate the different forms of social support with regard to physical activity in order to receive better insights into how support should be given during behaviour modification interventions.

Contrary to expectation, but in accordance with the study by Nigg et al. (2009), temptations not to be active were not significantly associated with physical activity in PREVIEW participants. While temptations have mostly been analysed for behaviours that people feel the desire to engage in as in e.g. smoking (cf. Fallon & Hausenblas, 2003), temptations in the field of physical activity may be experienced differently. With regard to smoking behaviour people need to abstain from smoking to enhance health. Regarding physical activity, people need to actively engage in physical activity for improved health outcomes. People usually do not experience a desire to engage in physical activities, but smokers/ recent quitters do experience a desire to smoke. Therefore, the weighting of the feeling of temptation (to smoke and to not be active) may be different between these behaviours.

However, the temptation scale employed in this study included items such as feeling not having the time to be active, being busy, having to work and feeling lazy. It could be hypothesised that older adults may not perceive time issues as limitations to be active in comparison to younger people who often name time as a barrier. Younger participants may have more obligations such as family responsibilities, i.e. driving their children to events or picking them up from school. Furthermore, temptations such as a lack of time may be more likely linked to maintenance of physical activity as suggested by van Stralen et al. (2009).

In physical activity research, temptations have received limited attention (Hausenblas et al., 2001). As suggested by theory (Prochaska & Velicer, 1997), in a study among young adults, affect temptations (e.g. anger, stress, satisfaction) was a distinguishing factor between the action and maintenance stage in men (Fallon et al., 2005). More research is needed with regard to physical activity temptations and its quality in comparison to other health behaviours and especially into the relevance of temptations in predicting and changing behaviour in relation to other theoretical constructs. One existing study found no influence of temptations on PA behaviour beyond self-efficacy (Nigg et al., 2009). However, more studies are needed to investigate the influence of temptations on different stages of PA behaviour change.

As physical activity is essential for weight management, the pathway from MVPA to weight change was examined as well. MVPA significantly influenced weight change as expected. However, only a small part of the variance in weight change was accounted for by MVPA. This finding suggests that other factors need to be considered to explain the change in weight. Besides physical activity, diet also plays a relevant role in weight management, even though it has been shown that physical activity is especially important during weight maintenance (Jakicic, 2002). It was expected that dietary behaviour and its determinants contribute to participants' change in weight, but this was not examined in this study. Hansen et al. (2018) investigated the influence of social-cognitive determinants of dietary behaviour on weight loss during the PREVIEW weight loss phase. Perceiving fewer disadvantages of healthy eating and less discouragement for healthy eating by family and friends were linked to greater weight loss. Furthermore, socioeconomic factors such as a better occupation or higher educational achievement may have influenced weight change (Ball & Crawford, 2005). This should be analysed further in future studies.

Evaluating the conceptual theory in PREMIT showed that in a real-world intervention for overweight participants with prediabetes, the expected disadvantages of behaviour as well as the social environment may contribute to successful behaviour change. These two behavioural determinants influenced physical activity as expected from theory. Contrary to expectations from health behaviour theory, self-efficacy, positive outcome expectancies and temptations were not significant among the study participants. Therefore, future interventions should include these components and further evaluate their relevance in the real world. Further information about how these determinants have changed due to the intervention will be given during evaluation of the action theory (section 12.4).

10.2 The interrelation of behavioural determinants in influencing PA

Research question 2 investigated the relationship between social-cognitive and perceived environmental variables in influencing physical activity. Hypothesis H2.1 and H2.2 hold the assumption that self-efficacy acted as a mediator between outcome expectancies and MVPA (H2.1) and social support and MVPA (H2.2). Hypothesis H2.3 and hypothesis H2.4 assumed a mediating effect of temptation between social support and MVPA (H2.3) and self-efficacy and MVPA (H2.4). Although social support and self-efficacy significantly influenced temptations, and outcome expectancies (benefits and disadvantages of physical activity) influenced self-efficacy as expected, neither temptations nor self-efficacy were significantly associated with physical activity and a mediation effect could not be found. Therefore, hypotheses H2.1, H2.2, H2.3, and H2.4 could not be confirmed.

First, it was hypothesised that self-efficacy mediated the relation between outcome expectancies and MVPA as has been found in a number of previous studies (E. S. Anderson et al., 2010; E. S. Anderson et al., 2006; Anderson-Bill et al., 2011). However, this hypothesis could not be confirmed, as no mediation effect was found. Instead, positive and negative outcome expectancies were found to significantly affect self-efficacy, i.e. the more benefits or the fewer disadvantages of physical activity participants expected, the more they believed in their capability to be physically active. The effect size was found to be of medium size. This finding supports the statement suggested by Williams et al. (2010), who argued that self-efficacy is a function of outcome expectancies and that participants consider outcome expectancies when rating self-efficacy (cf. Rhodes & Blanchard, 2007). The findings of this study confirm that outcome expectancies influenced self-efficacy, i.e. the answers to self-efficacy questions were not independent of expected outcomes. In the PREVIEW questionnaire participants were asked if they ‘can manage to carry out exercise intentions...’ under different circumstances (e.g. feeling depressed). The ‘can’ is likely to be interpreted as a broader motivation as suggested by Williams (2010) rather than solely as perceived capability as suggested by self-efficacy theory. Considering the entanglement of outcome expectancies and self-efficacy, other studies may have overrated the influence of self-efficacy in behavioural determination.

Hypothesis H2.2 was also not confirmed, as there was no significant indirect effect of social support on MVPA. According to previous work by Bandura (1997) and empirically confirmed by others (E. S. Anderson et al., 2010; E. S. Anderson et al., 2006; Ayotte, Margrett, & Hicks-Patrick, 2010; Resnick, Orwig, Magaziner, & Wynne, 2002; Rovniak et al., 2002), social support acts primarily through self-efficacy. The effect of social support on self-efficacy

could not be found in this study. Furthermore, self-efficacy was not found to be related to physical activity. The study by Anderson-Bill et al. (2011) found both a direct effect of social support as well as an indirect effect through self-efficacy. Among PREVIEW participants only a small direct effect of social support could be found. As discussed above, this study has suggested potential arguments as to why self-efficacy has not been found to be a significant determinant of MVPA, for example that participants may have experienced the weight maintenance phase as not very challenging compared to the weight loss phase, thus diminishing the relevance of self-efficacy on behaviour.

Furthermore, temptations were not found to mediate either the relation between social support and physical activity (H2.3) or the relation between self-efficacy and physical activity (H2.4). Temptation did not influence physical activity as expected. However, previous research found temptations in terms of lack of time to be an important determinant of physical activity (Prince et al., 2016; Trost et al., 2002). A study by Nigg et al. (2009) found that temptations did not account for explaining physical activity beyond self-efficacy. The PREMIT behaviour modification intervention was based on the TTM (Prochaska, Redding, & Evers, 2003), which assumes that in early stages of behaviour change, self-efficacy is important and in later stages temptation becomes relevant (balance in self-efficacy and temptation). Nevertheless, in this study, neither self-efficacy nor temptations influenced physical activity. Temptations may become more relevant in later stages of behaviour change, such as in the maintenance stage.

However, as expected, temptations were influenced by self-efficacy with a moderate effect. The more someone believed he/she is capable of being active in the presence of impediments, the fewer expected temptations are present. This may be an important finding especially for preventing relapses. In preventing (re-)lapses, increased self-efficacy may either lead to people not even experiencing temptations or to people being able to better resist temptations, or both. Moreover, temptations were influenced by social support, but only with a small effect. The more support participants received, the less tempted they felt to be physically inactive. This is also a helpful finding for designing behaviour modification intervention. It stresses the influence of the social environment even more, as social support seems to not only help in changing towards an active lifestyle, but also in influencing participants' perceived temptations, which helps to prevent lapses or relapses into old behavioural patterns (Yusufov et al., 2016).

The variance in MVPA was only to a small amount explained by hypothesised behavioural determinants indicating that other factors not assessed here may contribute to explaining MVPA. Besides this, objectively measuring MVPA may contribute to the small

amount of variance explained by hypothesised behavioural determinants. A study comparing the explanatory power of SCT constructs in self-reported versus objectively measured physical activity found that the explanatory power of behavioural determinants was less when using objectively-measured physical activity compared to self-reported physical activity (Curtis et al., 2018).

10.3 The effect of PREMIT on behavioural determinants

According to the action theory the influence of the PREMIT counselling sessions was evaluated by investigating differences over time between participants who frequently attended the PREMIT sessions and those who rarely/never attended the sessions. The change in determinants between high/low attenders was not evident in all social-cognitive and perceived environmental determinants and therefore H3.1 could not be confirmed. There was a difference in the change of outcome expectancies – disadvantages, temptations, and weight during CID 2 and CID 3 between high and low attenders.

For those who frequently attended the PREMIT sessions the mean value for expected disadvantages decreased, while it increased for those with low PREMIT session attendance. However, the effect of the interaction term, i.e. the percentage of variance explained by the interaction and its associated error that is accounted for by this effect, was small. A similar small effect was seen for the interaction between time and group (time*group) with regard to temptations: decreasing for high attenders and increasing for low attenders. The small effect sizes suggest that other factors besides group attendance may have also contributed to the change in expected outcome disadvantages and temptations.

However, even though effect sizes were small, the changes in expected disadvantages of physical activity and temptations to be active may indicate that the PREMIT session attendance was relevant for changing these determinants. Those who did not frequently attend the counselling sessions had not shown positive changes in these determinants whereas session attendance seemed to have contributed to a positive change in determinants. Here, the change in disadvantages of physical activity seemed to be most important as expected disadvantages of physical activity significantly influenced the MVPA whereas temptations did not influence MVPA in the PREVIEW sample during preparation and action stages of PREMIT.

Even though the effect of group attendance on weight change from CID 2 to CID 3 was clear, i.e. low attenders gained about one kilogram of weight whereas high attenders managed to maintain their weight (lost on average about 10 grams), group attendance only contributed to a small part to explaining this difference. Nevertheless, despite the small effect size, the

weight difference of one kilogram between those attending regularly and those not attending regularly should not be regarded as negligible because maintaining weight for approximately 4 months after a drastic weight reduction phase is effortful and can be considered a great success. Previous research has shown that often intervention participants regain weight within the following years after weight loss (J. W. Anderson, Konz, Frederich, & Wood, 2001; Curioni & Lourenco, 2005; Look Ahead Research Group, 2014).

There was no difference in change for self-efficacy, for benefits of expected outcomes, and for social support between the low and high attenders even though statistical tests in a sample with quite a large sample size tend to easily show significances. As this has not been the case, it may be reasonable to say that there may in fact have been no difference between high and low attenders with regard to these variables.

Investigating descriptive values of self-efficacy, expected benefits of physical activity and social support showed that the differences in the decrease of self-efficacy and expected benefits between CID 2 and CID 3 for the two groups, and in the increase of the social support value from CID 2 to CID 3 for the two groups are very small. Both high and low attenders experienced a decrease in self-efficacy. This may not be surprising, as the participants showed quite high values of self-efficacy at CID 2, the start of the intervention. This may be due to the fact that they successfully finished the weight loss phase and were eligible for the PREVIEW weight maintenance phase. A possible explanation might be that participants might have underestimated the difficulties of living a healthy lifestyle, i.e. being physically active for maintaining weight (after they have already successfully lost weight which might have seemed more difficult). Therefore, participant's self-efficacy decreased with time only after they directly experienced the difficulties, after which realistic perceptions were formed (cf. Reinecke, Schmidt, & Ajzen, 1996). Furthermore, it could be hypothesised that BCTs addressing self-efficacy (cf. Ashford, Edmunds, & French, 2010) may not have been the most effective techniques for PREVIEW participants.

Expected benefits also decreased during this time in both groups. This may be due to the fact that benefits of physical activity are not always proximal. Outcome proximity often plays a role in the adaption of health behaviour. For most preventive behaviours such as physical activity, the desired outcomes are rather distal than proximal. Undesired outcomes may however be more proximal (Maddux et al., 1995). The decrease in expected benefits from CID 2 to CID 3 in both groups could be caused by the fact that participants may have not experienced proximal beneficial outcomes during this time. This negative experience may have caused them to also not expect beneficial outcomes anymore (giving up hope) in the future,

ignoring the fact that beneficial outcomes may not be experienced directly, but rather distal in time after being physically active for a while.

Even though perceived social support did not differ between high and low attenders, its influence on physical activity was found to be significant (cf. evaluation of conceptual theory). Behaviour change intervention should investigate how social support as a determinant can better be influenced with appropriate BCTs. Even though PREVIEW participants received advice on how support could be encouraged/ asked for, the actual support needs to be given by someone else as here also the actual received support is measured (Sallis et al., 1987). Even though social support can be perceived differently than is actually given, this determinant may better be addressed though including family members in interventions settings.

In general, as seen in a study by Steinmetz, Knappstein, Ajzen, Schmidt, and Kabst (2016), BCTs might influence behaviour directly without having an effect on hypothesised determinants. In PREVIEW participants, an effect of BCTs as measured by group session attendance was only significant for disadvantages of physical activity and temptation. Even though appropriate evidence-based BCTs have been chosen to address PA determinants, BCTs may not have been effective in changing behavioural determinants as expected from theory and evidence in PREMIT participants, but possibly BCTs may have been effective in addressing different determinants, which were not investigated in this study. For example, the technique ‘problem-solving’ used in PREMIT to address temptations is commonly also used to influence motivation (cf. Michie et al., 2008), a determinant not examined in this study.

10.4 Placing PREMIT within the context of challenges in a real-world setting

PREMIT addressed the current challenges of complex behaviour change interventions and their effectiveness in real-world settings. PREMIT itself can be considered a complex intervention (cf. Guise et al., 2017) as it includes different intervention components to address behavioural determinants. Furthermore, as recommended by the MRC (Craig et al., 2013), PREMIT proposes theory- and evidence-based mechanisms on how the intervention is supposed to work and defines an underlying logic, making explicit how intervention components relate to outcomes (Hardeman et al., 2005).

PREMIT focused on external validity – as recommended for effective real-world studies (cf. Mazzucca et al., 2018) – aiming to produce robust effects. PREMIT was implemented within eight different countries, taking into account intercultural differences in order to meet the population-specific requirements. The PREMIT intervention anticipated implementation barriers to intervention translation as defined by Glasgow and Emmons (2007): PREMIT

focused on effectiveness considering contextual factors, taking into account resources and limits set by the target settings, and provided guidance through an intervention manual while keeping the intervention customisable to population needs. Train-the-trainer workshops were held to teach lay persons about basic behaviour modification and change mechanisms (cf. Onken et al., 2014), anticipating implementation barriers such as scarce personal resources and limited available budget (cf. Becker & Stice, 2017). The intervention manual helped trainers to lead the group sessions, including helpful training material and tips for the participants to adequately implement the intervention. Furthermore, trainers were taught how to adapt the manual to specific population needs. Still, to maintain high quality, behaviour modification experts supported trainers during monthly telephone conferences, which they used to ask questions or discuss difficult situations they may have been faced with during group sessions. Besides the monthly meetings, behaviour change experts could always be contacted in case questions arose.

Considering such practical issues during intervention development facilitates implementation into a real-world setting, saves time, and helps to bridge the gap between research and practice (Cardona-Morrell et al., 2010; Olswang & Prelock, 2015). Furthermore, PREMIT has been described in detail, so if it were to be replicated, it could be replicated with fidelity. This allows stakeholders to judge PREMIT's applicability and relevance to apply it to their practice setting (cf. Glasgow et al., 2004), helping to promote the intervention translation into community settings and to improve population health through appropriate public health policies and programs in the last translational step, T4 (cf. Khoury et al., 2010).

Here, the intervention translation into practice was further supported by detailed investigation of the intervention mechanism, thus enabling intervention adaptation to population needs. The intervening mechanism evaluation (H. T. Chen, 1990) of PREMIT illustrated the extent to which current challenges of behaviour modification in a real-world setting could be addressed. Action and conceptual theory were used to investigate the underlying mechanism through which the PREMIT intervention achieved its outcomes. Breaks in the suggested pathways could be identified and recommendations for adjustment and future improvement in a real-world setting could be made (cf. Rogers, 2000). Breaks in the hypothesised pathways could either be seen on the level of the action theory or conceptual theory. Results with regard to the action theory showed that no positive effect of PREMIT session attendance could be seen for self-efficacy, expected benefits of physical activity, and social support, i.e. it is supposed that the respective BCTs did not influence the determinants

as hypothesised. With regard to the conceptual theory, only the pathway from ‘expected disadvantages for physical activity’ and ‘social support’ to physical activity were significant.

The mechanism that worked entirely as hypothesised for participants of the PREMIT intervention was the following: BCTs were used to influence the determinant ‘expected disadvantages of physical activity’ in such a way that high attenders decreased their expected disadvantages. This determinant in turn significantly influenced PA behaviour, i.e. the fewer disadvantages were expected, the more physically active participants were, which in turn led to better weight change maintenance.

It is only to be hypothesised why all expected pathways could not be confirmed among overweight participants with prediabetes in a real-world setting. Perhaps BCTs to change determinants were not addressed or implemented in the group sessions as planned. Small deviations that may be necessary for tailoring the intervention to individual needs may have caused the BCTs to not be effective anymore. Or, BCTs may have been tailored incorrectly or tailored correctly but just did not work as hypothesised in the sample populations. Other factors such as environmental factors could have intervened to not see an effect as expected.

However, even though the hypothesised pathways could only partly be confirmed, weight maintenance worked better for those who frequently attended PREMIT. These results demonstrate that the PREMIT intervention was effective in a real-world setting. Other studies have also reported that group-based interventions are more effective in weight loss than interventions delivered to the individual (Greaves et al., 2011; Paul-Ebhohimhen & Avenell, 2009; Steinmetz et al., 2016). The efficacy/ effectiveness of group-based interventions has been confirmed in a systematic review by Borek, Abraham, Greaves, and Tarrant (2018) considering BCTs and delivery modes, but they recommend being cautious as – especially due study heterogeneity – the exact mechanisms of effectiveness may differ. Perhaps the effect of reporting on one’s behaviour or being observed during group sessions, often called the Hawthorne effect, may have influenced participants’ behaviour. Whereas a review about the Hawthorne effect found some evidence for this effect, the exact mechanisms or conditions for such an effect are unclear (McCambridge, Witton, & Elbourne, 2014). In PREVIEW participants, ‘being in a group’ itself could have led to better results of participants with high group attendance.

This study gave insights into the exact pathways leading to intervention success, but not all pathways worked as hypothesised and effect sizes were small. Despite endeavouring to consider all practical experiences with real-world interventions, implementing interventions in the real world seems to have specific needs that were seemingly not considered here. The exact

mechanisms of complex interventions in real-world settings may not be explained from an exclusively linear or rational perspective, but rather need to acknowledge that behaviour may include a ‘random’ component that is difficult to predict (Resnicow & Vaughan, 2006). The complex interaction of personal and environmental factors makes it difficult to predict behaviour and give general recommendations for effective interventions (see chapter 3).

When translating research into practice, this complexity needs to be considered. Being aware of and considering this complexity in developing and implementing interventions, responses can be adapted accordingly, and appropriate methods and tools can be applied for interventions to be effective in a real-world setting. The Cynefin framework (Kurtz & Snowden, 2003; Snowden & Boone, 2007) could be a helpful tool to correctly identify the situation or problem, i.e. helping to judge if the problem is simple, complicated, complex, or chaotic. Depending on the situational analysis, appropriate methods can be chosen. A common error, for example, is the application of scientific models that are reductionist and rely on linearity (Sweeney & Kernick, 2002) whereas the situation to be handled is more complex than the sum of its parts and linearity cannot be assumed in a complex environment. If the dynamic interaction between parts is not considered, behaviour can hardly be predicted (Ahn, Tewari, Poon, & Phillips, 2006).

When implementing PREMIT, the complexity of dynamic interactions was incorporated within the implementation framework of the PREVIEW study. Even though general recommendations cannot be given, there are some recommendations from the present study that can be hypothesised to be effectively translated into the community setting. Overweight participants with prediabetes seem to benefit from support by their social environment when trying to be regularly physically active to maintain previously lost weight. Furthermore, influencing participants’ expected disadvantages of physical activity facilitates behaviour modification. Changing outcome beliefs helped to improve PA behaviour. It seems plausible to use these results to implement behaviour modification interventions in community settings, because these are not a result of a strictly controlled efficacy study (as many other interventions are) but rather have been shown to be effective in the real world, following an extensive approach focusing on intervention effectiveness in a natural setting. It must be recognised however, that for complex interventions implemented into real-world settings, there is no best practice approach.

10.5 Methodological discussion, strengths and limitations

With its focus on effectiveness and its high number of participants taking part in a 3-year diabetes intervention trial, PREVIEW was unique. Other diabetes prevention studies either mainly focused on efficacy – whereas interventions that proved efficacious in an ideal and controlled setting are not necessarily effective in practice (H. T. Chen & Turner, 2012) – or included only few participants to test the effect of an efficacy study in the real world (Dunkley et al., 2014; Glasgow et al., 2004; Glasgow et al., 2003). As recommended for designing complex interventions (Craig et al., 2013), PREMIT was theory- and evidence- based, considered practical issues and was flexible to adjust to populations needs. Whereas most studies do only evaluate whether an intervention is efficacious/effective or not, the performed theory-driven evaluation clearly contributed to understanding the underlying mechanisms of behaviour modification.

Moreover, another strength of this study was that PA behaviour was measured objectively. Whereas self-reported measures are more commonly used due to reasons of convenience, subjective and objective measures of physical activity usually differ (Prince et al., 2008) with objective measures providing more precise measurements. Despite the relatively high number of missing values in MVPA, the assessment method can still be seen as a methodological advantage of PREVIEW.

However, when evaluating the PREMIT intervention, some issues need to be considered. First of all, participants were recruited via newspaper, television, healthcare providers, and voluntarily took part in the intervention. Self-selection might have led to the inclusion of participants who were especially motivated to make lifestyle changes. Self-selected PREMIT participants may differ from the general population in that they are of higher socio-economic status (Enzenbach, Wicklein, Wirkner, & Loeffler, 2019; Fry et al., 2017; Klijs et al., 2015; Tolonen, Dobson, & Kulathinal, 2005)}. The majority of the PREVIEW participants were highly educated (Huttunen-Lenz et al., 2019). However, Hankonen, Absetz, Haukkala, and Uutela (2009) have found that psychological mechanisms of lifestyle change of participants of the Finnish DPS did not significantly differ between different SES groups.

Furthermore, results need to be interpreted with caution as outcome expectancies and measurements of physical activity showed a rather high percentage of missing values that needed to be imputed. Whereas sensitivity analysis was performed for evaluating the action theory (RQ3), the method of analysis for RQ1 and RQ2 did not allow sensitivity analysis.

PREMIT – an intervention implemented into a real-world setting – mainly focused on external validity, i.e. examining effectiveness among heterogeneous participants as common

for natural settings. Being placed within the framework of the PREVIEW RCT, PREMIT participants were selectively chosen based on specific inclusion and exclusion criteria. According to these criteria, participants were rather homogenous. However, the participants were not selectively chosen with regard to other factors, such as socio-demographic and lifestyle variables. Therefore, heterogeneity could be assumed, especially because participants came from different countries.

While some significant pathways have been identified during this research and there was a benefit of attending PREMIT sessions with regard to weight maintenance, the greatest part of the variance in physical activity and weight change remained unexplained. Furthermore, session attendance only accounted for a small part of the variance explained in changing the hypothesised determinants. Other factors need to be included to better explain which factors contributed to PA behaviour and weight change. Such other factors may also act as intervening variables between assessed determinants and the outcome variable. Therewith this study does not imply causality even though longitudinal data have been analysed. Temporal sequence is not sufficient to imply causality (MacCallum & Austin, 2000).

More environmental factors in particular could be integrated in a model with social-cognitive and environmental factors to better understand the interplay of different factors in behavioural processes. Other environmental factors may have played a role in behavioural determination, for example weather conditions. As recruitment took place continuously, participants took part in group sessions during different times of the year and therewith were faced with different weather conditions. Bad weather or high temperatures may negatively influence physical activity and therewith play a role in explaining MVPA (Buchowski et al., 2009; Chan & Ryan, 2009; Tucker & Gilliland, 2007). Besides, not only climate conditions but also the built environment influences physical activity (McCormack & Shiell, 2011) whereas such environmental factors as well as their associations with physical activity may differ by country (cf. Ding et al., 2013).

Well-established validated questionnaires used to assess behavioural determinants may have been prone to bias such as answering as socially desirable. Furthermore, it is a challenge to exactly differentiate between social-cognitive and environmental variables, because the assessment itself may reflect an interaction of both. This may have been reflected in the assessment of the variable temptations. Self-regulatory strategies help to resist temptations. In case someone has learnt to apply self-regulation strategies in the face of upcoming temptations, this person may not indicate feeling highly tempted when answering the temptation questionnaire. As self-efficacy and social support reduced temptations by e.g. giving a person

confidence in his/her ability to resist temptations, successfully applying self-regulation strategies may have led to experiencing fewer temptations or self-regulatory strategies may have compensated temptations even though the temptations may have been present. Moreover, self-regulation has been found to influence physical activity (E. S. Anderson et al., 2006). This manner of internal interaction may have potentially influenced the relationship between temptations and MVPA whereas purely experiencing temptations may otherwise have significantly influenced MVPA. Such interaction on variable levels may have also been present for other variables (e.g. self-efficacy is weakened/strengthened by environmental sources). Whereas exactly differentiating between personal and environmental components may not be fully possible due to the fact that they may be deeply entangled (i.e. external temptation may be present but not experienced as such due to having applied self-regulatory strategies), adding more detail to the questionnaire items may help to differentiate better. For self-efficacy items, for example, it has been suggested to include ‘...if I wanted to’ in order to keep outcome expectancies constant (cf. D. M. Williams, 2010).

Despite some limitations, this study added to the small number of studies translating research evidence into real-world settings. Evaluating a PREMIT’s underlying mechanisms allowed identification of the causes of success or failure of a theory- and evidence-based behaviour modification intervention in a real-world setting. This could be used to inform and improve future interventions and support bridging the research-to-practice gap in order to influence population health. Besides suggested causes for breaks in hypothesised pathways, implementation studies assessing if poor implementation might have caused the insignificant influence of BCTs on behavioural determinants may give further insights into PREMIT’s effectiveness. Such studies are categorised into the last stage of the research-to-practice continuum (Landsverk et al., 2012). Even though implementation barriers have been considered during the intervention design phase, the actual implementation process may have influenced intervention effectiveness. Implementation studies focus on outcomes such as acceptability, adoption, feasibility or fidelity (Proctor et al., 2011). These outcomes will add to interpreting PREMIT’s effectiveness.

11 Summary and brief outlook

Using a theory-based evaluation approach (intervening mechanism evaluation) in order to investigate the effectiveness of a complex theory- and evidence-based behaviour modification intervention (PREMIT) in changing physical activity among overweight adults with prediabetes, this study showed that the intervention was successful in maintaining weight loss for those frequently attending group sessions. Investigating the hypothesised mechanisms revealed that the pathway from BCTs influencing expected disadvantages of physical activity, that in turn influenced MVPA and weight was confirmed, i.e. changing participants' expected disadvantages of physical activity was important to make positive lifestyle changes with regard to PA behaviour. Therefore, future interventions should use this determinant as an important adjusting screw in the behaviour modification process.

This study showed that the social environment plays an important role in the determination of PA behaviour while also influencing perceived environmental factors. While changing social support for being physically active may appear difficult as it may imply involving other people, it is recommended that interventions take the social environment into account. In this study, social support from family members was important for an active lifestyle in overweight participants with prediabetes. This has also been shown in other studies (Smith et al., 2017; Strom & Egede, 2012). Others have found that social support from media, health care providers, the workplace or the community may also influence PA behaviour (Gleeson-Kreig, 2008; Tamers et al., 2011). Creating a supportive environment, using a buddy system or group-based interventions, bringing people together in the neighbourhood and offering community-based activities and support services is likely to contribute to a more active lifestyle and therewith better health and well-being. Therefore, behaviour modification interventions benefit from including a social support component, optimally by building socially supportive environments.

Whereas expected disadvantages and social support were the most relevant determinants, this study also shows the importance of the interrelation of behavioural determinants, because – even though some determinants may not directly influence behaviour – they may be important in enhancing related determinants and therewith indirectly influencing behaviour. Additionally, they may affect behaviour themselves, also adding to improved behavioural outcomes. Knowing the interrelations is helpful in designing interventions to reach their best possible effect. The interplay between outcome expectancies and self-efficacy assessed here supported William's assumption (D. M. Williams & Rhodes, 2016) of the relative importance of outcome expectancies with regard to self-efficacy. This finding may help to refine theories.

Future studies could investigate this relationship as well as the relationship between social-cognitive and perceived environmental factors further.

The PREMIT intervention, implemented into a natural, real-world setting and considering practical implementation issues, was effective in promoting physical activity and weight maintenance among high attenders and therewith contributes to combating the rising burden of T2DM and its related diseases. Identifying which mechanisms worked for the PREVIEW population and having a detailed description of the PREMIT intervention helps stakeholders to decide if this intervention may work in their clinical or community setting and population, and therewith promotes the translational steps from research to practice. Participants only rarely attending PREMIT sessions were not able to well maintain their weight loss. Further investigation of the difference between low attenders and high attenders may contribute to a better understanding about potential other factors – besides the hypothesised mechanisms – that may have caused the reduced effect on weight maintenance among low attenders. Knowledge about those rarely attending will allow identification of their needs in order to develop cost-effective lifestyle interventions in the future.

To conclude, this study showed that a theory- and evidence-based behaviour modification intervention – leaving room to individually tailor the intervention to participants' needs – was effective in a practice setting. Furthermore, the mechanisms, i.e. how the intervention worked, could be revealed enabling further improvement of the intervention and adaptation for implementation on a community level. However, there is still more research necessary with regard to improving intervention effectiveness in the real world, i.e. understanding the exact mechanism of how an intervention reaches its outcomes. Different determinants could be included so that – even though there will be no 'best intervention' with regard to behaviour change – explaining a greater part of the variance in behavioural outcomes is possible. This knowledge could greatly contribute to improving the effectiveness of large-scale effective real-world interventions on a community level, which are urgently needed to counteract the increasing healthcare burden of life-style related diseases.

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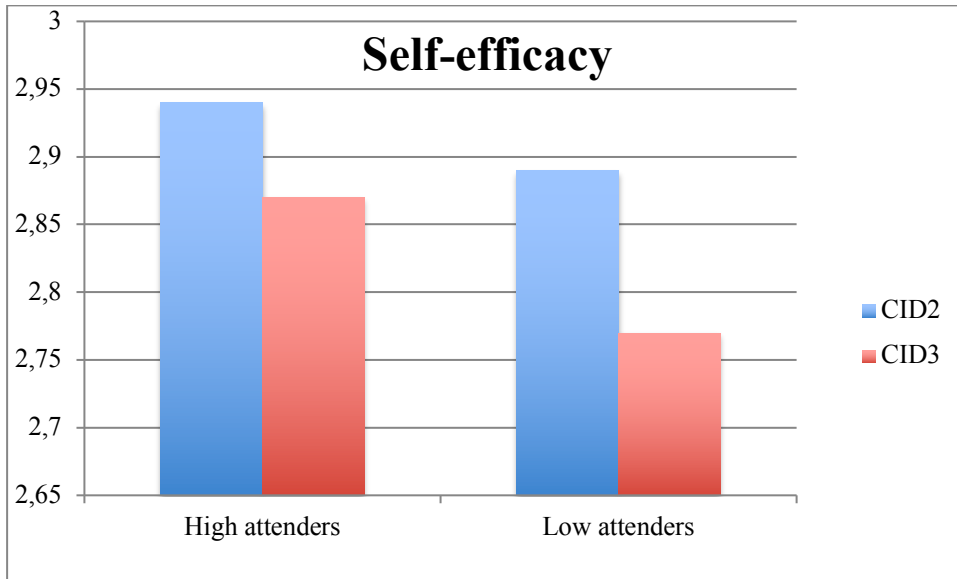
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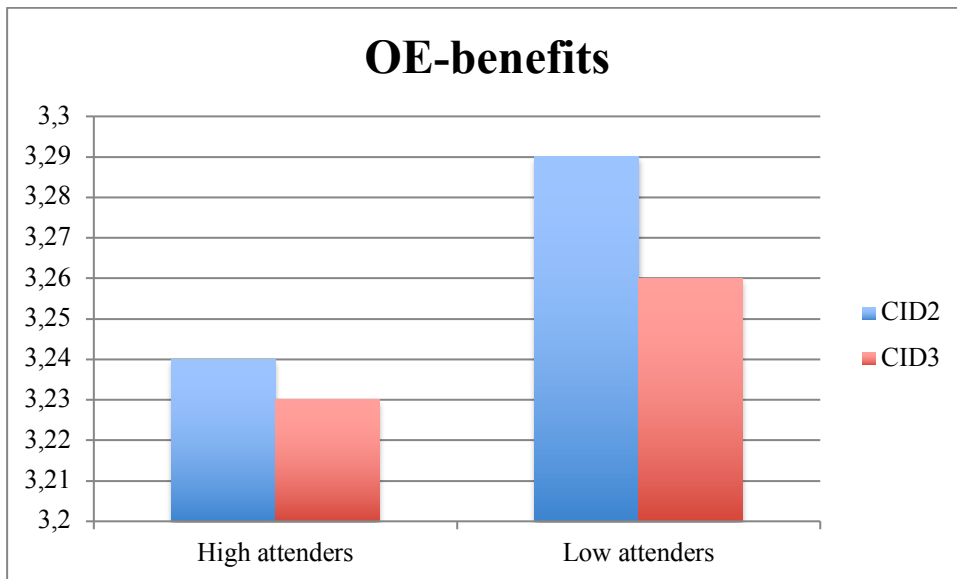
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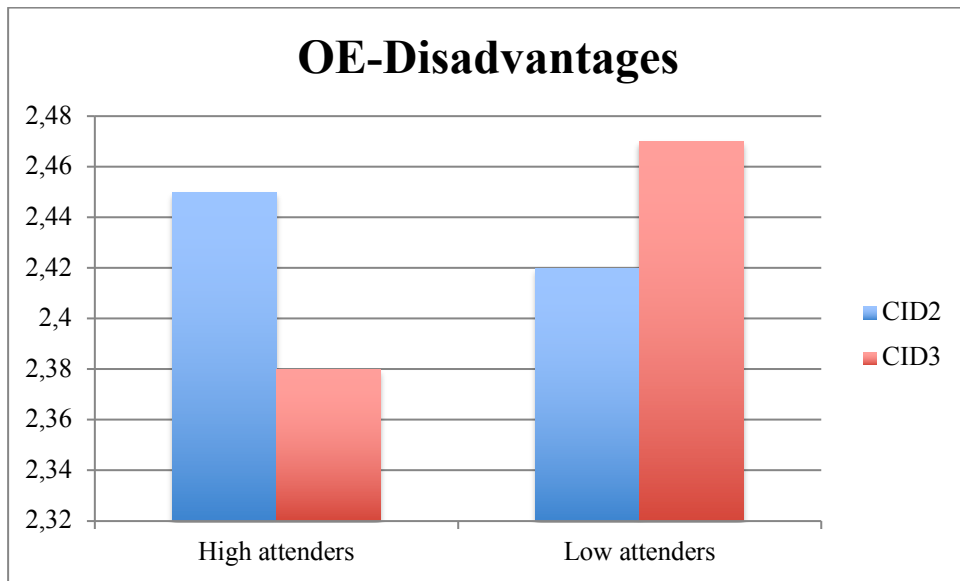
Appendix



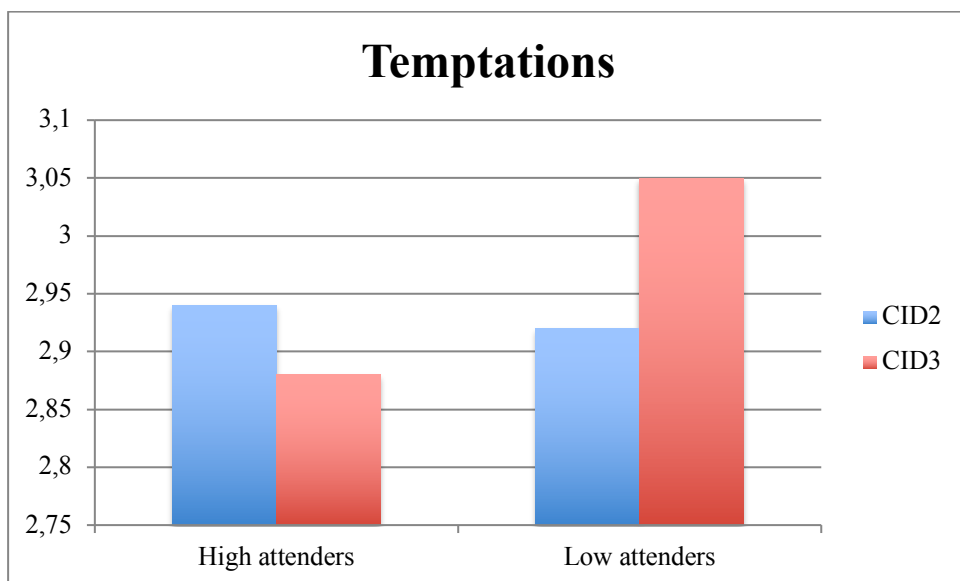
Mean self-efficacy for physical activity for two measurement points (CID 2 and CID3) and participants with low and high group attendance.



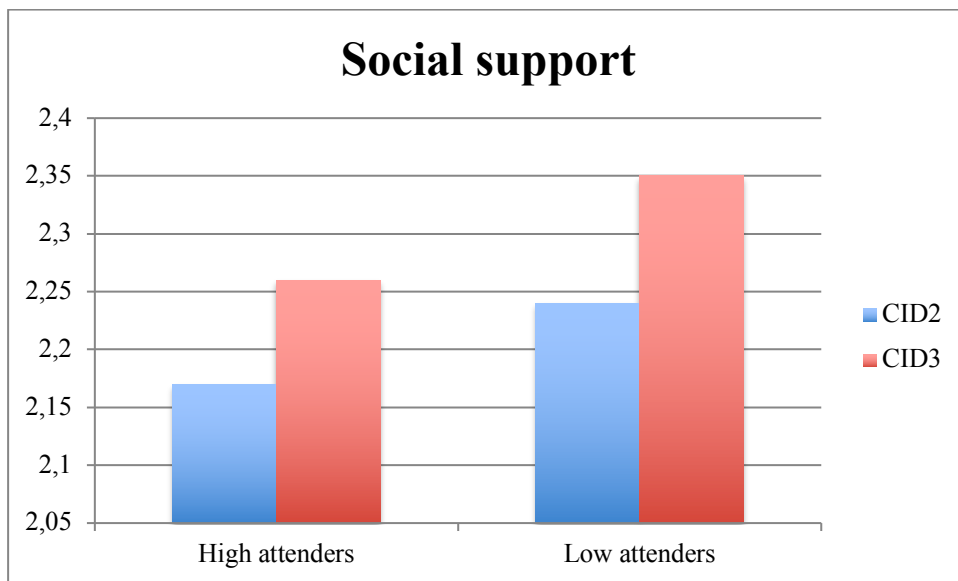
Mean benefits of physical activity for two measurement points (CID 2 and CID3) and participants with low and high group attendance.



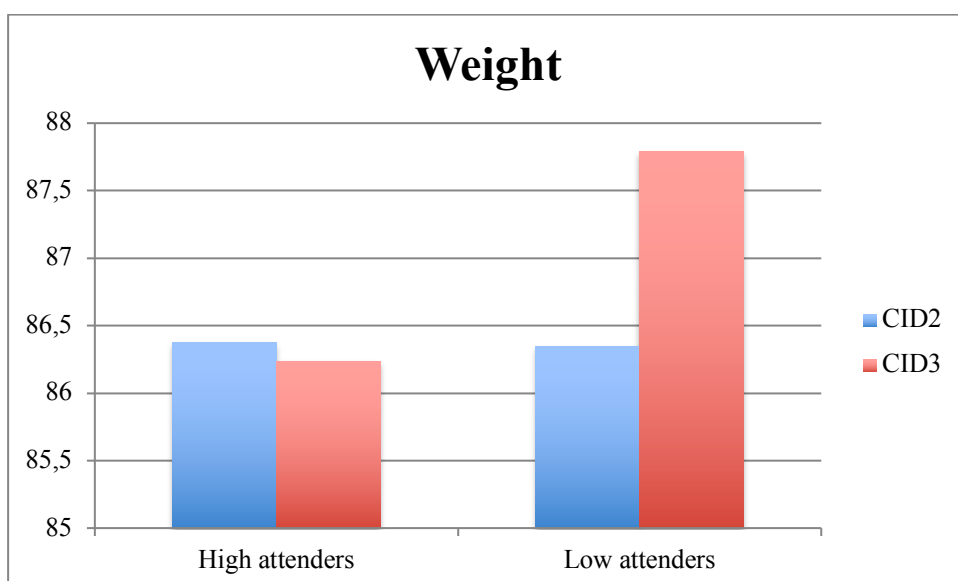
Mean disadvantages of physical activity for two measurement points (CID 2 and CID3) and participants with low and high group attendance.



Mean temptations to be inactive for two measurement points (CID 2 and CID3) and participants with low and high group attendance.



Mean social support to be physically active for two measurement points (CID 2 and CID3) and participants with low and high group attendance.



Mean body weight for two measurement points (CID 2 and CID 3) and participants with low and high group attendance.