Developing mHealth interventions

USING DUAL PROCESS THEORIES
TO REDUCE CARDIOVASCULAR DISEASE RISK



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USING DUAL PROCESS THEORIES TO REDUCE CARDIOVASCULAR DISEASE RISK

Ontwikkelen van mHealth interventies

GEBRUIK VAN DE TWEE SYSTEMEN THEORIE
OM RISICO OP HART- EN VAATZIEKTEN TE VERMINDEREN

Thesis

to obtain the degree of Doctor from the Erasmus University Rotterdam by command of the rector magnificus

Prof. dr. A. L. Bredenoord

and in accordance with the decision of the Doctorate Board.

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CHAPTER 1

Introduction

INTRODUCTION

Burden of cardiovascular diseases

Non-communicable diseases (NCDs), also called chronic diseases, are generally of long duration and are caused by a combination of environmental, genetic, physiological, and behavioral factors. NCDs account for 60% of all disability-adjusted life years (DALYs) globally, of which about one-fourth are attributable to cardiovascular diseases (CVDs) [1]. CVDs are the leading cause of mortality and one of the most important causes of disability [2]. CVDs cause a large burden of disease in the Netherlands too: they are the second most prevalent cause of morbidity and mortality [3]. The number of people with CVDs and associated costs are only expected to increase in the future, as the average age of the world population is projected to increase, and the health of the heart and blood vessels of individuals generally declines with age [4]. Therefore, it is a global priority to alleviate some of this burden [5].

Risk factors for CVDs

There are many factors that increase an individual's risk for CVDs. Some risk factors are genetic, such as familial hypercholesterolemia [6]. Other risk factors are behavioral; insufficient physical activity, sedentary behavior, high fat intake, high sugar intake, and insufficient or too much sleep all increase risk for CVDs [7-10]. Cardio metabolic risk factors for CVDs, such as overweight, (abdominal) obesity, high blood pressure, high cholesterol and high blood glucose often go hand in hand with the above mentioned behavioral risk factors [11]. Psychosocial factors that have been shown to increase risk for CVDs include stress at the workplace and in family life, anxiety disorders, depression, lack of social support, and low socioeconomic status [12]. Behavioral, cardio metabolic, and psychosocial risk factors for CVDs are largely modifiable during an individual's lifetime. Together, these risk factors account for a large part of overall CVD risk; for instance, for over 90% of risk for myocardial infarction in both sexes globally across all age groups [13]. Therefore, CVDs are mostly preventable.

CVD risk management

There are several ways to manage risk for CVDs. The central way to worldwide CVD reduction lies in the inclusion of CVD risk management interventions in universal healthcare packages. Basic medicines that should be available include aspirin, betablockers, and statins; surgical operations that are needed to treat some CVDs include coronary artery bypass and balloon angioplasty; and examples of medical devices required to treat certain CVDs are pacemakers and prosthetic valves [14]. This approach could be called treatment-focused, whereas there is a worldwide call for a shift towards prevention-focused health care systems.

CVD prevention can take three main forms: primary, secondary, and tertiary prevention. Primary prevention attempts to prevent CVDs before they develop, through for instance increasing tax on unhealthy food options; secondary prevention is directed at detecting and intervening on CVDs early, such as reducing hypertension; and tertiary prevention focuses on managing established CVD and avoiding further complications, for example providing cardiac rehabilitiation. An important way to prevent disease is to lead a healthy lifestyle. Getting sufficient physical activity, eating a healthy diet, and minimizing stress can significantly reduce risk for CVDs [13]. Even in high risk populations, a healthy lifestyle can be more effective in reducing disease risk than medication use [15].

Individual-level lifestyle interventions

Individual-level lifestyle interventions targeting behavioral, cardio metabolic, and psychosocial risk factors for CVDs are common worldwide [16]. They can take many shapes and forms: for example, they can be policies that encourage healthier behaviors, such as making healthier food options more visible and unhealthly food options less visible; they can distibute knowledge that allows for healthier decisions to be made, for example information campaigns on high blood pressure conditions; and they can teach healthy behavioral skills that can be applied in various health contexts, such as goal setting training.

Unfortunately, the effects of such interventions are generally moderate, i.e., the programs fail to have large effects on behavior, and effects are short-lived: the behavioral changes that they generate are not sustained long enough to achieve significant CVD risk reduction [16]. A hypothesized reason for these shortcomings is the limited extent to which interventions are based on, instead of being merely inspired by, health behavior theory [17-19]. Naturally, the quality of the theory used is vital: it has to incorporate up-to-date insights from the vast knowledge on behavior change that is already available; and preferably needs to have been found successful in predicting behavior at least observationally in previous studies.

Theory- and evidence-based interventions

Theories of health behavior outline which individual and environmental processes determine behaviors relevant to health outcomes such as CVDs. Some individual-level determinants of behaviors, for example diet and physical activity, include motivation, intention, and stress. Some environmental-level determinants of diet and physical activity include social support, time constraint, and the built environment. Health behavior theories' ability to predict behavior can be tested by measuring the constructs proposed in the theory and empirically testing their predictive power for the behavioral outcome under study. This can be done by observational studies, e.g., in large cohort

studies, by experimental studies, e.g., by conducting randomized controlled trials, or by quasi-experimental studies, e.g., by studying a certain policy change. If the results of such studies show a positive effect on behavior, then these theories are said to have predictive power of behavior. Growing evidence suggests that theory-based interventions lead to larger effects in health contexts than non-theory-based interventions [20-22].

Health behavior change techniques can be used to change individual-level determinants of behavior such as motivation, intention, and stress, and through them to modify the behavioral outcome of interest. Examples of such techniques are motivational interviewing, planning training, and mindfulness exercises. The effects of these techniques can been tested in experimental studies, e.g., to change physical activity in a lab setting, and in quasi-experimental studies, e.g., to change dietary behavior at the workplace. If the results of such experiments show a positive effect on behavior, then these behavior change techniques are called evidence-based. Interventions that are based on health behavior theory, and then systematically link theoretical constructs to evidence-based behavior change techniques, are hypothesized to be most effective of all [17].

Intention-behavior gap

Many individual-level health promotion interventions are based on a single theory, typically a prominent social cognition theory (e.g., protection motivation theory, theory of planned behavior) which describes behavior as the result of deliberative psychological processes, i.e., rational, well-reasoned, conscious thoughts [19]. While interventions based on such theories have generally been shown to be effective in changing behavioral intentions, they often stop short of changing actual behavior [23, 24]. A potential explanation for this shortcoming is that a substantive proportion of individuals hold stated intentions to perform a health behavior of interest, but for various reasons fail to act on them [25, 26]. For example, they may forget to enact their intentions, e.g., a planned visit to the gym slips from memory, or counter-intentional opportunities may come to light and compete with their existing intentions, e.g., a friend offers to come over and this is chosen over going to the gym [27]. Researchers have therefore sought to identify potential ways to promote better enactment of intentions in behavioral interventions, and minimize this 'intention-behavior gap' [28]. A further limitation of interventions based on social cognition theories is that they overlook spontaneous or impulsive behavior that is the result of automatic processes, not directly under the conscious control or even awareness of the individual, e.g., that a stressful phone call right before the planned gym visit triggers an impulsive abandonment of best laid plans, leading to an evening in [29, 30].

Dual process theories

It is increasingly recognized that researchers should base behavioral interventions on theoretical approaches that account for the multiple processes that lead to action. Dual process theories account for two types of processes that govern action: automatic processes, by which behavior is determined by impulses, and well-learned associations between context and action, and deliberative processes, by which action is determined by reasoned deliberation and the value attached to courses of action [30-33]. Some integrated theories further differentiate between two types of deliberative processes that lead to behavior: pre-intentional (motivational) and post-intentional (volitional) processes, proposing that intention enactment is facilitated in the volitional phase by a planning process [34].

The translation of intention into behavior is related to a person's self-regulatory skills [35-37], and self-control is considered to be a central feature of self-regulatory behavior [32, 38, 39]. Much in line with dual process theories, self-control has been proposed to influence health behavior in two main ways: through (a capacity to inhibit) impulse-driven, non-intentional responses, and by the deliberate alignment of intentions to attain long-term goals [40, 41]. Behavioral scientists in both health psychology and behavioral economics have been rapidly developing knowledge on the dual nature of cognitive processes that lead to health behavior, albeit from largely different perspectives: the two fields seldom conceptualize or operationalize theoretical constructs in the same ways, and with the same assumptions. Comparing the capacity of crucial constructs of dual process theories, such as self-control, to explain behavioral, cardio metabolic, and psychosocial risk factors can aid the selection of theoretical frameworks to build cardiovascular health promotion programs.

Tailored mHealth interventions

When it comes to the medium of interventions, web-based interventions have several advantages over face-to-face interventions: they are comparatively low cost, have a wide reach, and provide flexibility in intervention location and time [42, 43]. Access to web-based interventions may be further enhanced by delivering them via mobile phone optimized web browsers or dedicated mobile apps, instead of desktop optimized web browsers, called mHealth [44].

Interventions may provide an especially high social return in populations with an increased risk for CVDs later in life [45-48]. To have the intervention resonate with its intended audience, and thereby potentially increase intervention uptake and enhance behavior change and maintenance, one should assess the needs and preferences of the study population [49] and the perceived relevance of the theoretical framework

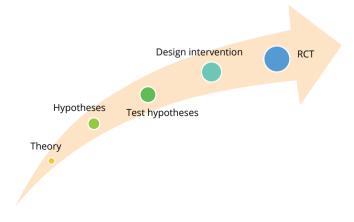
underlying the intervention [50] prior to the development of the intervention protocol. Qualitative studies are well suited for these tasks, given the broad, rich data that they provide. Resulting findings allow for the tailoring of intervention content.

Outline thesis and research questions

The overall aim of this thesis was to design, implement, and evaluate a theory- and evidence-based mHealth intervention to reduce cardiovascular risk (Figure 1). For this purpose, the following research questions were formulated:

- 1. How do theories and measures of self-control in psychology and economics relate to each other and to modifiable risk factors for CVDs?
- 2. What are the mHealth needs and preferences and the perceived physical activity determinants of a high CVD risk population?
- 3. How to design, implement and evaluate theory- and evidence-based cardiovascular mHealth promotion?

Figure 1. Research cycle of designing a theory- and evidence-based cardiovascular mHealth intervention.



OUTLINE THESIS

As a starting point for enabling the synthesis of insights on dual process theories of health behavior in health psychology and behavioral economics, **chapter 2** examines how self-control is conceptualized and measured in the two fields in a narrative review. Subsequently, **chapter 3** explores how various measures of self-control in health psychology and behavioral economics relate to each other and to various risk factors for CVDs, thereby testing the relevance of self-control dimensions for cardiovascular health promotion.

In chapter 4 women with an elevated risk for CVDs later in life, namely those who have experienced a hypertensive pregnancy disorder called severe preeclampsia, are asked about their needs regarding cardiovascular mHealth promotion: the extent to which they struggle to participate in cardiovascular health promoting behaviors, plan to make positive changes to these behaviors, and are interested in participating in an app-delivered intervention targeting these behaviors. To follow, these women's preferences regarding the delivery of app-based cardiovascular health promotion intervention are examined qualitatively, i.e., their wishes regarding app content, functionalities, and interface are thematically analyzed. In **chapter 5** the determinants of these women's physical activity are qualitatively assessed and thematically analyzed, thereby also examining the perceived relevance of the theoretical framework considered to serve as the basis of our planned intervention.

Chapter 6 presents the study design of an app-delivered, theory- and evidence-based physical activity intervention tailored to the needs, preferences, and perceived physical activity determinants of women with a prior hypertensive disorder of pregnancy. In **chapter 7**, the short-term efficacy of the eight-week intervention that used a three-condition randomized controlled trial (RCT) design and was delivered through a purpose-built app is analyzed. Program acceptability and program fidelity results are also presented.

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CHAPTER 2

Self-control in health behavior research across psychology and economics: a conceptual framework

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ARSTRACT

Background

Self-control is a key determinant of health behavior. There are a myriad of self-control theories and measures of self-control available in the prominent health behavior change disciplines of psychology and economics.

Aim

The aim of this study was to perform a narrative review of the theory and measurement of self-control in psychology and economics to create a common conceptual framework of self-control between the two fields

Findings

Differential research traditions have largely resulted in explanatory theories of self-control in psychology, and generally predictive theories of self-control in economics, and the proliferation of stated choice measures in psychology, and revealed choice measures in economics. Based on the reviewed literature, self-control can be conceptualized along three main characteristics: stability, process, and enactment. Along these three characteristics, six dimensions of self-control emerge.

Implications

The presented common conceptual framework of self-control in psychology and economics may enable intervention researchers to arrive at a more precise consensus of the dimensions of self-control and select theories and measurements most appropriate for their health outcome of interest. The empirical validity of the current framework needs to be evaluated by examining how dimensions of self-control relate to each other, to health behaviors, and to behavior change techniques.

Keywords: Self-control, psychology, economics, health behavior, intervention, narrative review.

BACKGROUND AND AIM

Despite being aware of the consequences of risky health behaviors, many people fail to meet relevant health behavioral guidelines [1, 2], thereby accumulating risk for non-communicable disease [3]. While interventions aimed at promoting participation in healthy behaviors are widespread, their effects are often moderate and short-lived [4]. A reason for the limitations of existing interventions may be their lack of theoretical basis [5-7].

Growing evidence suggests that basing behavior change interventions on theory leads to increased efficacy in health contexts [8-10]. However, selecting an appropriate theory as a basis for an intervention can be challenging given the large number of existing theories, and inconclusive evidence on if and how they differ from each other and their ability to foster behavior change [6]. To aid the selection of an appropriate theory-base for interventions, scholars have advocated for the comparison of theories, and theoretical constructs therein [11].

Once a theoretical construct is selected during the intervention design phase as an important predictor of the health behavior of interest, a measure of the construct is needed in order to be able to capture changes occurring to it due to the intervention, and to be able to examine its relation to health behavior. However, the array of empirical measures available for a given theoretical construct can be dizzying, with little guidance on if and how they differ from one to the other. To aid the selection of an appropriate measure, the comparison of multiple measures is recommended [12].

Selecting an appropriate theory and matching measurement device is even more challenging when conducting interdisciplinary research. Interdisciplinary research holds the promise of building better interventions by for example providing broader context, combining knowledge across disciplinary boundaries, and finding ways to address issues that span across multiple fields of research [13]. However, different fields may theorize about and measure key constructs differently.

The concept 'self-control' has been identified as an important predictor of behavior in many domains, including health, and serves as a prominent example of a dispersed literature between two main fields of inquiry relevant to health behavior change research: psychology and economics [14-17]. The relevance of combining insights on self-control from these two fields – such as the observation from psychology that people often make irrational choices, and the understanding from economics that incentives play a defining role in behavior – is compelling. The two fields have a variety

of theories and a plethora of measures of self-control. However, without a common conceptual framework to evaluate them, it is unclear where exactly they overlap and differ. The scattered nature of the self-control literature has been previously recognized, and some integration attempts have been made within fields, both regarding theory (e.g. [18-25]) and measurement (e.g. [26-31]). In order to be able target self-control more precisely in health behavior change interventions using insights from psychology and economics, a common conceptual framework of self-control is needed [32]. However, the literature on creating such a framework is still nascent, with only one study to date having attempted to do so [33]. Therefore, our aim is to add to this still limited literature. We do this by performing a narrative review of the theory and measurement of self-control in psychology and economics to create a common conceptual framework of self-control between the two fields.

Throughout the review we refer to the two main fields of inquiry as psychology and economics. While most of the evidence discussed in this review comes from the subfields that investigate health behavior (health psychology and behavioral economics), occasionally other evidence is included from the broader fields of psychology and economics.

Narrative review of the theories and measurement of self-control in psychology and economics

What are the main theories of self-control in the two fields?

Several self-control theories in psychology can be classified as dual process theories, discounting theories, feedback loop theories, and limited resource theories. So-called dual process theories describe self-control as a shift between two types of processes: an impulsive process reacting to visceral influences triggered by the environment, and a deliberative process guiding behavior away from impulses with effort [34, 35]. The main feature of discounting theories is their temporal element, i.e., self-control failures arise when short-term gratification is preferred by a current self, which would later be regretted by a future self as it has long-term costs [36-38]. The main feature of feedback loop theories is the cycle of evaluation of behavior compared to a stable or dynamic standard imposed by the self or the environment. After the comparison is completed, self-control is used to adjust the behavior, either consciously or non-consciously, to lessen the discrepancy between the behavior and the standard [39]. Finally, the main feature of limited source theories is that they describe self-control as a limited resource, whether governed by a finite reservoir of a self-control resource, or by a lack of motivation, attention, or effort available for subsequent attempts at self-control [40]. Generally, psychological theories of self-control posit that resisting temptation is

Table 1. Examples of theories of self-control in each category per discipline.

| Psychology | Economics |
|--|---|
| <u>Dual process theories</u> Hot/cool model [14, 52-54] Willpower is necessary for the cool system to be dominant and override the hot system's impulses and habits. | <u>Dual-self theories</u> Hot/cold state models [58] Individual is either in a hot or cold state at a single moment in time. Hot states, during which self-control failures can occur, are triggered by environmental cues. |
| Impulses versus reflective influences framework [55] Health behavior is determined by reflective and impulsive influences, and situational or dispositional moderators shift the weight between reflective and impulsive influence. The goal conflict model [56, 57] Food intake of restrained eaters is characterized by a conflict between two chronically accessible incentives or goals: eating enjownent and weight control. | Models of costly self-control [59-63] Impulsive processes are the default decision makers. Deliberative processes can exert influence on decisions to avoid self-control failures, but incur a cost to do so, i.e., exertion of self-control. Self-control failures result when this cost is too high to make it worthwhile for the deliberative processes to intervene. |
| Discounting theories Discounting model [36-38] Self-control failures arise when short-term gratification is preferred by a current self, which would later be regretted by a future self as it has long-term costs. | Hyperbolic discounting theories Hyperbolic discounting [46, 48, 64-66] (Quasi-)hyperbolic discounting engenders present-biased preferences (i.e., the phenomenon whereby an individual, when choosing between two future moments, gives stronger relative weight to the earlier moment when both moments are closer to the present [46]). Present bias, in turn, can lead to time inconsistency (i.e., self-control failures), which is where an individual fails to follow through on ex-ante preferences or plans [48]. |
| Eeedback loop theories Cybernetic model/control theory [67, 68] Self-regulation is a regulatory cycle of comparing the self against a relevant standard and reducing possible discrepancy. Self-awareness increases the salience of a standard, thereby increasing the likelihood of adjusting behavior to meet this standard. | No closely related category in economics |
| Common sense model of self-regulation [69, 70] People use 'common sense' to understand their illness, i.e., they develop potentially irrational representations of and coping behaviors with their health problem. This is a self-regulation process that evolves over time, causing revisions to the original illness representation and coping behaviors as the illness progresses. | |

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| Psychology | Economics |
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| No closely related category in psychology | Unitary-self theories. Temptation model [71, 72] Resisting choosing a tempting option invokes temptation costs, which can lead to self-control failures. Individuals may prefer to limit their future options to avoid suffering from temptation costs, even if the temptations would not be strong enough to lead to a failure of self-control (i.e. choosing the tempting option). |
| | |

One theory has been published in economics which mathematically formalizes absence of any other theories of this nature in economics (to the best of our he self-regulatory strength model from psychology. However, due to the knowledge), we do not describe limited source theories as a category of Self-regulatory strength/ego depletion/resource model [80] economic theories of self-control. Exerting self-control to change behavior requires willpower, a reservoir that can Self-regulatory strength/ego depletion/resource model [40, 73] Cognitive control theory [74] imited source theories be depleted.

Self-regulatory strength depletion can be understood in cognitive control terms. ec Different parts of the brain are linked to monitoring potential or actual unwanted outcomes. Sufficient task motivation is necessary for the operation of this circuit.

Process model [75-78]
Self-control at time 1 causes a temporary shift in motivation and attention, which undermines self-control at time 2.

Integrative model of effortful control [79]

The main cause of mental fatigue in long and high-demanding tasks is the intrinsic cost of weakening connectivity of neural networks underpinning effortful control. Effort reflects three different interrelated aspects of completing an effortful task: the mechanism of completion, the output of completion, and feeling/affect during completion.

2

effortful. For examples of theories in each category see Table 1.

Economics theories of self-control largely fall into the categories of dual-self theories. hyperbolic discounting theories, and unitary-self theories. Dual-self theories describe a conflict between selves that coexist at a single point in time, i.e., a deliberative self would like to engage in a particular action, but an impulsive self would like to engage in another [41, 42]. Most of these theories posit that resisting temptation incurs selfcontrol costs, i.e., is effortful. This category of theories contain much common conceptual content with psychological dual process theories [43]. Hyperbolic discounting theories in economics describe a conflict between selves that exist at different time points, i.e., the preferences of the current self regarding future behavior may conflict with the preferences of the future self, leading to present bias which, in turn, can lead to time inconsistency [36, 42]. Hyperbolic discounting theories in economics are essentially identical to discounting theories in psychology; however, they remain used by each field according to its own, distinct methodology (see measurement section for detail) [44, 45]. Hyperbolic discounting theories distinguish between sophisticated agents, i.e., people aware of future self-control problems, and naïve agents, i.e., people not aware of future self-control problems; and posit that sophistication is a prerequisite for avoiding tempting situations [46-48]. Although a similar concept to sophistication (i.e., awareness of future self-control problems) is not explicitly mentioned in the psychology literature, awareness is assumed to be a prerequisite for avoiding temptations as part of the process of deliberative action [49-51]. Finally, economics also describes unitary-self theories, where there is a single decision-maker and thus no conflict between selves [42]. In these theories, resisting a tempting option invokes temptation costs, which can lead to self-control failures. Individuals may prefer to limit their future options to avoid suffering from temptation costs, even if the temptations would not be strong enough to lead to a failure of selfcontrol. For examples of theories in each category see Table 1.

What are the main measures of self-control in the two fields?

There are over one hundred psychological measures of self-control, which can be broadly categorized into self-report or informant-report questionnaires, delay of gratification tasks, and executive function tasks [12]. Researchers in psychology most often measure self-control by eliciting stated choices. Stated choice measures collect data by presenting hypothetical situations and eliciting hypothetical choices, which do not result in tangible outcomes for the participant. Using validated questionnaires that are either filled in by the participant about themselves (self-report), or by important others in their environment about the participant (informant-report) fall under this category. Another way to collect data is by eliciting revealed choices. Revealed choice

measures come in two forms: choices are made in a questionnaire or a lab setting with tangible outcomes for the participant; or choices are made in real-life. Delay of gratification tasks and executive function tasks are revealed choice tasks. Delay of gratification task typically require individuals to forgo a smaller but immediate reward in exchange for receiving a larger reward in the future. Executive function tasks assess higher-order cognitive functions performed by the frontal lobe of the brain. For examples of measures in in each category see Table 2.

In economics, self-control failures are most commonly inferred from revealed choice measures of either time inconsistency or present bias [81]. Present bias is the most common explanation for time-inconsistent choices [42, 82]. In economics, self-control problems are even often equated to, or defined as, present bias [27, 83], for example when inferring self-control from Money Earlier or Later tasks in lab experiments with tangible outcomes [84]. A recent trend has been to measure time inconsistency directly, using time-yoked consumption or work effort experiments. During such measurements, plans or preferences for consumption/work effort at a future date are elicited from participants, and then compared to the participant's actual behavior at that future date. Occasionally, time-inconsistency and present bias are measured from observational data. An oft-cited example is the observation that many people buy a gym membership, which signals their intent to regularly use the gym, but subsequently fail to follow through on that intention. Money Earlier or Later tasks are also used in questionnaires to reveal present bias using stated choice methods, and a smaller literature adapts Money Earlier or Later tasks to health and other non-monetary domains to get stated choice measures of present bias (i.e., without tangible outcomes). For examples of measures in each category see Table 2.

What are the main differences in research traditions between the two fields?

While currently well aligned on topics concerning optimizing health behavioral interventions, traditionally, the fields of psychology and economics have developed from largely different ambitions. It follows that methodological traditions in psychology and economics have given rise to a differential focus in theorizing about self-control. Psychology has a long tradition of investigating why self-control occurs, following the overarching goal of the field to explain human behavior and cognition. This has resulted in the proliferation of explanatory, largely context dependent models of self-control. In contrast, economics models of self-control typically investigate when self-control failures will occur, likely due to the general goal of economics being to predict optimal, i.e., utility maximizing, behavior in a mathematically tractable way. This has led to the development of predictive, generalizable models of self-control.

A related substantial difference between the fields in terms of the measurement of self-control is whether they think that asking people to report on their experience is a

 Table 2. Examples of measures of self-control in each category per discipline.

| Psychology | Economics |
|--|--|
| Revealed choice measures Delay of gratification tasks These task typically require individuals to forgo a smaller but immediate reward in exchange for receiving a larger reward in the future, such as the delay of gratification task [84], discount rate estimation [86] and the marshmallow test | Revealed choice measures Present bias measurement using Money Earlier or Later tasks Present bias make a series of choices between smaller sooner and larger later monetary amounts, from which their present bias is measured [91-93]. |
| [87]. Executive function tasks | Present bias and time inconsistency measurement using time-yoked consumption/ work effort experiments Plans or preferences for consumption/work effort at a future date are elicited |
| These task, for example the lowa gambling task [88], Stroop task [89] and the Go/No-go task [90], assess higher-order cognitive functions performed by the frontal lobe of the brain. | from participants, and then compared to the participant's actual behavior at that future date [94-96]. |
| | Present bias and time inconsistency measurement from longitudinal observational data |
| | Data on consumption patterns over time [97-99], or other real-life decisions (e.g., preventive health [100], job search [101]) has been used to measure present bias and time inconsistency. |
| | Sophistication Sophistication has been measured by demand for commitment devices both in experimental [94, 102] and observational studies [100]. More recently, time-yoked consumption/work effort experiments have measured sophistication more directly using predictions of future behavior [96]. |
| <u>Stated choice measures</u> Self-report or informant-report questionnaires The narticipant or important others in their environment are asked to report on | <u>Stated choice measures</u> Self-report questionnaires Present hias measurement in the monetary domain from Money Farlier or I ater |
| the participant's self-control by for example using the Barratt Impulsiveness Scale [103], the GRIT Scale [104], the Risk Propensity Scale [105], the Brief Self-control Scale [106], the BIS/BAS [107], and the AS-36-3 Scale [108]. | tasks [81] and hypothetical scenarios [109, 110]. Present bias measurement in health and other non-monetary domains from Money Earlier or Later tasks [111]. |

valid (or sometimes the only) way of measuring cognitive processes, such as self-control. In psychology, self-report measures are generally accepted as valid, leading to the predominant use of so-called stated choice measures. On the other hand, economists generally believe that people cannot report on their cognitive processes accurately, which is why they are inferred from behavior instead, resulting in the predominant use of so-called revealed choice measures. An important result is that while in psychology self-control is measured directly, in economics, failures of self-control are inferred from time-inconsistent choices and/or present bias.

In spite of these important differences in theorizing about and measuring self-control, we posit that the theoretical and measurement traditions of self-control in the two fields can be integrated into a common conceptual framework.

Conceptual framework of self-control in psychology and economics

Based on the narrative review of the theory and measurement of self-control in psychology and economics above, we posit that there are three recurring characteristics that seem essential to precisely conceptualizing self-control: *stability, process,* and *enactment*. Along these three characteristics, we identify six dimensions of self-control (Figure 1).

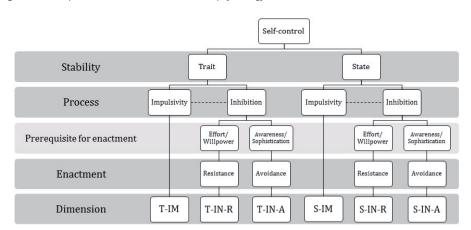


Figure 1. Conceptual framework of self-control in psychology and economics.

How do theories of self-control conceptualize stability, process, and enactment in the two fields?

When it comes to the stability of self-control, psychological theory makes a distinction between trait self-control, i.e., relatively stable across situations and over time [112, 113], and state self-control, which is assumed to vary across situations and time [14] and to be susceptible to influences such as mood [114, 115], working memory capacity [116, 117], motivation [75-77, 118], attention [75-77] previous attempts at self-control [119, 120], and the environment [121]. While economics theory does not explicitly differentiate between self-control as a trait and self-control as a state, the most common explanation for failures of self-control, present bias, is generally treated as a trait, i.e., a stable tendency to overweight immediate outcomes [36, 82]. However, the treatment of self-control as a trait is not universal: in some economic dual-self and unitary-self models, self-control has state characteristics in that it can vary across time and situations (see Table 3 for examples).

Psychological theory differentiates between impulsive and inhibitory processes of self-control. Some hypothesize that a higher degree of impulsive urges to succumb to temptation will require a higher level of inhibition to stay on course [12, 14]. Others consider impulsivity and inhibition to determine behavior independently of each other [122]. While self-control is predominantly treated as an inhibitory process in the economics literature due to the focus on (quasi-)hyperbolic models and the present bias they model, a number of dual- and unitary-self models allude to inhibitory and impulsive processes independently influencing self-control enactment (see Table 3 for examples).

In psychological theory, people are typically assumed to enact self-control in two different ways: exercising willpower to resist when a tempting situation presents itself, and anticipating future tempting situations and avoiding these situations [123-125]. Resistance and avoidance are generally thought to rely on inhibitory processes, while the level of impulsivity is often assumed to determine the amount of inhibition that is necessary to control oneself [124]. Enacting self-control relies on prerequisites: to resist temptations, one must exert effort, and to avoid temptations, one must be aware of temptations in the environment in the first place.

In economics, the predominance of (quasi-)hyperbolic models has also meant that economics has focused mainly on avoidance as a means to enact self-control, where the prerequisite to avoid temptations is sophistication. In contrast, several dual- and unitary-self models incorporate both avoidance and resistance, where resistance is modelled as incurring an effort cost (i.e., reducing short-term utility) to resist a temptation. For examples of theories in each dimension of self-control see Table 3.

Table 3. Examples of theories of self-control per self-control dimension as identified by the conceptual framework.

| Self-control dimension | Examples of psychology theories | Examples of economics theories |
|---------------------------|---|--|
| T-IM | Hot/cool model [14, 52-54], Impulses versus reflective influences framework [55] | Unitary-self theories [71, 72], dual-self theories [58-60, 126] |
| T-IN-R | Hot/cool model [14, 52-54], Impulses versus reflective influences framework [55], Cybernetic model/control theory [67, 68], Common sense model of self-regulation [69, 70] | Unitary-self theories [71], dual-self theories [59, 60, 126] |
| T-IN-A | Hot/cool model [14, 52-54], Impulses versus reflective influences framework [55], Discounting model [36-38], Cybernetic model/control theory [67, 68], Common sense model of self-regulation [69, 70] | Hyperbolic discounting theories [46, 48, 63-66], unitary-self theories [71, 72], dual-self theories [58-60, 126] |
| S-IM | Hot/cool model [14, 52-54], Impulses versus reflective influences framework [55] | Unitary-self theories [72], dual-self theories [58, 60, 126] |
| S-IN-R | Hot/cool model [14, 52-54], Impulses versus reflective influences framework [55], Cognitive control theory [74], Process model [75-78] | Dual-self theories [60, 126] |
| S-IN-A | Hot/cool model [14, 52-54], Impulses versus reflective influences framework [55], Cognitive control theory [74], Process model [75-78] | Unitary-self theories [72], dual-self theories [58, 60, 126] |

How do measures of self-control conceptualize stability, process, and enactment in the two fields?

The measures used in psychology and economics largely mirror the characteristics derived from the overview of theories of self-control in psychology and economics. In terms of stability, there are several psychological measures of trait and state self-control, although measures of trait self-control are more developed than those for state self-control [127]. In economics, measures of self-control (usually measures of present bias and time inconsistency [41, 81, 84]) are used but not explicitly conceptualized as measuring trait self-control. Whereas several psychological measures distinguish between impulsive and inhibitory processes [12], economics measures of self-control tend to focus on inhibitory processes. In terms of enactment, multiple measures in psychology assess indicators of resisting temptation as well as avoiding temptation, while economics measures of self-control predominantly assess indicators of avoiding temptation. For examples of measures in each dimension of self-control see Table 4.

Table 4. Examples of measures of self-control per self-control dimension as identified by the conceptual framework.

| Self-control dimension | Examples of psychology measures | Examples of economics measures |
|------------------------|---|---|
| T-IM | lowa gabling task [88], Brief Self-control Scale (impulsivity sub-scale) [106], Barratt Impulsiveness Scale [128], Risk Propensity Scale [105] | No closely related measure in economics |
| T-IN-R | lowa gabling task [88], Brief Self-control Scale (inhibition sub-scale) [106], GRIT [104], AS-36-3 [108] | No closely related measure in economics |
| T-IN-A | lowa gabling task [88], Discount rate estimation [86], Brief Self-control Scale (inhibition sub-scale) [106], AS-36-3 [108] | Present bias measurement using Money Earlier or Later experiments [81, 91-93, 111] and hypothetical scenarios [109, 110] Present bias and time inconsistency measurement using time-yoked consumption/work effort experiments [94-96] Present bias and time inconsistency measurement from longitudinal observational data about consumption expenditures over time [97-99] and other real-life decisions (e.g., preventive health [100], job search [101]) |
| S-IM | *State self-control [129-131] | No closely related measure in economics |
| S-IN-R | *State self-control [129-131] | No closely related measure in economics |
| S-IN-A | *State self-control [129-131] | No closely related measure in economics |

^{*} The measurement of state self-control is an emerging field: not enough empirical evidence is available to differentiate between the dimensions they measure.

In sum, when it comes to the stability of self-control, a distinction can be made between trait self-control, relatively stable across situations and over time, and state self-control, varying across situations and time. Concerning types of processes, we can differentiate between impulsive processes of self-control, reacting to visceral influences triggered by the environment, and inhibitory processes of self-control, guiding behavior with effort. Finally, that self-control can be enacted in two main ways: a person can come across tempting situations and exercise willpower to resist temptation, or can anticipate future tempting situations and avoid them.

Implications

Based on our narrative review of the literature on the theory and measurement of self-control in psychology and economics, we have created a common conceptual framework of self-control along three characteristics: stability, process, and enactment. Our review can aid intervention researchers to pre-specify during the intervention design phase the dimensions of self-control that they need to target. By being aware

of the theoretical and measurement implications of targeting certain self-control dimensions, they may be able to create interventions that are more effective in changing behavior through self-control. In the following paragraphs we discuss some implications of our findings.

Implications for theory refinement

While our review was able to identify recurring characteristics in theories of self-control, often, those characteristics were implicitly rather than explicitly described. For example, hyperbolic discounting models describe stable self-control tendencies, i.e., trait self-control, yet this is not formulated as such. The critical evaluation of self-control theories remains vital, and revisions should be made as needed – for example, as has been the case recently with the self-regulatory strength model [132, 133].

Implications for measurement refinement

While our review was able to identify the characteristics that emerged from the theory of self-control in measures of self-control as well, several knowledge gaps remain. Firstly, even though some measures posit to capture a certain type of characteristic, further validation remains necessary, as is the case in the guestion of whether the lowa gabling task captures 'hot', 'cold', or both processes [134]. Further, as several measures are hypothesized to capture the same dimension of self-control, it is possible that the dimensions of self-control that we have identified need to be further separated into sub-dimensions. Alternatively, if empirical investigation would reveal that the measures relate strongly to each other, redundancies of measures might be revealed. Previous research has found the size of correlations among different self-control measures to vary considerably [28, 122] – similar evaluations of measures from both psychology and economics are needed. Finally, the benefits and drawbacks of types of stated and revealed choice methods need to be investigated. The existing evidence from economics suggests that the difference between hypothetical stated choices and stated choices that are incentivized (i.e., akin to revealed choices) is not large (unless the stakes are very large), but that making choices consequential can reduce noise in responses [81, 135-1371. More empirical evidence is needed in this regard, particularly in larger and more representative samples and specifically for self-control measures [81].

Implications for matching theory to measurement

Ideally, researchers proposing theories of self-control would also immediately describe how to measure the theoretical constructs therein. Unfortunately, this is not always the case. This is exemplified by for example economics theories (implicitly) describing all six dimensions of self-control but focusing the measurement of self-control on one dimension. Therefore, while our review may aid the selection of theory, and the

subsequent selection of a measure of a self-control dimension, it remains unknown whether theory and measurement 'match' – expert review panels may help identify indicators of a good fit.

Implications for behavior change

The validity of our proposed framework should be further examined by assessing which dimensions of self-control are the most important predictors of which health behaviors [138]. To take it further, it should be assessed how dimensions of self-control can best be targeted to change a certain health behavior by applying specific health behavior change techniques in intervention programs [32]. For instance, targeting trait and state self-control specifically would likely have important health consequences, as trait and state self-control have been found to predict health behavior independently [138], and to be independently associated with long-term health outcomes [139]. If inhibitory processes and impulsive processes are assumed to contribute independently to self-control enactment, targeting them precisely could also achieve independent effects on health behavior [12, 14, 85, 106]. The finding that avoiding temptation may be more effective than resisting temptation in following through with plans of healthy behavior [138] is further preliminary evidence that it could be impactful to pre-specify the dimension(s) of self-control that intervention elements aim to target.

Limitations

Some weaknesses of the current review should be considered when interpreting the results. The choice of evidence for this paper was strategic rather than exhaustive, i.e., the included literature was selected to shed light on the parallels and differences in research on self-control in the two assessed fields. An assessment of risk of bias of the evidence included in this study or methodological limitations was not performed. Second, as not enough empirical evidence is available to differentiate between the dimensions that state self-control measures assess, the differentiation between them remains theoretical in nature. Finally, the current review only assessed the literature on self-control in psychology and economics, thereby having a limited scope to make generalizations about the conceptualization of self-control in other fields, such as consumer research, marketing, and neuroscience.

Conclusion

Differential research traditions have largely resulted in explanatory theories of self-control in psychology, and generally predictive theories of self-control in economics, and the proliferation of stated choice measures in psychology, and revealed choice measures in economics. Based on the reviewed literature, self-control can be conceptualized along three main characteristics: stability, process, and enactment.

Along these three characteristics, six dimensions of self-control emerge. The presented common conceptual framework of self-control in psychology and economics may enable intervention researchers to arrive at a more precise consensus of the dimensions of self-control and select theories and measurements most appropriate for their health outcome of interest. The empirical validity of the current framework needs to be evaluated by examining how dimensions of self-control relate to each other, to health behaviors, and to behavior change techniques.

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CHAPTER 3

How do trait self-control dimensions relate to modifiable risk factors for cardiovascular disease?

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ARSTRACT

Background

Unhealthy lifestyle behaviors and accompanying cardio metabolic ill-health are modifiable risk factors for cardiovascular disease (CVD). Trait self-control is an important predictor of healthy lifestyle behaviors and cardio metabolic health. Evidence is accumulating that trait self-control consists of at least two dimensions: impulsivity and inhibition

Purpose

The aim of the current study was to assess how various measures generally considered to capture impulsivity and inhibition relate to each other and to modifiable behavioral and cardio metabolic risk factors for cardiovascular disease.

Method

Data was analyzed from 4741 adults (18-65 years) who participated in the Lifelines Cohort Study and the additional LIFESTYLE Study. Participants self-reported their inhibition, as measured by the Brief Self Control Scale (BSCS), Grit Scale short-form (Grit-S), the Delaying Gratification Inventory short-form (DGI), and a measure for Present Bias (PB) often adopted in economics. Participants also self-reported their impulsivity, as measured by the Abbreviated Impulsiveness Scale (ABIS) and the Risk Propensity Scale (RPS). Respondents further reported their moderate to vigorous physical activity (MVPA), sedentary behavior, fat and sugar intake, and sleep quantity. Measurements to calculate body mass index (BMI), waist-hip ratio (WHR), and pulse pressure were collected during a standardized visit to the Lifelines clinic. Data were analyzed using a Pearson's correlation matrix and linear regressions.

Results

In general, different measures of inhibition were moderately associated with each other (*r* varying between .55 and .44), and several measures of inhibition and impulsivity related to each other moderately (*r* varying between -.58 and -.45). Regression analysis that included all trait self-control and confounder variables showed that higher inhibition and impulsivity were associated with higher physical activity and lower sedentary behavior. Furthermore, higher inhibition was associated with lower fat and sugar intake and higher sleep quantity. Higher inhibition and impulsivity were also associated with lower BMI. However, generally, inhibition was inconsistently related to cardio metabolic risk factors. The variance accounted for by trait self-control measures was small for all outcomes examined.

Discussion

Our findings support for the notion that trait self-control is a multidimensional construct, consisting of at least two dimensions, inhibition and impulsivity. We find both higher inhibition and impulsivity to be consistently associated with healthier outcomes, with inhibition having a stronger association overall. Our results indicate that both inhibition and impulsivity influence health independently and simultaneously.

Conclusions

Intervention designers aiming to identify individuals at risk of an intention-behavior gap concerning physical activity, sedentary behavior, fat and sugar intake, and sleep, may want to use measures of trait inhibition. To better understand the causal relationships between the variables examined in the current study, longitudinal investigation of these associations is warranted in the future.

INTRODUCTION

It is a priority public health concern to decrease risk for a leading cause of mortality and disability worldwide: cardiovascular diseases (CVDs) [1]. The number of people with CVDs and associated costs are only expected to increase in the future [2, 3]. A substantial proportion of CVD morbidity and mortality is preventable, as many risk factors of CVD are modifiable [4]. Insufficient physical activity, sedentary behavior, high fat intake, high sugar intake, and insufficient or too much sleep are all behavioral risk factors for CVD [4-7]. Modifiable cardio metabolic risk factors for CVD, such as overweight and (abdominal) obesity and high blood pressure, often go hand in hand with behavioral risk factors for CVD [8].

Interventions targeting modifiable behavioral and cardio metabolic risk factors for CVD have become common worldwide [9]. Such interventions are often based on wellestablished health behavior theories that attempt to explain individuals' behavior based on predictors such as knowledge, attitudes, and motivation [10]. These theories reliably succeed at predicting behavioral intention, but regularly fail to predict actual behavior, leading to the infamous 'intention-behavior gap' [11]. Indeed, the effects of health behavior interventions based on these theories are generally moderate and short-lived [9]. A potential explanation for the failure of these theories, as well as the interventions based upon these theories, may be their overestimation of conscious, rational, deliberative processes, and underestimation of nonconscious, automatic, impulsive processes involved in health behavior [12, 13]. To account for both types of processes, a relatively new string of theories describes two systems at work in the brain - one automatic system responding to impulses from the environment, and a deliberative system cool-headedly working towards long-term goals [14-20]. The role of self-control in the extent to which the impulsive and deliberative systems are active is likely pivotal [11, 17].

Indeed, self-control has been found to be an important predictor of modifiable risk factors for CVDs [17, 21-23]. Self-control is investigated as an important determinant of behavior in two main fields of health behavior intervention design, i.e., psychology and economics, albeit according to their own methodological traditions and research perspectives [24]. The psychological literature conceptualizes trait self-control as the relatively stable individual tendency to react to visceral impulses in the environment and the capacity to deliberately regulate behavior, thoughts, and emotions [17, 25, 26]. In economics, the predisposition for self-control *failures* is generally treated as a trait and is conceptualized as the stable tendency to overweigh immediate outcomes [27, 28]. The central role of trait self-control in engaging in health promoting behaviors is

virtually uncontested [22, 29], and that its field of study is far developed means that the validity and reliability of measurement instruments are generally considered high [30-35]. The persistent nature of trait self-control, in contrast to state self-control, which is assumed to vary across situations and time [17], is likely to make it especially relevant for the lifetime reduction of CVD risk, which accumulates over time [36, 37]. However, trait self-control is less of a feasible target for interventions than state self-control precisely because it is relatively stable across situations and time: social-cognitive variables that mediate its effects, such as motivation, are easier to change. On the other hand, measures of trait self-control may be used to identify individuals who would likely have difficulties in converting their healthy intentions into behavior [22, 29]. Understanding how measures of trait self-control relate to modifiable risk factors for CVDs would allow intervention designers to identify 'at-risk' individuals concerning their health outcome of interest, and subsequently tailor intervention content to these people's needs, such as provide them with the behavior change technique of planning [38]. However, trait self-control measures used both within and between the fields of psychology and economics vary [17, 21-23], correlations between different measures of trait self-control vary [39, 40], and associations between different measures of trait self-control and modifiable risk factors for CVD vary [17] in ways that do not give a clear picture of the relative importance of trait self-control dimensions for the reduction of CVD risk.

In line with dual process theories [30], the literature on trait self-control differentiates between inhibition and impulsivity. Some hypothesize that they independently influence whether healthy behavior will be enacted [22, 29]. Others posit that inhibition may be relatively more influential for behaviors that largely rely on purposeful action, such as engaging in physical activity, and that impulsive processes may be relatively more important for behaviors that are generally thought to be triggered by automatic processes, such as consuming foods with high fat and sugar content [41]. It is also possible that deliberative and impulsive processes do not act independently of each other: a higher degree of impulses to succumb to temptation may require a higher level of deliberation to stay on course of intended action [17, 31, 39, 42, 43]. Preliminary evidence suggests that trait self-control may be a multidimensional construct, with different measures capturing various dimensions, and with different dimensions being stronger predictors of some health behaviors than others [40, 44]. Therefore, in practice, both types of trait self-control processes may have an influential role in both behaviors that largely rely on purposeful action, and behaviors that are generally thought to be triggered by automatic processes [40, 45]. However, the existing evidence is scant and limited by small sample sizes, and examines only a small number trait self-control measures' relation to modifiable risk factors for CVD.

In sum, whereas the trait self-control literature is conceptually rich [24], there are two main unresolved empirical questions that have significant implications for health behavior intervention design: how do measures of two quintessential dimensions of trait self-self-control, impulsivity and inhibition, 1) relate to each other and 2) to various modifiable risk factors for CVD? This study aims to contribute to answering these questions by (i) assessing a large sample of adults in a population-based cohort, (ii) utilizing a wide range of measures of inhibition and impulsivity, (iii) exploring the interrelationships between these measures, and (iv) examining whether these measures relate differentially to a wide range of behavioral and cardio metabolic risk factors for CVD.

METHOD

Study design

This study was conducted among participants of the Lifelines Cohort Study. The Lifelines Cohort Study is a prospective population-based study examining health and health-related behaviors of 167,000 persons living in the North of the Netherlands. Further detail on the cohort and recruitment is provided elsewhere [46, 47].

Fthics

This study adheres most strictly to all applicable legal, ethical, and safety provisions of the Netherlands and the EU. The study was conducted in accordance with the principles of the Declaration of Helsinki [48]. The Medical Ethics Review Board of the University Medical Center Groningen has approved the Lifelines Cohort Study (METc 2007/152), and the LIFESTYLE Study (METc-2019-464). Written informed consent was obtained from all participants.

Study population

In Lifelines data collection waves 1A (2007-2014, n=151,113) participants completed questionnaires on a wide range of topics including demographics, health, health behavior, and psychosocial aspects, and they visited the Lifelines clinic for the standardized collection of various objective measurements. A random subsample of adults aged 18-65 who had consented to be contacted by email about add-on questionnaires, such as our LIFESTYLE study, was approached to participate in an additional data collection on psychological factors related to health behavior (n=55,500). Data collection for the current study consisted of two batches: some participant took part between October and November 2019 (n=15,000), others between February and April 2021 (n=40,500). For all participants, data was collected in two waves for the

current study: baseline (t_0) and follow-up 1 (t_1 = t_0 + 1 week). Of the 55,500 (15,000+40,500) adults invited to participate in the current study, 10,169 (3,173+6,996) completed the baseline questionnaire (18%). These 10,169 participants were invited to fill in the follow-up 1 questionnaire; 8,453 (2,366+6,087) of them completed the follow-up 1 questionnaire (83%).

Study population

The current study is based on LIFESTYLE follow-up 1 data, unless otherwise stated. This study used data on 4,741 participants who had no missing data on any predictor and confounder variables. Compared to participants in LIFESTYLE follow-up 1 who had some missing data on predictor and confounder variables and were therefore excluded from the main analyses (n=3712), the study population (n=4741) was more likely to be female (t=163.04, df=1, p<.001), was younger (t=13.78, df=8326, p<.001), was more likely to have been born in the Netherlands (χ^2 =25.78, df=1, p<.001), was less likely to be in a relationship (χ^2 =4.09, df=1, p>.05), was higher educated (χ^2 =305.86, df=2, p<.001), and had better self-rated health in response to the question "How would you rate your health, generally speaking?", rated from poor to excellent on a 5-point scale (χ^2 =96.95, df=4, p>.001). The size of these differences were small, e.g. on age (mean=51.08 (SD=11.77) versus mean=47.65 (SD=10.84)) having been born in the Netherlands (3,514 (95% of total sample) versus 4,654 (98% of total sample)), and self-rated good to excellent health (3331 (90% of the total sample) versus 4385 (92.5% of the total sample)).

Compared to participants in Lifelines data collection wave 1A, including those who participated in LIFESTYLE follow-up 1 but did not have complete responses on predictor and confounder variables (n=146372), the study population (n=4741) had a similar gender distribution (χ^2 =.17, df= 1, p>.05). However, the study population was older (t=-16.25, df=151111, p<.001), was more likely to have been born in the Netherlands (χ^2 =25.78, df=1, p<.001), was more likely to be in a relationship (χ^2 =11.08, df=1, p>.001), was higher educated (χ^2 =420.04, df=2, p<.001), and had better self-rated health (χ^2 =150.84, df=4, p>.001). The size of these differences were again small, e.g. age (mean=44.50 (SD=13.19) versus mean=47.65 (SD=10.84)), having been born in the Netherlands (141,802 (97% of total sample) versus 4,654 (98% of total sample)), and self-rated good to excellent health (128,878 (88% of the total sample) versus 4,385 (92.5% of the total sample)).

Measures of inhibition

Albeit not always explicitly described as such, several measures of trait self-control are assumed to capture the inhibitory dimension of trait self-control. Participants self-

reported their inhibition using the psychological instruments of the Brief Self Control Scale short-form (BSCS) [30, 31], the Grit Scale short-form (Grit-S) [33] and the Delaying Gratification Inventory short-form (DGI) [341. The BSCS consists of two subscales, i.e., Self-discipline (3 items, Cronbach's alpha (α)=.63), and Impulse control (4 items, α =.64). A composite sum score was calculated based on the two subscales (q=.71) with a higher (sum) score indicating higher inhibition [30]. Grit-S is a one factor structure instrument (8 items, α =.76), with a higher (mean) score indicating higher inhibition [33]. Similarly, the DGI short-form has one factor (10 items, α =.63), with a higher (sum) score indicating higher inhibition [34]. The economic inhibition measure, i.e., measuring present bias from choice lists (PB), was administered during the baseline wave of the LIFESTYLE Study [49]. The present bias parameter from the quasi-hyperbolic model was estimated [27, 28, 50]. The closer the value of the parameter to 0 (between 0 and 1), the more present biased and lower on inhibition one is (overweighing the value of immediate rewards); a value of 1 indicates no present or future bias; and the higher the value (above 1), the more future biased and higher on inhibition one is (overweighing the value of delayed rewards).

Measures of impulsivity

Albeit not always explicitly described as such, several measures of trait self-control are assumed to capture the impulsivity dimension of trait self-control. Participants self-reported their impulsivity using the psychological instruments of the Abbreviated Impulsiveness Scale (ABIS) [32] and the Risk Propensity Scale (RPS) [35]. The ABIS consists of three subscales, i.e., Attention (5 items, α =.69), Motor (4 items, α =.76) and Non-planning (4 items, α =.70) [32]. A composite sum score was calculated based on the three subscales (α =.79), with a higher (sum) score indicating higher impulsivity [51]. The RPS is a one factor instrument (7 items, α =.78), with a higher (mean) score indicating a higher impulsivity [35].

Behavioral and cardio metabolic risk factors for CVD

Participants self-reported their behavioral risk factors for CVD. Fat and sugar intake was measured with the Dietary Fat and Free Sugar Short Questionnaire (DFS) (26 items, α =.60) asking about intake in the past week [52]. Participants self-reported their hours of MVPA (all days) and sedentary behavior (only weekdays) in the past week, as measured by the International Physical Activity Questionnaire (IPAQ) [53]. Participants also self-reported their sleep quantity (i.e., average hours of sleep per night in the past week). Body mass index (BMI; kg/m²), waist and hip circumference (cm) [54], and systolic and diastolic blood pressure (mmHg) [55] were measured in a standardized manner in the Lifelines clinic during Lifelines wave 2A [56]. For the purpose of this study, data on waist and hip circumference were converted to waist-hip ratio (WHR), and systolic

and diastolic blood pressure were converted to pulse pressure (i.e., systolic blood pressure minus diastolic blood pressure).

Confounders

Age, gender (male, female), relationship status (in a relationship, other), country of birth (Netherlands, other), educational level (lower [no primary school education to lower or preparatory secondary vocational education], middle [junior general secondary education to pre-university secondary education], higher [higher vocational education to university education]), and whether the participant was part of the first or second batch (first batch having participated between October and November 2019 (n=15,000), and second batch having participated between February and April 2021 (n=40,500)) were considered confounders in the association between trait self-control and modifiable risk factors for CVD. Data on these variables was self-reported during Lifelines wave 1A, with the exception of batch number, which was automatically generated by the online data capture tool.

Statistical analysis

Descriptive statistics were used to characterize the study population. Associations between measures of trait self-control were examined using a correlation matrix, reporting the Pearson's Correlation Coefficient (r). According to Evans' empirical classification of interpreting correlation strength, r < 0.20 indicates a very weak, 0.20-0.39 a weak, 0.40-0.59 a moderate, 0.60-0.79 a strong, and $r \ge 0.80$ a very strong correlation [57]. Sets of linear regression analyses were used to assess the (independent) associations of trait self-control measures with multiple modifiable risk factors for CVD. For these analyses trait self-control measures were standardized to allow for comparisons between variables using different measurement systems. The first set of models included each measure of trait self-control for each modifiable risk factor for CVD separately (i.e., Models 1). The second set of models were adjusted for confounders, including age, gender, relationship status, country of birth, educational level, and batch number (i.e., Models 2). Finally, the independent associations of trait self-control measures were assessed by models adjusted for confounders, as well as all other measures of trait self-control. In Models 3, the Partial n², the proportion of variance accounted for by the independent variable, was reported; values between 0.01 and 0.059 indicate a small effect size, between 0.06 and 0.139 a medium effect size, and 0.14 or higher a large effect size [58]. Due to the expected relationship between trait self-control measures, multicollinearity statistics were assessed: all variance inflation factor values were under 2.4, i.e. well within the acceptable range [59]. All analyses were conducted with IBM SPSS Statistics for Windows version 28.0 [60]. Significance levels of p<.05, p<.01 and p<.001 were used to indicate significant associations.

Associations remained at the same significance level after correcting for multiple testing using the False Discovery Rate method [61, 62].

RESULTS

Demographics

Table 1a and 1b show the characteristics of the study population (4,741). Over half of participants was female (59%) and on average 48 years of age. Nearly all participants were born in the Netherlands (98%) and were in a relationship (86%). Most participants had a higher educational level (41%) or a middle educational level (39%). 2005 participants (42%) were part of the first batch of data collection, while 2736 (58%) were part of the second batch. On average, participants engaged in 11 hours of MVPA per week, and were sedentary for nearly 32 hours per 5 weekdays. Overall, the study population reported to be in the lower ranges of fat and sugar intake [52]. Generally, participants slept about 8 hours per night, were slightly overweight (BMI 26), and had a somewhat higher than normal pulse pressure (54) [63]. The average male participant had a healthy waist-hip ratio (0.96), while the average female participant would be classified as obese based on her waist-hip ratio (0.86) [64, 65].

Relationship between measures of trait self-control

Table 2 shows associations between the various measures of inhibition and impulsivity included in this study. Several measures of inhibition associated moderately with each other: BSCS and Grit-S (r = .55), BSCS and DGI (r = .50), and DGI and Grit-S (r = .44). Other measures of inhibition were very weakly associated with each other: BSCS and PB (r = .05). Measures of impulsivity associated weakly with each other: ABIS and RPS (r = .25).

A number of measures of inhibition associated moderately with impulsivity: BSCS and ABIS (r = -.58) Grit-S and ABIS (r = -.54), and DGI and ABIS (r = -.45). Other associations between measures of inhibition and impulsivity were weak to very weak: BSCS and RPS (r = -.23), Grit-S and RPS (r = -.12), DGI and RPS (r = -.12), and PB and ABIS (r = .03).

Trait self-control and modifiable risk factors for CVDs

Table 3 shows independent associations of measures of trait self-control with modifiable, whether behavioral or cardio metabolic, risk factors for CVDs. In the appendix, tables 1-7 show detail on Models 1 and 2, and insignificant Models 3 associations as well.

Table 1a. Descriptive statistics of the study population (n=4741).

| Demographics | | Total |
|---------------------------------|--|---------------------------------------|
| Gender | Female Male | 2789 (59%) 1952 (41%) |
| Age | Years | 48 (10.84) |
| Country of birth | Netherlands Other | 4654 (98%) 87 (2%) |
| Relationship status | ln a relationship Not in a relationship | 4073 (86%) 313 (14%) |
| Educational level | Lower Middle Higher | 977 (20%) 1834 (39%) 1930 (41%) |
| Batch | Participated in 2019 Participated in 2021 | 2005 (42%) 2736 (58%) |
| Trait self-control ^a | | |
| BSCS | > Score, > inhibition | 24.26 (3.69) |
| Grit-S | > Score, > inhibition | 3.66 (0.50) |
| DGI | > Score, > inhibition | 35.31 (4.21) |
| РВ | > Score, > inhibition | 1.29 (1.30) |
| ABIS | > Score, > impulsivity | 26.01 (4.87) |
| RPS | > Score, > impulsivity | 3.58 (1.28) |

Values and means (SD) for normally distributed continuous variables and frequencies (percentage) for categorical variables.

Table 1b. Descriptive statistics of the study population.

| Modifiable risk factors for CVD | a | Total | n |
|---------------------------------|--------------------------|---------------|------|
| MVPA | Hours/week | 10.95 (12.41) | 4410 |
| Sedentary behavior | Hours/5 weekdays | 31.63 (15.63) | 4371 |
| Fat and sugar intake (FSI) | > Score, > FSI | 44.35 (6.62) | 4577 |
| Sleep quantity | Hours/night | 8.05 (1.03) | 4534 |
| ВМІ | Kg/m² | 25.81 (4.07) | 4588 |
| Waist-hip ratio (WHR) | Waist/hip in cm | 0.90 (0.09) | 4588 |
| Pulse pressure | Sys BP - Dias BP in mmHg | 53.89 (11.50) | 4583 |

Values and means (SD) for normally distributed continuous variables.

^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS). Reported values are not standardized.

^a MVPA and sedentary behavior as measured by the International Physical Activity Questionnaire (IPAQ); FSI by the Dietary Fat and Free Sugar Short Questionnaire (DFS); sleep quantity as by Lifelines wave 1A; BMI in clinic during Lifelines wave 2A in kilograms and meters, formula is kilograms divided by meters²; pulse pressure in clinic during Lifelines wave 2A in mmHg, formula is systolic blood pressure minus diastolic blood pressure; WHR in clinic during Lifelines wave 2A in centimeters, formula is waist circumference divided by hip circumference.

Table 2. Correlations between measures of trait self-control a (n=4741).

| | 1 | 2 | 3 | 4 | 5 |
|-------------|--------|--------|-------|------|--------|
| Inhibition | | , | | , | |
| 1. BSCS | - | | | | |
| 2. Grit-S | .55*** | | | | |
| 3. DGI | .50*** | .44*** | | | |
| 4. PB | 05*** | 02 | 01 | | |
| Impulsivity | | | | | |
| 5. ABIS | 58*** | 54*** | 45*** | .03* | |
| 6. RPS | 23*** | 12*** | 12*** | .02 | .25*** |
| | | | | | |

^{*}p<0.05, **p<0.01, ***p<0.001

Strongest correlations between measures, supporting the notion that trait self-control consists of two distinct dimensions of inhibition and impulsivity, are in bold.

Inhibition and behavioral risk factors for CVDs

Higher inhibition, as measured by Grit-S and DGI, was associated with higher MVPA (β =0.93, 95% CI 0.47,1.39; and β =0.75, 95% CI 0.32,1.18, respectively). Higher inhibition, as measured by Grit-S, DGI and PB, was associated with lower sedentary behavior (β =-0.82, 95% CI -1.41,-0.23; β =-0.91, 95% CI -1.46,-0.37; and β =-0.75, 95% CI -1.21,-0.29, respectively). Higher inhibition, as measured by DGI and PB, was associated with lower fat and sugar intake (β =-0.76, 95% CI -0.99,-0.53; and β =-0.22, 95% CI -0.41,-0.03, respectively). Higher inhibition, as measured by BSCS was associated with higher sleep quantity (β =0.05, 95% CI 0.01,0.09).

Impulsivity and behavioral risk factors for CVDs

Higher impulsivity, as measured by ABIS and RPS, was associated with higher MVPA (β =0.59, 95% CI 0.01,1.07; and β =0.74, 95% CI 0.35,1.13, respectively). Higher impulsivity, as measured by ABIS, was associated with lower sedentary behavior (β =-0.96, 95% CI -1.58,-0.34).

Inhibition and cardio metabolic risk factors for CVDs

Higher inhibition, as measured by BSCS and DGI, was associated with lower BMI (β =0.88, 95% CI -1.03,-0.73; and β =-0.8, 95% CI -0.93,-0.66, respectively). Higher inhibition, as measured by Grit-S and PB, was associated with higher BMI (β =0.31, 95% CI 0.17,0.46; and β =0.22, 95% CI 0.1,0.33, respectively). Higher inhibition, as measured by BSCS and DGI, was associated with lower WHR (β =-0.009, 95% CI -0.01,-0.006; and β =-0.008, 95%

^a Inhibition, as measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), and a Present Bias measure (PB); and impulsivity, as measured by the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).

Table 3. Associations of measures of trait self-control a with modifiable risk factors for cardiovascular disease^b

Independent ^c relationships of trait self-control and behavioral risk factors for CVDs

| · | | | | |
|--------------------------------|--------------------------------------|------|------------------------------------|------|
| | Inhibition: β (95% CI) | η² | Impulsivity: β (95% CI) | η² |
| Increased MVPA | Grit-S: 0.93 (0.47,1.39)*** | .004 | ABIS: 0.59 (0.01,1.07)* | .001 |
| | DGI: 0.75 (0.32,1.18)*** | .003 | RPS: 0.74 (0.35,1.13)*** | .003 |
| Decreased sedentary behavior | Grit-S: -0.82 (-1.41,-0.23)** | .002 | ABIS: -0.96 (-1.58,-0.34)** | .002 |
| | DGI: -0.91 (-1.46,-0.37)** | .002 | | |
| | PB: -0.75 (-1.21,-0.29)** | .002 | | |
| Decreased fat and sugar intake | DGI: -0.76 (-0.99,-0.53)*** | .009 | - | |
| | PB: -0.22 (-0.41,-0.03)* | .001 | | |
| Increased sleep quantity | BSCS: 0.05 (0.01,0.09)* | .001 | - | |
| | | | | |

Independent ^c relationships of trait self-control and cardio metabolic risk factors for CVDs

| | Inhibition: β (95% CI) | η² | Impulsivity: β (95% CI) | η² |
|---------------------------|-----------------------------------|------|------------------------------|------|
| Decreased BMI | BSCS: -0.88 (-1.03,-0.73)*** | .027 | ABIS: -0.39 (-0.54,-0.24)*** | .006 |
| | DGI: -0.8 (-0.93,-0.66)*** | .029 | | |
| Increased BMI | Grit-S: 0.31 (0.17,0.46)*** | .004 | - | |
| | PB: 0.22 (0.1,0.33)*** | .003 | | |
| Decreased waist-hip ratio | BSCS: -0.009 (-0.01,-0.006)*** | .009 | - | |
| | Grit-S: -0.003 (0,0.005)* | .001 | | |
| | DGI: -0.008 (-0.01,-0.006)*** | .01 | | |
| Increased waist-hip ratio | PB: 0.003 (0.001,0.005)** | .002 | - | |
| Decreased pulse pressure | DGI: -0.53 (-0.91,-0.15)** | .002 | - | |
| Increased pulse pressure | PB: 0.43 (0.11,0.74)** | .002 | - | |

^{*}p<0.05, **p<0.01, ***p<0.001

n varied per outcome; see Table 1b, and supplementary Tables 1-7 for details.

Betas, 95% confidence intervals and η^2 derived from multiple regression analyses.

Cardiovascular health promoting changes in outcomes in green text; cardiovascular health risk inducing changes in outcomes in red text. Most meaningful health-related changes associated with one unit change in standardized trait self-control measure scores in bold.

- ^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).
- ^b MVPA and sedentary behavior as measured by the International Physical Activity Questionnaire (IPAQ); FSI by the Dietary Fat and Free Sugar Short Questionnaire (DFS); sleep quantity as by Lifelines wave 1A; BMI in clinic during Lifelines wave 2A in kilograms and meters, formula is kilograms divided by meters²; pulse pressure in clinic during Lifelines wave 2A in mmHg, formula is systolic blood pressure minus diastolic blood pressure; WHR in clinic during Lifelines wave 2A in centimeters, formula is waist circumference divided by hip circumference.
- ^cAdjusted for gender, age, country of birth, relationship status, educational level, batch number, and other measures of trait self-control.

CI -0.01,-0.006, respectively). Higher inhibition, as measured by Grit-S and PB, was associated with higher WHR (β =0.003, 95% CI 0,0.005; and β =0.003, 95% CI 0.001,0.005, respectively). Higher inhibition, as measured by DGI, was associated with lower pulse pressure (β =-0.53, 95% CI -0.91,-0.15). Higher inhibition, as measured by PB, was associated with higher pulse pressure (β =0.43, 95% CI 0.11.0.74).

Impulsivity and cardio metabolic risk factors for CVDs

Higher impulsivity, as measured by ABIS, was associated with lower BMI (β =-0.39, 95% CI -0.54.-0.24).

DISCUSSION

This study set out to assess the relationship between different measures of trait self-control, and their associations with key behavioral and cardio metabolic risk factors for CVDs. In general, different measures of inhibition were moderately associated with each other (r varying between .55 and .44), and several measures of inhibition and impulsivity related to each other moderately (r varying between -.58 and -.45). Regression analysis that included all trait self-control and confounder variables showed that higher inhibition and impulsivity were associated with higher physical activity and lower sedentary behavior. Furthermore, higher inhibition was associated with lower fat and sugar intake and higher sleep quantity. Higher inhibition and impulsivity were also associated with lower BMI. However, generally, inhibition was inconsistently related to cardio metabolic risk factors. The variance accounted for by trait self-control measures was small for all outcomes examined.

Relationship between measures of trait self-control

Of the 15 trait self-control measure pairs examined, six pairs correlated moderately with each other, two pairs weakly, and four very weakly, while the other three pairs showed no significant correlation. The direction and strength of correlations between measures that are generally assumed to capture inhibition and impulsivity provide support for the notion that trait self-control consists of at least two dimensions, inhibition and impulsivity, and can therefore be considered a multidimensional construct [40]. The negative correlations found between some measures of inhibition and impulsivity suggest that inhibition involves more than the control of impulses, i.e. inhibition can be present without impulsivity [22, 29].

While most measures of inhibition were interrelated, the measure of present bias was inversely related to other measures of inhibition. The economics literature does not

explicitly describe whether present bias, one of the most important proxies of trait self-control in that literature, is a measure of inhibition or impulsivity, although it would be reasonable to assume that the theoretical construct relates more to inhibition [24]. Additionally, when measured empirically in the context of money, as is most common and as we do in this study, it is plausible that present bias may be more reliant on inhibitory rather than impulsive processes. This is because money is not a consumption good in itself, but is a means to future consumption [66], and as a result the affective intensity [67], and thus impulsivity, involved in choices over money is likely to be lower relative to choices over consumption goods, such as snacking or sedentary behaviors [68, 69].

Trait self-control and behavioral risk factors for CVD

Even though the variance accounted for by measures of trait self-control was small for all behavioral outcomes, as captured by Eta squared [58], several associated changes in outcomes may be meaningful. Notably, one standardized unit change in some measures of inhibition and impulsivity were associated with over half an hour to nearly an hour increase in weekly MVPA, and decrease in weekly (weekday) sedentary behavior. It is unexpected that higher impulsivity was associated with higher physical activity and lower sedentary behavior, but not with higher fat and sugar intake, given its general association with short-term gratification, such as snacking and screen time [40, 41, 70-72]. That higher inhibition was associated with lower fat and sugar intake [70, 71] and higher sleep quantity [73] is in line with previous findings; however, the unit change accompanying these associations seems too small for practical implications. We find some evidence for the notion that inhibition is more strongly associated with health behaviors than impulsivity [40, 44]. Overall, higher inhibition and impulsivity were both consistently associated with healthier behavior in this study. Our findings contradict hypotheses that inhibition and impulsivity necessarily work in tandem [17, 31, 39, 42, 43], and rather support research that posited both impulsivity and inhibition to independently [22, 29] and simultaneously [40, 45] influence health behavior.

Trait self-control and cardio metabolic risk factors for CVDs

While the variance accounted for by measures of trait self-control was small for all cardio metabolic outcomes, as captured by Eta squared [58], the size of some associated changes may be meaningful. Notably, a standardized unit increase in inhibition was associated with nearly one unit decrease in BMI, and a standardized unit increase in impulsivity was associated with a nearly half-a-unit decrease BMI. These findings reconfirm our previous interpretation that inhibition may be more strongly associated with health behaviors than impulsivity, and that higher impulsivity may be associated with health benefits. However, our other findings on the associations between trait

self-control and cardio metabolic risk factors for CVDs show an inconsistent picture: higher inhibition, as captured by the various measures included in our study, related to both higher and lower BMI, higher as well as lower waist-hip ratio, and higher as well as lower pulse pressure.

Application for intervention design

Our study identified some associations between dimensions of trait self-control (impulsivity versus inhibition) and modifiable risk factors for CVDs, which may allow intervention designers to identify 'at-risk' individuals concerning their health outcome of interest, and subsequently tailor intervention content to these people's needs, such as provide them with the behavior change technique of planning [38]. Overall, measures of inhibition may be better suited for this aim for interventions that plan to target the intention-behavior gap in MVPA, sedentary behavior, fat and sugar intake, and sleep.

Limitations

Several limitations should be considered when interpreting the results of this study. Firstly, our study population was significantly different from its source population: for example, participants were more likely to have been born in the Netherlands, to be higher educated, and to have higher self-rated health. Although mean differences on such variables were small between the populations, the generalizability of our results may be limited to more diverse groups. Second, the cross-sectional nature of the data used means that causality cannot be inferred from our results, and that the temporal ordering between the assessed variables can only be assumed to a limited extent. However, as trait self-control is considered to be relatively stable across situations and time, this may not compromise our results severely. Third, while our scope of included trait self-control measures was relatively large, not all available self-report measures of inhibition and impulsivity were included. Fourth, participating in a study requires deliberative thought, which means that self-reported data collected on impulsivity, supposedly largely reliant on automatic cognitive processes, reflected individuals' perceptions and experiences. Whether or not participants are aware of, or have access to, processes that are automatic and are purported to affect behavior beyond their awareness is an open question [74]. Empirical investigations find comparable validity between using self-reported versus physiological measures of automatic processes (most prominently, implicit association tests), with physiological measures showing less variability of effect size [75]. Future studies should weigh the value of the added participant burden of using physiological measures, and choose measures of impulsivity accordingly in their study. Fifth, whereas we have adjusted for several confounders, we acknowledge there could be residual confounding where variables (e.g., cognition, family background) induce a spurious association between certain trait self-control

measures and CVD risk factors. Finally, while it is certainly of use to examine the association of inhibition and impulsivity with modifiable CVD risk factors, some conceptualizations of trait self-control differentiate between (sub-)dimensions even further, which were left unexamined in this study. For example, some posit that people enact trait self-control in two different ways: exercising willpower to resist when a tempting situation presents itself, and anticipating future tempting situations and avoiding these situations [24, 76-78].

Future directions

The current study examined the relationship between validated measures of trait self-control, and their association with modifiable risk factors for CVD. To better understand the causal relationships between the variables examined in the current study, longitudinal investigation of these associations is warranted in the future. In addition, lower-level examination of the data could reveal even more detail of the dimensions of trait self-control and their relationship to health (behavior): associations between individual measurement items (as opposed to pre-specified scales) of trait self-control could be examined. Assessing the relationship between the resulting item clusters could be used to specify the concept of trait self-control free of a-priori assumptions of which measurement items capture which dimensions. Such analyses may reveal even clearer patterns of the relative importance of certain clusters of trait self-control for modifiable CVD risk.

Conclusion

Our findings support for the notion that trait self-control is a multidimensional construct, consisting of at least two dimensions, inhibition and impulsivity. We find both higher inhibition and impulsivity to be consistently associated with healthier outcomes, with inhibition having a stronger association overall. Our results indicate that both inhibition and impulsivity influence health independently and simultaneously. Intervention designers aiming to identify individuals at risk of an intention-behavior gap concerning physical activity, sedentary behavior, fat and sugar intake, and sleep, may want to use measures of trait inhibition. To better understand the causal relationships between the variables examined in the current study, longitudinal investigation of these associations is warranted in the future.

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SUPPORTING INFORMATION

Table 1. Associations of measures of trait self-control a with moderate to vigorous physical activity (n=4410).

| | Model 1 β (95% CI) | Model 2 ^c β (95% CI) | Model 3 ^d β (95% CI) | η² |
|--------|-----------------------|------------------------------------|------------------------------------|-------|
| BSCS | 0.82 (0.45,1.18)*** | 0.83 (0.47,1.19)*** | 0.47 (-0.02,0.96) | 0.001 |
| Grit-S | 0.95 (0.59,1.32)*** | 1.11 (0.75,1.47)*** | 0.93 (0.47,1.39)*** | 0.004 |
| DGI | 0.76 (0.39,1.12)*** | 1.04 (0.68,1.40)*** | 0.75 (0.32,1.18)*** | 0.003 |
| РВ | 0.04 (-0.33,0.4) | 0.08 (-0.27,0.44) | 0.09 (-0.26,0.44) | 0.000 |
| ABIS | -0.01 (-0.38,0.36) | -0.31 (-0.67,0.06) | 0.59 (0.01,1.07)* | 0.001 |
| RPS | 0.01 (-0.27,0.46) | 0.57 (0.2,0.94)** | 0.74 (0.35,1.13)*** | 0.003 |

Betas, 95% confidence intervals and η^2 derived from multiple regression analyses.

Table 2. Associations of measures of trait self-control ^a with sedentary behavior ^b (n=4371).

| | Model 1 β (95% CI) | Model 2 ^c β (95% CI) | Model 3 ^d β (95% CI) | η² |
|--------|------------------------|------------------------------------|------------------------------------|-------|
| BSCS | -0.54 (-1,-0.08)* | -0.68 (-1.14,-0.22)** | -0.4 (-1.02,0.23) | 0.000 |
| Grit-S | -0.79 (-1.25,-0.33)*** | -0.88 (-1.34,-0.43)*** | -0.82 (-1.41,-0.23)** | 0.002 |
| DGI | -0.71 (-1.17,-0.25)** | -1.03 (-1.49,-0.57)*** | -0.91 (-1.46,-0.37)** | 0.002 |
| РВ | -0.88 (-1.34,-0.41)*** | -0.73 (-1.2,-0.27)** | -0.75 (-1.21,-0.29)** | 0.002 |
| ABIS | -0.29 (-0.75,0.18) | 0.06 (-0.4,0.53) | -0.96 (-1.58,-0.34)** | 0.002 |
| RPS | 0.42 (-0.05,0.88) | -0.11 (-0.58,0.37) | -0.14 (-0.64,0.36) | 0.000 |

Betas, 95% confidence intervals and $\eta^2\,\text{derived}$ from multiple regression analyses.

^{*}p<0.05, **p<0.01, ***p<0.001

^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).

^b As measured by the International Physical Activity Questionnaire (IPAQ).

^c Adjusted for gender, age, country of birth, relationship status, educational level, and batch number.

^d Additionally adjusted for other measures of trait self-control.

^{*}p<0.05, **p<0.01, ***p<0.001

^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).

^b As measured by the International Physical Activity Questionnaire (IPAQ).

^cAdjusted for gender, age, country of birth, relationship status, educational level, and batch number.

^d Additionally adjusted for other measures of trait self-control.

Table 3. Associations of measures of trait self-control ^a with fat and sugar intake ^b (n=4577).

| | Model 1 β (95% CI) | Model 2 ^c β (95% CI) | Model 3 ^d β (95% CI) | η² |
|--------|------------------------|------------------------------------|------------------------------------|-------|
| BSCS | -0.58 (-0.78,-0.39)*** | -0.61 (-0.8,-0.42)*** | -0.22 (-0.47,0.04) | 0.001 |
| Grit-S | -0.5 (-0.69,-0.3)*** | -0.53 (-0.72,-0.34)*** | -0.01 (-0.34,0.15) | 0.000 |
| DGI | -0.84 (-1.03,-0.65)*** | -0.9 (-1.09,-0.71)*** | -0.76 (-0.99,-0.53)*** | 0.009 |
| РВ | -0.25 (-0.44,-0.06)* | -0.21 (-0.4,-0.02)* | -0.22 (-0.41,-0.03)* | 0.001 |
| ABIS | 0.35 (0.15,0.54)*** | 0.48 (0.29,0.67)*** | 0.02 (-0.24,0.27) | 0.000 |
| RPS | 0.27 (0.08,0.46)** | 0.04 (-0.16,0.24) | -0.14 (-0.35,0.07) | 0.000 |

Betas, 95% confidence intervals and $\eta^2\,\text{derived}$ from multiple regression analyses.

Table 4. Associations of measures of trait self-control ^a with sleep quantity ^b (n=4534).

| | Model 1 β (95% CI) | Model 2° β (95% CI) | Model 3 ^d β (95% CI) | η² |
|--------|------------------------|------------------------|------------------------------------|-------|
| BSCS | 0.08 (0.05,0.11)*** | 0.07 (0.04,0.1)*** | 0.05 (0.01,0.09)* | 0.001 |
| Grit-S | 0.05 (0.02,0.08)*** | 0.05 (0.02,0.08)*** | 0.09 (-0.03,0.05) | 0.000 |
| DGI | 0.04 (0.01,0.07)** | 0.04 (0.01,0.07)* | -0.01 (-0.05,0.03) | 0.000 |
| РВ | -0.01 (-0.04,0.02) | 0 (-0.03,0.03) | 0 (-0.03,0.03) | 0.000 |
| ABIS | -0.06 (-0.1,-0.04)*** | -0.07 (-0.1,-0.04)*** | -0.04 (-0.08,0.01) | 0.001 |
| RPS | -0.05 (-0.08,-0.02)*** | -0.04 (-0.08,-0.01)** | -0.02 (-0.05,0.01) | 0.000 |

Betas, 95% confidence intervals and η^2 derived from multiple regression analyses.

^{*}p<0.05, **p<0.01, ***p<0.001

^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).

^b As measured by the Dietary Fat and Free Sugar Short Questionnaire (DFS).

^c Adjusted for gender, age, country of birth, relationship status, educational level, and batch number.

^d Additionally adjusted for other measures of trait self-control.

^{*}p<0.05, **p<0.01, ***p<0.001

^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).

^b Measured identically to Lifelines wave 1A.

^c Adjusted for gender, age, country of birth, relationship status, educational level, and batch number.

^d Additionally adjusted for other measures of trait self-control.

Table 5. Associations of measures of trait self-control with BMI b n=4588.

| | Model 1 β (95% CI) | Model 2 ^c β (95% CI) | Model 3 ^d β (95% CI) | η² |
|--------|------------------------|------------------------------------|------------------------------------|-------|
| BSCS | -0.88 (-0.99,-0.76)*** | -0.88 (-0.99,-0.76)*** | -0.88 (-1.03,-0.73)*** | 0.027 |
| Grit-S | -0.34 (-0.46,-0.22)*** | -0.3 (-0.42,-0.19)*** | 0.31 (0.17,0.46)*** | 0.004 |
| DGI | -0.98 (-1.1,-0.87)*** | -0.92 (-1.04,-0.81)*** | -0.8 (-0.93,-0.66)*** | 0.029 |
| РВ | 0.25 (0.13,0.37)*** | 0.25 (0.13,0.36)*** | 0.22 (0.1,0.33)*** | 0.003 |
| ABIS | 0.36 (0.24,0.48)*** | 0.29 (0.17,0.41)*** | -0.39 (-0.54,-0.24)*** | 0.006 |
| RPS | 0 (-0.12,0.12) | 0.13 (0.01,0.25)* | -0.05 (-0.18,0.07) | 0.000 |

Betas, 95% confidence intervals and η^2 derived from multiple regression analyses. *p<0.05. **p<0.01. ***p<0.001

Table 6. Associations of measures of trait self-control a with waist-hip ratio b (n=4588).

| | Model 1 β (95% CI) | Model 2 ^c β (95% CI) | Model 3 ^d β (95% CI) | η² |
|--------|---------------------------|------------------------------------|------------------------------------|-------|
| BSCS | -0.008 (-0.01,-0.005)*** | -0.01 (-0.01,-0.008)*** | -0.009 (-0.01,-0.006)*** | 0.009 |
| Grit-S | -0.005 (-0.007,-0.002)*** | -0.004 (-0.006,-0.002)*** | -0.003 (0,0.005)* | 0.001 |
| DGI | -0.012 (-0.014,-0.009)*** | -0.01 (-0.012,-0.008)*** | -0.008 (-0.01,-0.006)*** | 0.010 |
| РВ | 0 (0,0) | 0.003 (0.001,0.005)*** | 0.003 (0.001,0.005)** | 0.002 |
| ABIS | 0.004 (0.001,0.006)** | 0.004 (0.002,0.006)*** | -0.002 (-0.005,0) | 0.001 |
| RPS | 0.004 (0.001,0.006)** | 0.001 (-0.001,0.003) | -0.002 (-0.004,0) | 0.001 |

Betas, 95% confidence intervals and η^2 derived from multiple regression analyses. *p<0.05, **p<0.01, ***p<0.001

^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).

^b Measured in clinic during Lifelines wave 2A in kilograms and meters; formula is kilograms divided by meters².

^cAdjusted for gender, age, country of birth, relationship status, educational level, and batch number.

d Additionally adjusted for other measures of trait self-control.

^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).

^b Measured in clinic during Lifelines wave 2A in centimeters; formula to calculate waist-hip ratio (WHR) is waist circumference divided by hip circumference.

^cAdjusted for gender, age, country of birth, relationship status, educational level, and batch number.

^d Additionally adjusted for other measures of trait self-control.

Table 7. Associations of measures of trait self-control ^a with pulse pressure ^b (n=4583).

| | Model 1 β (95% CI) | Model 2 ^c β (95% CI) | Model 3 ^d β (95% CI) | η² |
|--------|------------------------|------------------------------------|------------------------------------|-------|
| BSCS | -0.08 (-0.41,0.25) | -0.26 (-0.58,0.06) | -0.18 (-0.61,0.25) | 0.000 |
| Grit-S | -0.36 (-0.69,-0.03)* | -0.25 (-0.58,0.06) | -0.17 (-0.58,0.23) | 0.000 |
| DGI | -0.55 (-0.89,-0.22)*** | -0.48 (-0.8,-0.17)** | -0.53 (-0.91,-0.15)** | 0.002 |
| РВ | -0.3 (-0.03,-0.64) | 0.43 (0.11,0.74)** | 0.43 (0.11,0.74)** | 0.002 |
| ABIS | 0.26 (-0.07,0.6) | -0.04 (-0.36,0.28) | -0.39 (-0.81,0.04) | 0.001 |
| RPS | -0.97 (-1.30,-0.64)*** | -0.26 (-0.59,0.07) | -0.3 (-0.64,0.05) | 0.001 |

Betas, 95% confidence intervals and η^2 derived from multiple regression analyses. *p<0.05. **p<0.01. ***p<0.001

^a As measured by the Brief Self Control Scale (BSCS), the Grit Scale short-from (Grit-S), the Delaying Gratification Inventory short-form (DGI), a Present Bias measure (PB), the Abbreviated Impulsiveness Scale (ABIS), and the Risk Propensity Scale (RPS).

^b Measured in clinic during Lifelines wave 2A in mmHg; formula is systolic blood pressure minus diastolic blood pressure.

^cAdjusted for gender, age, country of birth, relationship status, educational level, and batch number.

^d Additionally adjusted for other measures of trait self-control.



CHAPTER 4

Needs and preferences of women with prior severe preeclampsia regarding app-based cardiovascular health promotion

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ABSTRACT

Background

Women with prior severe preeclampsia are at an increased risk for cardiovascular diseases later in life compared to women who had a normotensive pregnancy. The objective of this study was to assess their needs and preferences regarding app-based cardiovascular health promotion.

Methods

Patients (n = 35) of the Follow-Up PreEClampsia Outpatient Clinic (FUPEC), Erasmus MC, the Netherlands, participated in an anonymous online survey. The main outcomes under study were women's needs for health behavior promotion, and their preferences with respect to intervention delivery. Descriptive statistics were used to evaluate needs, and thematic analysis was used to analyze preferences.

Results

Women's primary need for health behavior promotion pertained to their fat and sugar intake and physical activity; for some, to their mental health (practices), fruit and vegetable intake, salt intake, and water intake; and for a few, to their alcohol and tobacco use. Most women preferred an app-based intervention to include, in descending order: the tracking of health-related metrics, an interactive platform, the use of behavior change strategies, the provision of information, and personalization.

Conclusions

Cardiovascular health promotion targeting women with prior severe preeclampsia should feel relevant to its audience. App-based interventions are likely to be well received if they target fat and sugar intake and physical activity. These interventions should preferably track health-related metrics, be interactive, contain behavior change strategies, provide information, and be personalized. Adopting these findings during intervention design could potentially increase uptake, behavior change, and behavior change maintenance in this population.

Keywords: Preeclampsia, cardiovascular health promotion, intervention design, needs and preferences assessment.

INTRODUCTION

The leading cause of death in women worldwide are cardiovascular diseases (CVDs), contributing to 35% of female deaths [1]. Some risk factors for CVDs are unique to women, such as hypertensive disorders of pregnancy. These disorders affect 5 to 10% of pregnancies globally, and their prevalence is increasing [2, 3]. Of all hypertensive disorders of pregnancy, preeclampsia, which complicates 2 to 5% of all pregnancies [4], increases CVD risk the most: it has been linked to a two- to eightfold increased risk throughout the lifespan [5-7]. Maternal factors associated with an increased risk of preeclampsia are antiphospholipid antibody syndrome, prior preeclampsia, chronic hypertension, pre-gestational diabetes, and obesity [8]. Given that the causes and the early diagnosis of preeclampsia are not yet fully understood [4, 9], attention to the cardiovascular follow-up and risk management of women with prior preeclampsia is warranted [6, 7]. CVD risk can be decreased substantially by participating in healthy lifestyle behaviors [10, 11]. Therefore, efficacious health promotion interventions are warranted in this high-risk group [12].

Health behavior change interventions have been widely applied in the general population with demonstrable efficacy [13-17]. When it comes to the medium of interventions, web-based interventions have several advantages over face-to-face interventions: they are comparatively low cost, have a wide reach, and provide flexibility in intervention location and time [18, 19]. Web-based interventions were previously found to appeal to women with prior preeclampsia due to the flexibility they provide, i.e., they fit more easily into the demanding and unpredictable schedules of (often young and working) mothers [20-22]. Access to web-based interventions may be further enhanced by delivering them via mobile phone optimized web browsers or dedicated mobile apps, instead of desktop optimized web browsers, called mHealth [23]. Health apps are proliferating rapidly —there are now more than 350,000 available for download [24]. A prerequisite of health app use is owning a smartphone: about half of the world's population [25] and 84% of the Dutch population meets this criterion [26]. Over half of Dutch women already use health apps, primarily to monitor their health behaviors, with another quarter being open to using one in the future [26].

It is increasingly recognized that to design an intervention that resonates with its intended audience, one should assess the needs and preferences of the study population prior to the development of the intervention protocol. This may increase intervention uptake, and enhance behavior change and maintenance [27]. Both quantitative and qualitative methods have been previously used to yield insight on needs and preferences, and to provide recommendations for the design of mHealth

interventions in the general population [28], and in specific patient groups, such as hypertensive and CVD patients [29-31], and obstetric and gynecological patients [32-35]. In women with prior preeclampsia, previous research has offered insights into preferences for postpartum lifestyle counseling [21], the factors that influence the use of mHealth to monitor preeclampsia-related symptoms [36], and the acceptability of a specific web-based health promotion intervention [37]. To our knowledge, the needs of women with prior severe preeclampsia regarding the behavioral target of app-based cardiovascular health promotion, and their preferences for the delivery of such an intervention, have not been previously assessed.

With this study we aim to further understanding of the needs and preferences of women with prior severe preeclampsia for app-based cardiovascular health promotion. We define needs as the extent to which women struggle to participate in certain health-promoting behaviors, plan to make positive changes to these behaviors, and are interested in participating in an app-delivered program targeting these behaviors. More specifically, our objective is to gain insight into women's needs regarding behaviors related to cardiovascular health, namely: physical activity, fat and sugar intake, fruit and vegetable intake, salt intake, water intake, mental well-being (practices), alcohol use, and tobacco use [11]. Our second aim is to understand women's preferences regarding the delivery of app-based cardiovascular health promotion. Our related objective is to explore their wishes regarding app content, functionalities, and interface.

METHOD

Study setting

Study participants were recruited from an outpatient clinic for women with prior severe preeclampsia. In the Erasmus Medical Center (Erasmus MC), cardiovascular follow-up and risk management is provided for women with prior severe preeclampsia at the multidisciplinary Follow-Up PreEClampsia Outpatient Clinic (FUPEC), unique in the Netherlands [38]. Presently there are around 1500 patients enrolled at the clinic, with an additional 100 to 150 women registering each year.

Study population

Participant recruitment at the FUPEC and online data collection took place between September and November 2020 (n = 35). Inclusion criterion for participation was having experienced severe preeclampsia at least once, as per the definition of the American Congress of Obstetricians and Gynecologists [39]. Exclusion criteria for participation were: <18 years of age, pregnant at time of inclusion, <3 months after delivery, any

circumstance preventing moderate-to-vigorous intensity physical activity (e.g., illness, injury, surgery, rehabilitation), no working knowledge of Dutch, and no possession of a smartphone. No upper age limit was applied. These exclusion criteria were employed to obtain a sample of women similar to those who will enroll in an app-based cardiovascular health promotion program [40]. A total of six women were excluded: three women were <3 months after delivery, and three women had insufficient knowledge of Dutch. Invited women were informed that participation in the study was voluntary, and that they could withdraw at any point, without having to provide a reason. Women who chose to participate signed an informed consent form prior to participation. Recruitment was considered complete after data saturation was reached consistent with recommended qualitative data collection procedures, i.e., when authors LLK and MFVDB agreed that new themes were not expected to arise from the inclusion of additional participants [41].

Patient and public involvement

Patients and members of the public were not involved in the design, conduct, or reporting of this study.

Design

An anonymous online survey was administered.

Sampling strategy

The study used criterion sampling, i.e., participants had to have prior experience with severe preeclampsia [42].

Procedure

Women were asked at their FUPEC consultation whether they were interested in joining the study. Women who did not show up at their scheduled consultation were asked via email. Those that expressed interest either at the consultation or via email received the survey. Of the 122 women asked, 119 agreed to receive the survey. Of these women, 55 started the survey, and 35 provided complete responses. Only complete responses were used in the current analyses. Women who did not provide complete responses (n = 20) were comparable to the study sample (n = 35) in for example age, educational level, and when they had experienced severe preeclampsia (data not shown). The survey assessed four topics: demographics, needs for app-based cardiovascular health promotion, perceived determinants of physical activity, and preferences for app-based cardiovascular health promotion. The current study used data on the first, second, and fourth topics. Data on the third topic was collected for the purpose of a qualitative assessment of physical activity determinants, the results

of which will be published separately. The survey was hosted online on the data capture tool Limesurvey [43]. Data were imported into IBM SPSS Statistics and NVivo for analyses [44, 45].

Main outcome measures

The main outcomes of this study were participants' needs and preferences with respect to app-based cardiovascular health promotion. The recruitment materials and survey were developed by members of the research team, including JERVL and JJD as clinicians and MFVDB as medical student of the Follow-Up PreEClampsia Outpatient Clinic (FUPEC). Questions assessing needs were based on previous studies gauging the needs of a population prior to developing an mHealth intervention [29, 33], and were surveying health behaviors that are relevant for cardiovascular health promotion [11]. Questions assessing preferences were based on prior studies that examined the preferences of a population regarding content, functionality and interface before developing an mHealth intervention [29, 33, 34], and by the persuasive design framework of web-based interventions [46]. The questions have not been previously validated.

Participants answered one question each about the three components of needs: struggling to participate in certain health-promoting behaviors, planning to make positive changes to these behaviors, and being interested in participating in an appdelivered program targeting these behaviors. Spearman's rho correlation analyses were performed between the three items for each health behavior to support their validity as positively related, but distinct components (for coefficients and significance levels see supporting information, supporting table 1). We assessed needs regarding physical activity, fat and sugar intake, fruit and vegetable intake, salt intake, water intake, mental well-being (practices), alcohol use, and tobacco use [11]. First, participants reported on their struggle to follow a healthy lifestyle concerning these behaviors (e.g., "How often do you struggle to make healthy choices when it comes to fat and sugar intake?") on a seven-point scale (1 = very rarely to 7 = very often). Second, participants reported their behavior change intentions regarding these behaviors (e.g., "How often do you think of making positive changes to your physical activity?") on a seven-point scale (1 = very rarely to 7 = very often). Last, participants reported their interest in partaking in an app-based intervention targeting these behaviors (e.g., "How interested would you be in partaking in an app-based intervention targeting fruit and vegetable intake?") on a seven-point scale (1 = not interested to 7 = very interested). For questions about alcohol and tobacco use, the response option not applicable (N/A) was included to accommodate for women who do not engage in these behaviors. Participants were assumed to engage in all the other studied behaviors to some extent, therefore, the response option N/A was not added.

Participants also reported their preferences for the delivery of an app-based intervention. To this aim, participants responded to a series of open-ended questions assessing three aspects of intervention delivery: content (e.g., "What should this app contain?"), functionality (e.g., "What should this app do?"), and interface (e.g., "How and with whom would you like to communicate via the app?"). Participants also reported on the acceptable number of weeks and hours per week of the intervention ("Time demand: What do you think is reasonable?").

Participants reported their demographic characteristics: age (years), number of children (number), living situation (with or without partner, with or without children), educational level (lower, middle, higher; classified using the International Standard Classification of Education [47]), paid employment status (yes, no; if yes, number of hours per week), when they had experienced severe preeclampsia (between three months and one year ago; between one and three years ago; over three years ago), and whether preeclampsia-related health complaints were still present (yes, no; if yes, what complaints).

Data analysis

Participants' demographic characteristics, and responses on scaled items used to identify the needs of the population in terms of health promotion target behavior were reported using descriptive statistics. Scale ratings between 1 and 4 were collapsed into No, and ratings between 5 and 7 were collapsed into Yes. For alcohol and tobacco use, N/A was collapsed into No as well.

Thematic analysis was used to identify themes in participants' preferences regarding intervention delivery [48-50]. Inductive content analysis for emergent themes was applied, consistent with guidelines for the analysis of qualitative data using the grounded theory approach [51]. After reading and re-reading participants' responses, LLK and MvdB defined coding instances, and identified five recurring themes in these instances. They then returned to the data independently and categorized each coding instance into one of the five themes. A small number of coding instances were categorized as belonging to two themes (for examples of the thematic analysis procedure see supporting information, supporting table 2). Initial interrater percent agreement was 91%. Subsequently, categorizations were revisited until 100% agreement was reached.

RESULTS

Characteristics of the study population

Table 1 shows the characteristics of the study population (n = 35). Participants had a median age of 35 years. Most women had one child (54%) and were living with a partner (80%). The majority were highly educated (80%) and in paid employment (80%), working a median of 28 hours per week. Most women experienced severe preeclampsia more than three years ago (54%). Half of women were still experiencing health complaints related to preeclampsia (49%), such as fatigue and anxiety, and problems with concentration and memory (examples of participants' complaints are published under supporting information, supporting table 3).

Table 1. Characteristics of the study population.

| Demographic characteristics | | (n = 35) |
|--------------------------------|--------------------------------|-------------|
| Age* | Years | 35 [32, 44] |
| Number of children | 0 | 2 (6%) |
| | 1 | 19 (54%) |
| | 2 | 12 (34%) |
| | 3 | 2 (6%) |
| Living situation | With partner and children | 26 (74%) |
| | Without partner, with children | 7 (20%) |
| | With partner, without children | 2 (6%) |
| | Without partner and children | 0 (0%) |
| Educational level** | Lower | 0 (0%) |
| | Middle | 7 (20%) |
| | Higher | 28 (80%) |
| Paid employment | Yes | 28 (80%) |
| | No | 7 (20%) |
| | If yes, hours/week* | 28 [20,32] |
| Preeclampsia characteristics | | |
| Time since severe preeclampsia | ≥3 months to 1 year | 8 (23%) |
| | 1-3 years | 8 (23%) |
| | ≥3 years | 19 (54%) |
| Preeclampsia-related health | Yes | 17 (49%) |
| complaints still present | No | 18 (51%) |

Displayed value is frequency (percentage of total participants) unless marked with a *, in which case the displayed value is the median [interquartile range].

^{**}Classified using the International Standard Classification of Education.

Needs regarding health promotion target behavior

Table 2 shows the needs of participants in terms of the target behavior of the intervention. In descending order, participants struggled to follow a healthy lifestyle with respect to their fat and sugar intake (43%), physical activity (31%), water intake (20%), mental well-being (practices) (17%), salt intake (15%), alcohol use (11%), fruit and vegetable intake (6%), and tobacco use (6%). Results regarding planning to make positive changes to these behaviors, and being interested in participating in an appbased intervention targeting these behaviors showed a similar pattern; although generally, more women reported planning to make positive changes and being interested in an app-based intervention, than they reported struggling with health behaviors.

Table 2. Needs regarding health promotion target behavior.

| (n = 35) | | Struggling to follow a healthy lifestyle regarding | Planning to make positive changes to | Interested in participating in intervention targeting |
|----------------------------|-----|--|--------------------------------------|---|
| Physical activity | Yes | 11 (31%) | 16 (46%) | 17 (49%) |
| | No | 24 (69%) | 19 (54%) | 18 (51%) |
| Fat and sugar intake | Yes | 15 (43%) | 22 (63%) | 17 (49%) |
| | No | 20 (57%) | 13 (37%) | 18 (51%) |
| Fruit and vegetable intake | Yes | 2 (6%) | 13 (37%) | 10 (28%) |
| | No | 33 (94%) | 22 (63%) | 25 (72%) |
| Salt intake | Yes | 5 (15%) | 9 (25%) | 9 (25%) |
| | No | 30 (85%) | 26 (75%) | 26 (75%) |
| Water intake | Yes | 7 (20%) | 11 (31%) | 7 (20%) |
| | No | 28 (80%) | 24 (69%) | 28 (80%) |
| Mental well-being | Yes | 6 (17%) | 15 (43%) | 12 (34%) |
| (practices) | No | 29 (83%) | 20 (57%) | 23 (66%) |
| Alcohol use | Yes | 4 (11%) | 4 (11%) | 3 (9%) |
| | No* | 31 (89%) | 23 (89%) | 25 (91%) |
| Tobacco use | Yes | 2 (6%) | 2 (6%) | 1 (3%) |
| | No* | 7 (94%) | 5 (94%) | 11 (97%) |

Displayed value is frequency (percentage of total participants).

Scale ratings between 1 and 4 were collapsed into No, and ratings between 4 and 7 were collapsed into Yes.

^{*} The option not applicable (N/A) was included for alcohol and tobacco use. N/A was collapsed into *No* as well: 15% and 74% reported N/A for struggling with the behavior, 23% and 80% reported N/A for planning to make positive changes to the behavior, and 20% and 66% reported N/A for being interested in an intervention concerning alcohol and tobacco use, respectively.

Preferences regarding intervention delivery

Table 3 shows the five themes of preferred intervention delivery, in descending order: tracking of health-related metrics (i.e., monitoring outcomes over time), interactivity (i.e., two-way communication with other people or app), behavior change strategy (i.e., methods to alter determinants of behavior), information (i.e., health-related information), and personalization (i.e., tailored delivery). Example quotes of each theme are presented below in English (example quotes are published in their original language under supporting information, supporting table 4). Table 3 also summarizes participants' preferred intervention duration: 12 weeks (interquartile range 5 to 52 weeks), 2 hours and 45 minutes per intervention week (interquartile range 1 to 5 hours).

Table 3. Preferences regarding intervention delivery.

| Themes* | (n = 35) | |
|--------------------------------|------------|--|
| Tracking | 31 (89%) | |
| Interactivity | 26 (74%) | |
| Behavior change strategy | 24 (69%) | |
| Information | 20 (57%) | |
| Personalization | 19 (54%) | |
| Preferred time demand** | | |
| Time, number of weeks (n = 23) | 12 [5, 52] | |
| Time, hours per week (n = 32) | 2.75 [1,5] | |
| | | |

^{*}Displayed value is frequency (percentage of total participants).

Tracking

The majority of participants (89%) mentioned the tracking of various health-related metrics as a preferred component of the intervention, for example "Measurement of steps, heart rate, exercise intensity", "Tracking nutrition", and "Monitoring well-being".

Interactivity

Three out of four women (74%) preferred the program to contain interactive elements, such as "Exercising together remotely", "Points for exercise and drinking [water], competition with participants", and "Asking questions to specialists and be able to approach fellow [preeclampsia] sufferers".

^{**}Displayed value is median [interquartile range]. Not all women reported a meaningful number to this question, therefore n < 35.

Behavior change strategy

Nearly three-quarter of participants (69%) mentioned behavior change strategies that they would like the app to include, for example "Tips on how to build up a daily routine", "Amount of exercise per day/week and intervene accordingly: stimulate if it is not enough, reward if it is sufficient" (Note: this coding instance was also coded as another theme, Tracking), and "Tips (exercises, e.g., meditation) for reducing stress, busy mind, relaxation".

Information

Over half of women (57%) reported provision of information to be a desired element of the intervention, such as "Lots of information, but not just to 'scare' you, as in, if you don't move, you get this disease! Instead, for example, it has been proven that if you exercise X times a week, your blood pressure drops by X. Digestible, smaller bits of information", "Relationship between preeclampsia and exercise, and what effects this can have", and "High blood pressure in combination with exercise, how much do you have to sweat or be out of breath, what is enough in terms of amount of exercise. Which exercises can help with certain complaints, which exercises help to create a basic level of fitness and how do you train from there. What food can you eat before, during and after exercise".

Personalization

Over half of participants (54%) preferred the program to be personalized, for example "Reminder of exercises, goals; compliments on results/knowledge/overview" (Note: this coding instance was also coded as another theme, Interactivity), "Enough choices to turn things on and off", and "During the recovery process, I would have liked to have received feedback about which aspects were 'normal', and which need more attention or patience, and how to deal with them".

DISCUSSION

The objective of this study was to identify the needs and preferences of women with prior severe preeclampsia for app-based cardiovascular health promotion. Women's primary need for health behavior promotion pertained to their fat and sugar intake and physical activity; for some, their mental health (practices), fruit and vegetable intake, salt intake, and water intake; and for a few, their alcohol and tobacco use. Most women preferred the intervention to include, in descending order: the tracking of health-related metrics, an interactive platform, the use of behavior change strategies, the provision of information, and personalization.

Interpretation of key findings

Our results indicate that women's primary need lied in addressing their fat and sugar intake and physical activity. Both of these behaviors are closely linked to CVD risk, emphasizing the need for interventions that target these behaviors in this priority population [6, 11]. Participants' interest in improving these behaviors could be due to their awareness of their heightened CVD risk [52, 53], further strengthened by their wish to provide a healthy environment to their child(ren) [54]. Previous research showed that women with prior preeclampsia wish to receive support in adopting a healthy lifestyle [21], and that their post-partum period is a window of opportunity for behavior change [55].

After their need to address fat and sugar intake and physical activity, women's following priority was to gain better means to manage their mental health: half of participants reported to still experience health complaints related to preeclampsia, such as fatigue and anxiety, and problems with concentration and memory. Previous research has identified a negative impact of preeclampsia on mental health [56, 57]. A healthy lifestyle, such as engaging in physical activity, has been linked to improved mental health, therefore, future interventions could target multiple needs simultaneously [58-60]. Participants' need to address their fruit and vegetable intake, salt intake and water intake was modest, and their need to address alcohol and tobacco use was low. Implementing interventions targeting these behaviors in this group may yield low uptake and little behavior change.

We found that women with prior severe preeclampsia have a desire to gain information as part of a cardiovascular health promotion program, further emphasizing that providing informational lifestyle counselling is consistent with patients' preferences [22, 52]. Some women wanted to receive information on the relationship between preeclampsia, lifestyle behaviors, and CVD risk. Therefore, clinicians might want to consider devoting more time to elaborating on evidence-based recommendations to manage CVD risk after severe preeclampsia through the adoption of preventive health behaviors [6]. Moreover, participants were interested in receiving more detailed information on the interrelation between different health behaviors such as diet and physical activity, and how certain physical or mental health complaints may be alleviated. Therefore, informational intervention content could be enriched by consulting various specialists, such as dieticians, physiotherapists, or psychologists.

Additionally, participants preferred to receive more than 'just information': they were open to receiving instruction on behavior change strategies, such as planning, incentives, and stress reduction [61]. The primary preference of participants was the

tracking of their health-related metrics, such as dietary intake, physical activity intensity, and mental well-being. This finding is in line with studies demonstrating that patient autonomy is an integral part of the successful self-management of chronic diseases [62]. Interactivity was also a prominent preference of our participants: for example, they wanted to use the app to communicate with specialists, and to chat with and exercise together with other women who had severe preeclampsia. Interactive gamelike elements were also described, such as the collection of points and competition with other participants. Finally, our participants described a wish for the intervention to contain personalized elements, such as the option to customize content and the provision of feedback. These results, and previous findings that these intervention elements can enhance intervention effects and user usage and adherence, suggest that future app-based programs aimed to improve cardiovascular health in women with prior severe preeclampsia would benefit from including such elements in their delivery [63-65].

Strengths and limitations

The current study has several strengths. It is the first study to conduct an in-depth assessment of the needs and preferences of women with prior severe preeclampsia for app-based cardiovascular health promotion. Secondly, it yields several applicable suggestions for intervention researchers to inform the design of apps for women with prior severe preeclampsia, potentially increasing intervention uptake, behavior change, and behavior change maintenance. Finally, our findings could be applicable to other populations, such as women with a history of other types of hypertensive pregnancy disorders, or other pregnancy complications, such as intrauterine growth restriction or gestational diabetes. However, our study also had some limitations that should be taken into account when interpreting the results. It could be that as our study population was drawn from an outpatient clinic specialized in the cardiovascular followup and risk management of women with prior severe preeclampsia, participants had a higher awareness of their increased risk for CVDs than most women with prior preeclampsia. Second, some participant quotes offered little context, limiting the interpretation of preferences (e.g., participants did not specify whether a behavior change strategy would be useful in all health behavior contexts, or only the context they used to exemplify the strategy). Third, our study population was highly educated, limiting the generalizability of our findings to all socioeconomic groups, e.g. in terms of preferences regarding health apps. Fourth, the size of our study sample might have been too small to allow for generalizations to be made based on our quantitative findings, i.e. regarding needs. Fifth, while the experience of medical staff has provided some input on the comprehensibility and acceptability of our study materials, future studies should also including members of the target population in the pilot testing phase to garner external and lay perspectives. Finally, our study did not assess the extent to which self-perceived need for behavior change reflects actual unhealthy behavioral habits, i.e., quantitative data on participants' health behavior was not collected, nor were participants informed of ideal values of all health behaviors under study.

Conclusion

Cardiovascular health promotion targeting women with prior severe preeclampsia should feel relevant to its audience. App-based interventions are likely to be well received if they target fat and sugar intake and physical activity. These interventions should preferably track health-related metrics, be interactive, contain behavior change strategies, provide information, and be personalized. Adopting these findings during intervention design could potentially increase uptake, behavior change, and behavior change maintenance in this population.

Ethics approval and consent to participate

Informed consent was obtained from all subjects. This study adheres most strictly to all applicable legal, ethical, and safety provisions of the Netherlands and the EU. The study was conducted in accordance with the principles of the Declaration of Helsinki [66]. The Medical Ethics Committee of the Erasmus MC has approved this study (MEC-2020-0390).

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SUPPORTING INFORMATION

Supporting table 1. Correlations between components of needs per health behavior.

| Physical activity ($n = 35$) | Struggling with behavior | Interested in intervention |
|---------------------------------------|----------------------------|----------------------------|
| Planning change | 0.36* | 0.51** |
| Interested in intervention | 0.23 | - |
| Fat and sugar intake (n = 35) | Struggling with behavior | Interested in intervention |
| Planning change | 0.36* | 0.40** |
| Interested in intervention | 0.42** | - |
| Fruit and vegetable intake (n = 35) | Struggling with behavior | Interested in intervention |
| Planning change | 0.37* | 0.55** |
| Interested in intervention | 0.46** | - |
| Salt intake (<i>n</i> = 35) | Struggling with behavior | Interested in intervention |
| Planning change | 0.47** | 0.47** |
| Interested in intervention | 0.41** | - |
| Water intake (n = 35) | Struggling with behavior | Interested in intervention |
| Planning change | 0.42** | 0.40** |
| Interested in intervention | 0.56** | - |
| Mental well-being (practices) (n = 35 |) Struggling with behavior | Interested in intervention |
| Planning change | 0.46** | 0.54** |
| Interested in intervention | 0.70** | - |
| Alcohol use (n = 27) | Struggling with behavior | Interested in intervention |
| Planning change | 0.55** | 0.53** |
| Interested in intervention | 0.59** | - |
| Tobacco use (n = 7) | Struggling with behavior | Interested in intervention |
| Planning change | 1.00** | 0.63 |
| Interested in intervention | 0.63 | - |
| | | |

Spearman's rho coefficients under 0.4 represent a weak correlation, between 0.4 and 0.79 a moderate correlation, and between 0.8 and 1 a strong correlation.

For alcohol and tobacco use N/A was treated as system missing, therefore n < 35.

^{* =} Statistically significant at p < 0.05, one-tailed; ** = Significant at p < 0.01, one-tailed.

Supporting table 2. Thematic analysis procedure examples.

Ouote:

"Measuring heart rate, how many minutes you have been active, being able to score the activity yourself"

Coding instance identification:

Measuring heart rate + how many minutes you have been active + being able to score the activity yourself = 3 coding instances in total

Categorization of coding instance into theme:

Measuring heart rate = Coding instance categorized as tracking

How many minutes you have been active = Coding instance categorized as tracking

Being able to score the activity yourself = Coding instance categorized as personalization

Ouote:

"Amount of exercise per day/week and intervene accordingly: stimulate if it is not enough, reward if it is sufficient"

Coding instance identification:

Amount of exercise per day/week and intervene accordingly: stimulate if it is not enough, reward if it is sufficient = 1 coding instance in total

Categorization of coding instance into theme:

Amount of exercise per day/week and intervene accordingly: stimulate if it is not enough, reward if it is sufficient = Coding instance categorized as tracking *and* behavior change strategy

Quote:

"Incorporate into daily routine, exercises that you can do anywhere"

Coding instance identification:

Incorporate into daily routine + exercises that you can do anywhere = 2 coding instances in total

Categorization of coding instance into theme:

Incorporate into daily routine = Coding instance categorized as behavior change strategy Exercises that you can do anywhere = Coding instance categorized as information

Supporting table 3. Examples of participant quotes: health complaints still present due to prior preeclampsia.

| Quote in Dutch (Original) | Quote in English (Translation) |
|---|--|
| "Hoofdpijn, prikkelgevoelig, angstig, soms moe" | "Headache, sensitive to stimuli, anxious, sometimes tired" |
| "Geheugen-, concentratie-, leer-, oriëntatieproblemen, zeer prikkelgevoelig, zeer vermoeid" | "Problems with memory, concentration, learning and orientation, very sensitive to stimuli, very tired" |
| "Hypertensie" | "Hypertension" |
| "Korte termijn geheugen" | "Short-term memory" |
| "Ik ben nog snel moe en heb minder energie" | "I am still quickly fatigued and have less energy" |
| "Snel overprikkeld, niet op woorden kunnen komen, mindere concentratie" | "Easily overstimulated, unable to find words, less concentration" |
| "Mijn mentale draagkracht en conditie zijn nog lager" | "My mental capacity and condition are still lower [than before preeclampsia]" |
| "Ik heb nog steeds een hoge bloeddruk" | "I still have high blood pressure" |
| "Vergeetachtig, traumatische beelden zien, warrig" | "Forgetful, seeing traumatic images, confused" |

Supporting table 4. Examples of participant quotes: intervention delivery preferences.

| Theme | Quote in Dutch (Original) | Quote in English (Translation) |
|--|--|--|
| Tracking | "Meten van stappen, hartslag, intensiteit van sporten" | "Measurement of steps, heart rate, exercise intensity" |
| Tracking | "Het bijhouden van voeding" | "Tracking nutrition" |
| Tracking | "Welzijn monitoren" | "Monitoring wellbeing" |
| Interactivity | "Samen sporten op afstand" | "Exercising together remotely" |
| Interactivity | "Punten bij beweging en [water] drinken, competitie met deelnemers" | "Points for exercise and drinking [water], competition with participants' |
| Interactivity | "Vragen stellen aan specialisten en lotgenoten kunnen benaderen" | "Asking questions to specialists and be able to approach fellow [preeclampsia] sufferers" |
| Behavior change strategy | "Tips over hoe iemand de dagelijkse routine inbouwt" | "Tips on how to build up a daily routine" |
| Behavior change strategy (and Tracking) | "Hoeveelheid beweging per dag/week en hierop ingrijpen: stimuleren als het te weinig is, belonen als het voldoende is" | "Amount of exercise per day/week and intervene accordingly: stimulate if it is not enough, reward if it is sufficient" |
| Behavior change strategy | "Tips (oefeningen, bijvoorbeeld meditatie) voor het verminderen van stress, drukte in het hoofd, ontspanning" | "Tips (exercises, e.g., meditation) for reducing stress, busy mind, relaxation" |
| Information | "Veel informatie, maar niet alleen 'bang maken' als in: als je niet beweegt, krijg je deze ziekte! Wel bijvoorbeeld, bewezen is dat als je X keer per week sport, je bloeddruk met X daalt. Dus maak het behapbaar, kleinere stukjes info" "Lots of information, but n 'scare' you, as in, if you dor. get this disease! Instead, fo has been proven that if you times a week, your blood pr by X. Digestible, smaller bit information" | |
| Information | "Relatie tussen preeclampsie en beweging en welke effecten dit kan hebben" | "Relationship between preeclampsia and exercise, and what effects this can have" |
| Information | "Hoge bloeddruk in combinatie met sporten, hoeveel moet je zweten of buiten adem zijn, wat is genoeg qua hoeveelheid sporten. Welke oefeningen kunnen helpen bij bepaalde klachten, welke oefeningen helpen bij het creëren van een basisconditie en hoe ga je van daaruit verder trainen. Welke voeding kun je voor, tijdens en na het sporten innemen" | "High blood pressure in combination with exercise, how much do you have to sweat or be out of breath, what is enough in terms of amount of exercise. Which exercises can help with certain complaints, which exercises help to create a basic level of fitness and how do you train from there. What food can you eat before, during and after exercise" |

Supporting table 4. Continued

| Theme | Quote in Dutch (Original) | Quote in English (Translation) |
|--|--|---|
| Personalization (and Interactivity) | "Herinnering aan oefeningen, doelen; complimenten over resultaten/ kennis/ overzicht" | "Reminder of exercises, goals, compliments on results/knowledge/ overview" |
| Personalization | "Genoeg keuzes om zaken aan en uit te zetten" | "Enough choices to turn things on and off" |
| Personalization | "In hersteltraject had ik wel feedback willen krijgen over welke aspecten 'normaal' waren en welke meer aandacht of geduld behoeven en hoe daarmee om te gaan" | "During the recovery process, I would have liked to have received feedback about which aspects were 'normal', and which need more attention or patience, and how to deal with them" |



CHAPTER 5

Perceived determinants of physical activity among women with prior severe preeclampsia: a qualitative assessment

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ABSTRACT

Background

The objective of this study was to (1) qualitatively identify the perceived determinants of physical activity among women who have experienced severe preeclampsia, and (2) examine whether these determinants are consistent with the overarching motivational, volitional, and automatic processes described in the integrated behavior change (IBC) model, a novel model that describes physical activity as being a result of motivational, volitional, and automatic processes.

Methods

Patients (n = 35) of the Follow-Up PreEClampsia (FUPEC) Outpatient Clinic, Erasmus MC, the Netherlands, participated in an anonymous online survey. The main outcomes under study were their perceived determinants of physical activity. Responses were analyzed using thematic analysis.

Results

Thirteen themes emerged from the analysis. Six themes corresponded with motivational processes (future health, physical appearance, future reward or regret, attitude, doing it for others, and perceived ability), two with volitional processes (scheduling and planning), and two with automatic processes (affect and stress). Three themes were classified as environmental factors (time constraint, social support, and physical environment).

Conclusions

A range of facilitating and hindering factors were described by women with prior severe preeclampsia as the determinants of their physical activity. These factors corresponded well with the overarching motivational, volitional, and automatic processes described in the IBC model. In addition, motivational and environmental factors beyond the IBC model were described. Addressing these perceived determinants could enhance the efficacy of physical activity interventions in this population.

Keywords: Preeclampsia, cardiovascular health, physical activity, perceived determinants, qualitative study.

INTRODUCTION

Preeclampsia has been associated with a two- to eightfold increase in lifetime risk for cardiovascular disease (CVD) [1-3]. Therefore, cardiovascular follow-up and risk management are recommended for women with prior preeclampsia [2, 3]. CVD risk can be substantially reduced by engaging in sufficient levels of moderate-to-vigorous physical activity (MVPA) [4]. International guidelines advise adults to accumulate at least 150 minutes of moderate physical activity, or 75 minutes of vigorous physical activity, or an equivalent combination of MVPA spread throughout the week [4]. Over 31% of women worldwide fail to meet these guidelines [5]. Consequently, efficacious MVPA interventions are warranted, especially for priority groups such as women with prior severe preeclampsia [6].

Interventions promoting MVPA seldom achieve large and long-term effects [7]. A primary reason for these limitations could be their insufficient foundations in behavioral theory [8-11]. It is increasingly recognized that to maximize their efficacy, behavioral interventions should be based on theories that account for multiple processes that drive behavior [12-14]. Dual-system theories describe two types of processes that lead to action: *automatic* processes, determining behavior by impulses and habitual associations between context and action, and *deliberative* processes, determining behavior by reasoned deliberation and the value attached to the action [14-17].

To account for these multiple processes and provide more comprehensive explanations of behavior, integrated theories that derive their hypotheses from more than one theory have been proposed. A novel theory in this regard is the integrated behavior change (IBC) model. The IBC model integrates several well-established behavioral theories and posits that three types of processes determine MVPA: motivational, volitional, and automatic processes [18-20]. Motivational processes are modelled by variables that represent deliberative decision making, such as intention and intrinsic motivation. To follow, the IBC model proposes that the enactment of intentions formulated in the motivational phase are facilitated in the volitional phase by planning variables. Finally, automatic processes are represented by variables that bypass the intention-mediated processes, such as affect and habit. Since its conception, the IBC model has been used to explain a number of health behaviors, including MVPA, in observational studies [21-29].

Both quantitative and qualitative methods have been previously used to assess the *perceived* determinants of MVPA, and to offer recommendations for the design of MVPA interventions in the general postpartum population [30-32], and in women with prior

preeclampsia specifically [33, 34]. These studies provide broad, rich data on the perceived determinants of MVPA, thereby contributing converging evidence of theoretical frameworks. Previously, only one comparable qualitative study used a theoretical framework, the theory of planned behavior, to interpret their results [35]. The IBC model has been qualitatively assessed only once before, in the context of MVPA in older adults [36].

The objective of this study is twofold. First, we aim to qualitatively identify the perceived determinants of MVPA among women who have experienced severe preeclampsia. Second, we aim to examine whether the identified determinants are in line with the overarching motivational, volitional, and automatic processes described in the IBC model. Both contributions may have utility in the development of effective MVPA interventions in women with prior preeclampsia.

MFTHOD

The study follows the Standards for Reporting Qualitative Research (SRQR) guidelines [37].

Study setting

The current study was conducted in the context of an outpatient clinic for women with prior severe preeclampsia. In the Erasmus Medical Center (Erasmus MC), cardiovascular follow-up and care is provided to women with prior severe preeclampsia at the multidisciplinary Follow-Up Pre-EClampsia Outpatient Clinic (FUPEC), the only clinic of its kind in the country [38]. There are currently around 1500 patients registered at the clinic, with an additional 100 to 150 women enrolling each year.

Study population

Participants were recruited at the FUPEC clinic between September and November 2020 (n = 35). Inclusion criterion for participation was having experienced at least one pregnancy complicated by severe preeclampsia, as defined by the American Congress of Obstetricians and Gynecologists [39]. Exclusion criteria for participation were: <18 years of age, pregnant at time of inclusion, <3 months after delivery, any circumstance preventing MVPA (e.g. illness, injury, surgery, rehabilitation), insufficient knowledge of the Dutch language, and no possession of a smartphone. These exclusion criteria were applied to obtain a sample of women similar to those who will participate in a future app-based cardiovascular health promotion intervention [40]. A total of six women were excluded (three women were <3 months after delivery; three women had insufficient knowledge of Dutch). Invited women were informed that participation in

the study was voluntary and that they could withdraw from the study at any point without having to provide a reason. Women who chose to participate signed an informed consent form in advance of participation. The inclusion of participants was halted when the first two authors (LLK, MvdB) agreed that no new themes were expected to emerge from the inclusion of subsequent participants [41].

Patient and public involvement

Patients and members of the public were not involved in the design, conduct, or reporting of this study.

Design

An anonymous online survey was administered.

Sampling strategy

The study used criterion sampling, i.e. participants needed to have prior experience with severe preeclampsia [42].

Implementation

Women were asked at their FUPEC appointment whether they were interested in participating in an anonymous online survey. Women who did not make it to their scheduled appointment were asked by email. Those that indicated interest either at the appointment or by email received the survey. Of the 122 women approached, 119 agreed to receive the survey. Of those 119 women, 55 started the survey. Of those 55 women, 35 provided complete responses. Only complete responses were used in the current analysis. Women who did not provide complete responses (n = 20) were comparable to the study sample (n = 35) in age, educational level, when they had experienced severe preeclampsia, and whether or not, on an average week, they reached 150 minutes of MVPA (data not shown). The survey assessed four topics: demographics, needs for a cardiovascular health promotion intervention, perceived determinants of MVPA, and preferences for an a cardiovascular health promotion intervention. The current study used data on the first and third topics. Data on the second and fourth topics was collected for the purpose of a needs and preferences assessment, the results of which will be published separately. The survey was hosted online on the data capture tool Limesurvey [43]. Data were imported into IBM SPSS Statistics and NVivo for analyses [44, 45].

Main outcome measures

The main outcome of this study was participants' perceived determinants of MVPA, measured by five open questions in the anonymous online survey. These questions

were based on prior qualitative research on MVPA [30-32, 34, 36, 46]. Women answered the questions by typing their answers in open text fields.

In order to tap into motivational and volitional processes influencing MVPA, participants reported their general and preeclampsia-specific facilitators of and barriers to MVPA by answering the following questions: "What are your reasons for being physically active?", "What makes it easier for you to be physically active?", and "What makes it harder for you to be physically active?". In addition, in order to tap into automatic processes influencing MVPA, participants were prompted to recall a specific time when they had engaged in MVPA in the past ("Think of a moment after you have been physically active"), and to report on thoughts and feelings prior to that moment by answering the following questions: "What thoughts went through your head in that moment?", and "What emotions did you feel in that moment?".

Participants also reported their demographic characteristics: age (years), number of children (number), living situation (with or without partner, with or without children); educational level (lower, middle, higher; classified using the International Standard Classification of Education [47]); paid employment status (yes, no; if yes, number of hours per week); when they had experienced severe preeclampsia (between three months and one year ago, between one and three years ago, over three years ago); whether their preeclampsia-related complaints were still present (yes, no; if yes, what complaints); whether or not, on an average week, they reached 150 minutes of MVPA (yes, no); and whether COVID-19 restrictions had an effect on their MVPA (yes, no).

Data analysis

Descriptive statistics were used to report participants' demographic characteristics. Thematic analysis was used to identify themes across the data [48-50]. After reading and re-reading participants' responses, LLK and MvdB defined coding instances, and identified thirteen recurring themes in these instances. They then returned to the data independently, and categorized each coding instance into one of the thirteen themes. Initial interrater percent agreement was 71%. Subsequently, categorizations were jointly revisited until 100% agreement was reached. Finally, identified themes were matched to the overarching motivational, volitional, and automatic processes described in the IBC model, resulting in the coding tree of the current data (see Figure 1) [51].

RESULTS

Characteristics of the study sample

Table 1 shows the characteristics of the study sample (n = 35). Participants had a median age of 35 years. Most women had one child (54%) and were living with a partner (80%). The majority were highly educated (80%) and in paid employment (80%). Those in paid employment worked a median of 28 hours per week. Most women experienced severe preeclampsia more than three years ago (54%). Almost half of women were still experiencing health complaints related to severe preeclampsia (49%), e.g., fatigue and anxiety, and problems with concentration and memory (examples of participants' complaints are published under supporting information, Table 1). One in two women reported that they did not reach 150 minutes of MVPA per week (51%). The majority of women reported that the COVID-19 pandemic did not affect their MVPA levels (60%).

Overview of overarching themes

Figure 1 shows the coding tree of the qualitative analysis. In total, thirteen themes emerged from the analysis. These themes were matched to four overarching themes: motivational processes [a-f], volitional processes [g-i], automatic processes [j-l], and environmental factors [m-o].

Overview of themes

Themes within overarching themes are presented in descending order. Six themes corresponded with motivational processes: future health [a], perceived ability [b], attitude [c], future reward or regret [d], physical appearance [e], and doing it for others [f]. Two themes corresponded with volitional processes: scheduling [g], and planning [h]. Two themes corresponded with automatic processes: affect [i], and stress [j]. Finally, three themes were classified as environmental factors: time constraint [k], social support [l], and physical environment [m]. Example quotes of each theme are presented below in English (example quotes in their original language can be found under supporting information, Tables 2-5). The prevalence of themes in the total number of participants is displayed in Table 2, and in the total number of quotes in Table 3.

Motivational processes

Health

All women (100%) mentioned their future health, including physical, mental, and general health, as a motivator of their MVPA. Women reported their physical health as a motivator to be physically active, for example "Preparation for a healthy next pregnancy", and "If I stay healthy and maintain my weight, I will have a lower chance for cardiovascular diseases". Participants also mentioned their mental health as a

facilitator of their MVPA, for example "Feeling good mentally", and "I recover better mentally if I feel well physically". Women also reported general health, i.e. health states that reflect both mental and physical well-being, as a motivator of their MVPA, for example "I want to feel less tired", and "I want to overcome my constant fatigue".

Table 1. Characteristics of the study population.

| Demographics | | Total (n = 35) |
|--|---|----------------|
| Age* | Years | 35 [32,44] |
| Number of children | 0 | 2 (6%) |
| | 1 | 19 (54%) |
| | 2 3 | 12 (34%) |
| | | 2 (6%) |
| Living situation | With partner and children | 26 (74%) |
| | Without partner, with children | 7 (20%) |
| | With partner, without children Without partner and children | 2 (6%) |
| | · | 0 (0%) |
| Educational level** | Lower | 0 (0%) |
| | Middle Higher | 7 (20%) |
| | nigner | 28 (80%) |
| Paid employment | Yes | 28 (80%) |
| | No | 7 (20%) |
| | If yes, hours/week* | 28 [20,32] |
| Preeclampsia characteristics | | |
| Time since severe preeclampsia | ≥3 months to 1 year | 8 (23%) |
| | 1-3 years ≥3 years | 8 (23%) |
| | 25 years | 19 (54%) |
| Pre-eclampsia related complaints still present | Yes | 17 (49%) |
| | No | 18 (51%) |
| Physical activity | | |
| Reaching ≥150 minutes of MVPA*** per week | Yes | 17 (49%) |
| | No | 18 (51%) |
| COVID-19 effects on MVPA | No effect | 21 (60%) |
| | Negative Positive | 12 (34%) |
| | rusiuve | 2 (6%) |

Displayed value is frequency (percentage of total participants) unless marked with a *, in which case the displayed value is the median [interquartile range].

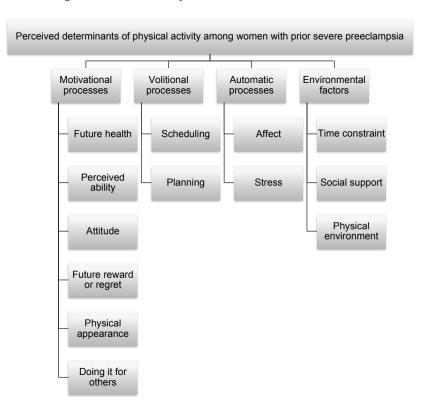
^{**} Classified using the International Standard Classification of Education.

^{***} MVPA= moderate-to-vigorous physical activity.

Perceived ability

The majority of women (66%) mentioned their perception of (temporarily) having a reduced ability to engage in MVPA as a barrier to their MVPA, for example "Many episodes of headaches", and "Afraid to be intensely physically active after preeclampsia".

Figure 1. The coding tree of the thematic analysis.



Attitude

Approximately half of the women (49%) reported on their attitude towards physical activity. Most have reported their attitude to facilitate their MVPA, for example "I don't see exercising as an obligation, but as something pleasant", while a few reported it as a barrier, for example "I'd rather do other things".

Future reward or regret

More than one-third of women (40%) mentioned an expected future reward or regret of physical activity to motivate their MVPA, for example "As soon as you finish you will feel great", and "I will have a bad conscience if I don't go".

Table 2. Prevalence of themes in total number of participants.

| Overarching themes and themes | Number of participants mentioning theme (Percentage of total participants n = 35) |
|-------------------------------|--|
| Motivational processes | |
| Future health | 35 (100%) |
| Perceived ability | 26 (66%) |
| Attitude | 17 (49%) |
| Future reward or regret | 14 (40%) |
| Physical appearance | 10 (29%) |
| Doing it for others | 6 (17%) |
| Volitional processes | |
| Scheduling | 12 (34%) |
| Planning | 5 (14%) |
| Automatic processes | |
| Affect | 27 (77%) |
| Stress | 7 (20%) |
| Environmental factors | |
| Time constraint | 23 (66%) |
| Social support | 22 (63%) |
| Physical environment | 20 (57%) |

Table 3. Prevalence of themes in total number coding instances.

| Overarching themes and themes | Number of coding instances mentioning theme (Percentage of total coding instances n = 411) |
|-------------------------------|--|
| Motivational processes | |
| Future health | 97 (24%) |
| Perceived ability | 54 (13%) |
| Attitude | 33 (8%) |
| Future reward or regret | 18 (4%) |
| Physical appearance | 10 (2%) |
| Doing it for others | 7 (2%) |
| Volitional processes | |
| Scheduling | 14 (3%) |
| Planning | 6 (1%) |
| Automatic processes | |
| Affect | 48 (12%) |
| Stress | 8 (2%) |
| Environmental factors | |
| Time constraint | 45 (11%) |
| Social support | 32 (8%) |
| Physical environment | 36 (9%) |

Physical appearance

Approximately one-third of participants (29%) reported physical appearance as a facilitator of their MVPA, for example "To keep my body beautiful".

Doing it for others

Almost one-fifth of women (17%) mentioned other people as a motivator of their MVPA, for example "I want to set a good example for my daughter".

Volitional processes

Scheduling

Over one-third of women (34%) reported scheduling to promote their MVPA, for example "Friends that I made an arrangement to exercise with", and "Obligation [to attend physiotherapy]".

Planning

Some women (14%) mentioned adequate planning as a facilitator of their MVPA, for example "A good planning"".

Automatic processes

Affect

The majority of women (77%) reported specific feelings prior to participating in MVPA, for example "Fear", and "Happy".

Stress

One-fifth of women (20%) mentioned stress in their daily life as an obstacle to their MVPA, for example "Little relaxation", and "Being overstimulated after a long day".

Environmental factors

Time constraint

Two-thirds of women (66%) reported time constraint as a barrier to their MVPA, for example "I need to have enough time to exercise, so that I don't feel hastened to finish too soon", and "Much to do at home with the baby".

Social support

Almost two-third of participants (63%) discussed social support as a facilitator of their MVPA, for example "Friends to walk with", and "Encouragement from FUPEC [doctors]".

Physical environment

Over half of women (57%) reported their physical environment as a determinant of their MVPA, for example "Bad weather", and "Sports facilities I really like".

DISCUSSION

The objective of this qualitative study was to identify the perceived determinants of MVPA among women who have experienced severe preeclampsia, and to examine the extent to which these determinants relate to those proposed in the IBC model. Our findings demonstrate that women with prior severe preeclampsia perceive a wide range of facilitating and hindering factors to determine their MVPA. In total, thirteen themes emerged from the analysis. These themes were matched to four overarching themes: motivational processes, volitional processes, automatic processes, and environmental factors. We found these themes to correspond well with the overarching processes identified in the IBC model. In addition, motivational and environmental factors beyond the IBC model were reported by participants.

Interpretation of key findings

Our study provides detailed data on the perceived determinants of MVPA in women with prior severe preeclampsia. All women reported concerns about their future health, such as reducing their future risk for CVD, as a motivator of their MVPA. While future health has been previously found to be a motivator for adopting a healthy lifestyle in women with prior preeclampsia [35], the prevalence of this facilitator in our population is noteworthy, considering that previous studies found approximately one-tenth of postpartum women to report their future health as an important motivator of their MVPA [31]. Two-third of our participants reported their perceived ability to engage in MVPA to be reduced temporarily by for example headaches: about three times more often than the general postpartum population [31]. A link between preeclampsia and migraine headaches have previously been hypothesized [52]. Our finding that fatigue and stress are perceived by many as a barrier to MVPA is consistent with previous studies in postpartum women [30]. Some women in our study were hoping to alleviate their health complaints by engaging in MVPA, a mechanism backed by research [53-55], and a wish echoed by other postpartum women [31]. Some women aimed to accommodate healthy future pregnancies by engaging in MVPA, in line with previous research that found preparation for a future pregnancy, and the young family stage in general, to provide unique motivation to engage in MVPA [32, 56-58].

In general, we found that the perceived determinants of MVPA among our participants had reasonable correspondence with the overarching motivational, volitional, and automatic processes described in the IBC model [51]. In addition, our study identified a motivational determinant of MVPA beyond those described in the IBC model: future reward or regret. Future reward and future regret have been previously identified as potential determinants of MVPA in the general population [59-61]. Furthermore, in

addition to the processes described in the IBC model, we found the perceived environmental factors of time constraint, social support and physical environment to influence MVPA, in line with prior research in postpartum women [30-32]. Basing behavioral interventions on theory, and qualitatively assessing the choice of theory during the design stage, can add to the efficacy of subsequent interventions [62]. In combination with evidence from previous observational studies [21-29], the results of our study suggest that the IBC model, potentially extended with the variables of future reward or regret, time constraint, social support, and physical environment, may be a suitable theory-base for MVPA interventions in women with prior severe preeclampsia.

Implications for practice

Results from this study provide entry points for improving lifestyle counseling at the clinic, and for other types of lifestyle interventions that health care practitioners may use to promote MVPA in women with prior preeclampsia. Most participants expressed their appreciation for existing support and requested additional support from their healthcare professionals in their quest for sufficient MVPA, in line with prior research in this population [33, 34].

In light of our finding that many women perceive themselves to be less able to engage in MVPA after having experienced severe preeclampsia, practitioners are encouraged to convey to their patients that clinical guidelines advise them to accumulate as much MVPA as the general population [63]. Given evidence on the reciprocal relationship between mental health and MVPA [55], and on the negative impact of preeclampsia on mental health [64, 65], practitioners could emphasize to their patients that engaging in MVPA will not only benefit their physical health, but also their mental health.

Several volitional processes described by our participants resembled some well-established behavior change techniques, i.e. the active ingredients of behavior change interventions [66]. The scheduling described by our participants can be likened to temptation bundling, i.e. linking an action one wants to do with an action one needs to do [67], and commitment, i.e. pre-committing oneself to MVPA by ways of financial or social investment [68]. Some participants used planning to stay active [69]. Given these techniques' apparent relevance, and similarity to techniques previously suggested to aid the MVPA of postpartum women [30], they could be valuable components of MVPA interventions in this population.

Strengths and limitations

Our study has several strengths. Our findings provide health care practitioners with insight into the perceived determinants of MVPA in women with prior severe

preeclampsia, allowing them to tailor lifestyle counselling to their patients' needs. Second, our comparison of the perceived determinants of MVPA with a novel theoretical framework, the IBC model, supports health care practitioners in providing care in a theory-based manner. Finally, our findings may be applicable to other populations. such as women with other types of prior hypertensive pregnancy disorders, or other pregnancy complications, such as gestational diabetes or intrauterine growth restriction. However, some limitations should be considered when interpreting the results of our study. It is possible that our study population, self-selected from an outpatient clinic specialized in the cardiovascular follow-up and risk management of women with prior severe preeclampsia, may have had a higher awareness of their increased risk for CVDs than the average woman with prior preeclampsia. Second, as most of our participants were highly educated, our findings are less generalizable to all socioeconomic groups. Third, some quotes of participants provided little context, which limited the interpretation of the reported determinant (e.g. whether it is a facilitator or barrier of MVPA). Fourth, the relationship between perceived environmental factors and actual environmental factors was not assessed in this study; therefore, it is possible that the perceived environmental factors reported by participants more closely reflect (a lack of) perceived behavioral control, or other individual-level variables. rather than true environmental constraints. Finally, participating in a qualitative study requires deliberative thought, which means that our data collected on the automatic determinants of MVPA reflect individuals' perceptions and experiences; whether or not participants are aware of, or have access to, processes that are automatic and are purported to affect behavior beyond their awareness is an open question [70].

Conclusion

A wide range of factors determine MVPA among women with a history of severe preeclampsia. The identified factors correspond well with the overarching motivational, volitional, and automatic processes described in the IBC model. In addition, motivational and environmental factors beyond the IBC model were identified. Targeting these factors could enhance MVPA intervention efficacy among women with prior severe preeclampsia.

Ethics approval and consent to participate

This study adheres most strictly to all applicable legal, ethical, and safety provisions of the Netherlands and the EU. The study was conducted in accordance with the principles of the Declaration of Helsinki [71]. The Medical Ethics Committee of the Erasmus MC has approved this study (MEC-2020-0390).

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SUPPORTING INFORMATION

Table 1. Examples of participant quotes: complaints still present due to prior severe preeclampsia.

| Quote in Dutch (Original) | Quote in English (Translation) |
|---|--|
| "Hoofdpijn, prikkelgevoelig, angstig, soms moe" | "Headache, sensitive to stimuli, anxious, sometimes tired" |
| "Geheugen-, concentratie-, leer-, oriëntatieproblemen, zeer prikkelgevoelig, zeer vermoeid" | "Problems with memory, concentration, learning and orientation, very sensitive to stimuli, very tired" |
| "Hypertensie" | "Hypertension" |
| "Korte termijn geheugen" | "Short-term memory" |
| "Ik ben nog snel moe en heb minder energie" | "I am still quickly fatigued and have less energy" |
| "Snel overprikkeld, niet op woorden kunnen komen, mindere concentratie" | "Easily overstimulated, unable to find words, less concentration" |
| "Mijn mentale draagkracht en conditie zijn nog lager" | "My mental capacity and condition are still lower [than before preeclampsia]" |
| "Ik heb nog steeds een hoge bloeddruk" | "I still have high blood pressure" |
| "Vergeetachtig, traumatische beelden zien, warrig" | "Forgetful, seeing traumatic images, confused" |

Table 2. Examples of participant quotes: Motivational processes.

| Theme | Quote in Dutch (Original) | Quote in English (Translation) |
|-------------------------|--|--|
| Future health | "Conditie opbouwen" | "To build up my physical stamina" |
| Future health | "Afvallen" | "Lose weight" |
| Future health | "Als ik gezond en op gewicht blijf heb ik minder kans om hart- en vaatziekten te krijgen" | "If I stay healthy and maintain my weight, I will have a lower chance for cardiovascular diseases" |
| Future health | "Voorbereiding op een gezonde volgende zwangerschap" | "Preparation for a healthy next pregnancy" |
| Future health | "Extra afvallen omdat de zwangerschapskilo's er toch minder snel afgaan na zo'n heftige tijd." | "I want to lose the baby weight, it disappears slower after such challenging times" |
| Future health | "(Om voldoende te bewegen) om zo gezond mogelijk te leven" | "I am physically active to stay as healthy as possible" |
| Future health | "Minder moe willen zijn" | "I want to feel less tired" |
| Future health | "Goed voor mijn herstel en gezondheid" | "Good for my recovery and health" |
| Future health | "De constante vermoeidheid willen overwinnen" | "I want to overcome my constant fatigue" |
| Future health | "Goed voelen mentaal" | "Feeling good mentally" |
| Future health | "Ik herstel beter mentaal, als ik me fysiek ook goed voel" | "I recover better mentally if I feel well physically" |
| Perceived ability | Vaak hoofdpijn | "Many episodes of headaches" |
| Perceived ability | "Nog lichte pijn aan keizersnede" | "Still having light pain because of my caesarean" |
| Perceived ability | "Vermoeidheid door prikkelgevoeligheid" | "Fatigue due to sensitivity to stimulation" |
| Perceived ability | "Angst om intensief te bewegen na pre-eclampsie" | "Afraid to be intensely physically active after preeclampsia" |
| Attitude | "Zie het niet als verplichting maar echt als iets leuks!" | "I don't see exercising as an obligation but as something pleasant!" |
| Attitude | "Doe liever andere dingen" | "I'd rather do other things" |
| Future reward or regret | "Zodra je klaar ben voel je jezelf super" | "As soon as you finish you will feel great" |
| Future reward or regret | "Straks voel ik mij fitter" | "I immediately feel more fit" |
| Future reward or regret | "Het gevoel van een slecht geweten" | "I will have a bad conscience if I don't go" |
| Physical appearance | "Om mijn lichaam mooi te houden" | "To keep my body beautiful" |
| Doing it for others | "Goed voorbeeld voor dochter" | "I want to set a good example for my daughter" |
| Doing it for others | "Laten zien aan de buitenkant dat er niks mis was" | "I wanted to show the world that there is nothing wrong" |

Table 3. Examples of participant quotes: Volitional processes.

| Theme | Quote in Dutch (Original) | Quote in English (Translation) |
|------------|---|---|
| Scheduling | "Sociale aspect" | "Social aspect" |
| Scheduling | "Vrienden waarmee beweegafspraak is gemaakt" | "Friends that I made an arrangement to exercise with" |
| Scheduling | "Verplichting [van de fysiotherapie]" | "Obligation [to attend physiotherapy]" |
| Planning | "Na een lange werkdag nog een spinnig les doen, gaat helaas niet. Wel een rustigere yogales bijvoorbeeld. De intense lessen plan ik op mijn vrije dagen". | "After a long day at work I cannot do a spinning class, but I can do a yoga lesson. I plan to attend more vigorous lessons on free days" |
| Planning | "Goed plannen" | "A good planning" |

Table 4. Examples of participant quotes: Automatic processes.

| Theme | Quote in Dutch (Original) | Quote in English (Translation) |
|--------|--|---|
| Affect | "Blij" | "Нарру" |
| Affect | "Ben trots dat ik zo hard heb gewerkt" | "I am proud that I have worked this hard" |
| Affect | "Frustratie" | "Frustration" |
| Affect | "Angst" | "Fear" |
| Stress | "Stress" | "Stress" |
| Stress | "Weinig ontspanning" | "Little relaxation" |
| Stress | "Overprikkeld zijn na een lange dag" | "Being overstimulated after a long day" |

Table 5. Examples of participant quotes: Environmental factors.

| Theme | Quote in Dutch (Original) | Quote in English (Translation) | |
|----------------------|---|---|--|
| Time constraint | "Of heb ik voldoende tijd om te sporten zodat ik tijdens het sporten me niet opgejaagd voel om het snel af te ronden." | "I need to have enough time to exercise, so that I don't feel hastened to finish too soon." | |
| Time constraint | "Veel te doen thuis met baby" | "Much to do at home with the baby" | |
| Social support | "Vrienden om even te wandelen" | "Friends to walk with" | |
| Social support | "Meer tips en vaste plan van en professional" | "More tips and a steady plan from a professional" | |
| Social support | "Aansporing vanuit FUPEC" | "Encouragement from FUPEC" | |
| Physical environment | "Buiten sporten" | "Exercising outside" | |
| Physical environment | "Slecht weer" | "Bad weather" | |
| Physical environment | "Flexibele tijden" | "Flexible times" | |
| Physical environment | "Sportfaciliteiten die ik echt leuk vind" | "Sport facilities I really like" | |



CHAPTER 6

Moving from intention to behavior:
a randomized controlled trial protocol for
an app-based physical activity intervention
(i2be)

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ABSTRACT

Introduction

Efficacy tests of physical activity interventions indicate that many have limited or short-term efficacy, principally because they do not sufficiently build on theory-based processes that determine behavior. The current study aims to address this limitation.

Methods and analysis

The efficacy of the eight-week intervention will be tested using a three-condition randomized controlled trial delivered through an app, in women with a prior hypertensive pregnancy disorder. The intervention is based on the integrated behavior change model, which outlines the motivational, volitional, and automatic processes that lead to physical activity. The mechanisms by which the behavior change techniques lead to physical activity will be tested.

Following stratification on baseline factors, participants will be randomly allocated in-app to one of three conditions (1:1:1). The *information condition* will receive information, replicating usual care. Additionally to what the information condition receives, the *motivation condition* will receive content targeting motivational processes. Additionally to what the motivation condition receives, the *action condition* will receive content targeting volitional and automatic processes.

The primary outcome is weekly minutes of moderate-to-vigorous physical activity, as measured by an activity tracker (Fitbit Inspire 2). Secondary outcomes include weekly average of Fitbit-measured daily resting heart rate, and self-reported body mass index, waist-hip ratio, cardiorespiratory fitness, and subjective well-being. Tertiary outcomes include self-reported variables representing motivational, volitional, and automatic processes. Outcome measures will be assessed at baseline, immediately post-intervention, and at three and 12 months post-intervention. Physical activity will also be investigated at intervention midpoint. Efficacy will be determined by available case analysis. A process evaluation will be performed based on program fidelity and acceptability measures.

Trial registration number: Netherlands trial register NL9329.

Keywords: Physical activity, behavior change, theory-based, evidence-based, m-health.

INTRODUCTION

International guidelines advise adults to accumulate at least 150 minutes of moderate physical activity, or 75 minutes of vigorous physical activity, or an equivalent combination of moderate-to-vigorous intensity physical activity (MVPA) per week [1]. However, over 27% of people worldwide fail to meet these guidelines [2]. Insufficient MVPA has detrimental physical and mental health consequences. For instance, insufficient MVPA is a prominent behavioral risk factor for the development of cardiovascular diseases (CVDs), a leading cause of poor health and mortality worldwide [3]. Therefore, the development and efficacy testing of behavior change interventions promoting increased MVPA is highly warranted [4]. If found to be efficacious, such interventions may have important implications for the design of future effectiveness trials and subsequent policy.

Behavior change interventions promoting MVPA have been widely applied in the general population, and although these interventions have demonstrable efficacy, they rarely achieve large and long-term effects [5-7]. Reasons for these limitations may be their lack of theoretical basis, and limited application of evidence-based behavior change techniques [8]. There is growing evidence that basing behavioral interventions on theory leads to increased efficacy in health contexts, including MVPA [9-11], and, importantly, increased precision and less variability in behavior change relative to interventions that are not based on theory [12].

Many MVPA promoting interventions are based on a single theory, typically a prominent social cognition theory (e.g., protection motivation theory, theory of planned behavior) which describes behavior as the result of deliberative psychological processes [13]. However, interventions based on such theories have generally been shown to be more effective in changing behavioral *intentions* than *actual* behavior [14, 15]. A potential explanation for this shortcoming is that a substantive proportion of individuals hold stated intentions to perform a behavior of interest, like MVPA, but for various reasons fail to act on them [16, 17]. For example, they may forget to enact their intentions, or counter-intentional opportunities may come to light and compete with their existing intentions [18]. Researchers have therefore sought to identify potential ways to promote better enactment of intentions in behavioral interventions, and minimize this 'intention-behavior gap' [19]. A further limitation of interventions based on social cognition theories is that they overlook spontaneous or impulsive behavior that is the result of automatic processes, not directly under the conscious control or awareness of the individual [20, 21].

It is increasingly recognized, therefore, that researchers should base behavioral interventions on theoretical approaches that account for multiple processes that lead to action. Dual-system theories account for two types of processes that govern action: *automatic* processes, by which behavior is determined by impulses and well-leaned associations between context and action, and *deliberative* processes, by which action is determined by reasoned deliberation and the value attached to courses of action [21-24]. Integrated theories that draw their hypotheses from more than one theory have been proposed, with a view to account for these multiple processes, and to provide more comprehensive explanations of behavior. A recent integrated theory-based approach in this vein is the integrated behavior change (IBC) model [25]. The IBC model integrates insights of multiple well-established behavioral theories to identify the multiple processes that may be implicated in MVPA [25-27].

The model identifies three processes: motivational, volitional, and automatic processes. The motivational processes are modelled by variables that represent deliberative decision making derived from social cognition and motivational theories. Specifically, the model specifies belief-based variables, such as intention and attitudes from the theory of planned behavior, and motivational variables, such as intrinsic motivation from the self-determination theory, as key behavioral determinants. In addition, the IBC model differentiates between pre-intentional (motivational) and post-intentional (volitional) processes, and, consistent with dual-phase theories, proposes that intention enactment is facilitated in the volitional phase by a planning process. Finally, the IBC model proposes that automatic processes impact behavior beyond an individual's awareness, bypassing the intention-mediated processes. Automatic processes are represented by variables that reflect implicit decision-making, such as affect and habit. Since the development of the first IBC model, several observational studies have used it to successfully explain a number of health behaviors ranging from fat and sugar intake to sunscreen use [28-36]. While these observational results are encouraging, application of the IBC model as a basis for behavioral interventions is still in its infancy and warrants further investigation.

The present study

The aim of the current study is to test the efficacy of a behavioral intervention based on the IBC model to promote MVPA. Our study population consists of women with a prior hypertensive pregnancy disorder, for whom an increase in MVPA would be particularly helpful in reducing their later-life risk for CVDs (see *Study population* below). The content of the intervention will comprise health behavior change techniques based on the IBC model, one of the first interventions to do so [37]. We will systematically select behavior change techniques closely linked to the variables described in the model

(Figure 1). The selection of techniques is guided by taxonomies of behavior change techniques [8, 38], evidence syntheses examining the association between these techniques and theoretical variables [39-42], and research showing the efficacy of these techniques in changing health behavior [43-51].

Behavior Change Techniques Processes Mechanism of Action Variables Motivational Interviewing Based Counselling Intrinsic Motivation Motivational Intention INTENTION-BEHAVIOR GAP Action Planning ction Planning oping Planning Coping Planning Commitment Volitional Physical Activity Affect Positive Psychology Automatic Stress windiumess-base Stress Reduction

Figure 1: The integrated behavior change model and intention-behavior gap.

The intervention will be delivered via a smartphone application, the i2be app, using persuasive technology elements. This m-health approach was selected given evidence that smartphone-based interventions have multiple advantages over face-to-face interventions [52]: they are comparatively low in cost, have a wide reach, provide flexibility in intervention location and time, and are scalable [53-55]. In addition, previous online interventions using persuasive technology elements to change behavior have demonstrated superior effects in promoting MVPA [54, 56] and user engagement [57, 58] when compared with interventions that did not use such elements.

The study will have three conditions. Each condition will include different sets of behavior change techniques aimed at tapping into the different processes identified in the IBC model. This study design will provide insight into the relative efficacy of groups of techniques that target change in the variables that represent the motivational, volitional, and automatic processes that predict behavior based on the IBC model.

The study population will consist of women with a prior hypertensive pregnancy disorder. It is hypothesized that women who develop such complications have unrevealed CVD risk factors prior to pregnancy, which are then exacerbated by the metabolic stress of pregnancy, consequently contributing to the occurrence of hypertensive pregnancy disorders [59]. Hypertensive pregnancy disorders, such as preeclampsia, eclampsia, and HELLP (Hemolysis, Elevated Liver enzymes, Low Platelet count) syndrome, are cardio-metabolic risk factors for CVDs [60, 61]. For example, women with preeclampsia, a hypertensive pregnancy disorder, have a two- to eightfold increased risk for CVDs later in life relative to women with a normotensive pregnancy [62, 63].

We have decided to use this study population, i.e. women with prior hypertensive pregnancy disorders, for several reasons. Firstly, an MVPA intervention may provide an especially high social return in this population due to these women's increased risk for CVDs later in life [61, 64-66]. Second, these women are likely to be motivated to participate in an MVPA intervention, partly due to the 'window of opportunity' that their new motherhood presents, and partly due to their elevated risk for CVDs later in life. Third, these women typically do not have any physical limitations that would prevent their participation in an MVPA intervention, as other patient groups with a high CVD risk might have. Finally, these women are relatively young and healthy (their increased risk for CVDs is not likely to show until later in life), which may make our findings generalizable to other young and healthy adult populations.

METHODS AND ANALYSES

The protocol follows the 'Standard Protocol Items: Recommendations for Interventional Trials' (SPIRIT) guidelines [67].

Study population

Given that the associated CVD risk among women with a prior hypertensive pregnancy disorder is largest for those with a history of preeclampsia, especially severe preeclampsia, we aim to first draw participants from this population [62, 63]. In the Netherlands, unique cardiovascular follow-up and care is provided to women with prior severe preeclampsia at the multidisciplinary Follow-Up Pre-Eclampsia Outpatient Clinic (FUPEC) of the Erasmus MC, the only clinic of its kind in the country.[68] There are currently around 1000 patients registered in the clinic, with an additional 100 to 150 women enrolling each year. In case the intended sample size (*N* = 630; see *Sample size calculation* below) cannot be fully recruited from the FUPEC clinic, further

recruitment will take place, first through the official Dutch patient organization for women with preeclampsia and/or HELLP syndrome (HELLP foundation). Second, we would then recruit women with other prior hypertensive pregnancy disorders through the Department of Gynecology and Obstetrics of the Erasmus MC, and other hospitals in the Netherlands.

Inclusion criteria for enrollment is having been diagnosed with a hypertensive pregnancy disorder in the past. Exclusion criteria for enrollment into the trial are: <18 years of age, pregnant at time of inclusion, <3 months after delivery, any physical health limitations preventing MVPA (e.g., illness, injury, surgery, rehabilitation), no working knowledge of Dutch or English language, and no possession of a smartphone. Invited women are informed that participation in the trial is voluntary. Women who choose to participate will be asked to sign an informed consent form in advance of participation. Participants will be informed that they may leave the study at any point in time without having to provide a reason. Following drop-out, no further data will be collected. Participants dropping out of the study will not be substituted.

Patient and public involvement

Patients of the FUPEC clinic have been involved in the design of the i2be app. Through a qualitative survey (N = 35), we have gained qualitative information on the processes described by the IBC model, and on the needs of the population in terms of m-health intervention delivery. Patients and members of the public will not be involved in the conduct or reporting of this study.

Design

The intervention will last for eight weeks, and outcome measures will be collected at four time points: baseline, immediately post-intervention, and at three and 12-months post-intervention. MVPA will additionally be investigated at the intervention midpoint, i.e. four weeks after the start of the intervention. The study will adopt a three-condition randomized controlled design. Participants will be stratified on time since pregnancy (<12 months post-partum versus \geq 12 months post-partum), and self-reported average weekly minutes of MVPA in the last month (low: x < 2.5 hours; medium: 2.5 hours \leq x < 7 hours; high: 7 hours \leq x), and randomly allocated (1:1:1) in-app to one of the three parallel intervention conditions (the *information* condition, the *motivation* condition, or the *action* condition) using permuted block randomization (using variable block sizes of six or nine). Participants will not be directly informed of the condition to which they have been allocated, but as participants will be presented with the content of the intervention, they cannot be considered blind to allocation. Randomization to intervention condition is carried out automatically by the app, and the data on allocation

is held securely by the app developers, Avegen (a digital health company). As this data is not accessible by the research team during the 8-week intervention period and while outcome measures are being collected immediately post-intervention, the research team will be blind to the allocation of participants during that period.

This study design will allow us to gain insight into the incremental effect of behavior change techniques that target variables representing the volitional and automatic processes in the *action* condition, in addition to the effect of techniques that target variables representing the motivational processes in the *motivation* condition. The size of this incremental effect will be benchmarked against the incremental effect of targeting motivational processes alone in the *motivation* condition, and the provision of information only in the *information* condition. The *information* condition will replicate usual care, as it contains information that women with a prior hypertensive pregnancy disorder receive from their health care provider.

Intervention conditions

Participants in the *information* condition receive the 'Get Informed' module, which provides them with information on topics related to MVPA. Firstly, the relationship between hypertensive pregnancy disorders, increased risk of CVDs, and MVPA is explained. Second, the World Health Organization guidelines for MVPA are presented, examples of MVPA are given, and it is explained how Fitbit devices measure MVPA. Finally, recommendations on how to warm-up, cool-down, lower risk of injury, and achieve all-round health and well-being are provided. This content largely corresponds to the usual care offered to women with prior hypertensive pregnancy disorders, and primarily serves to stimulate those in the *information* condition to use the app.

In addition to the 'Get Informed' module, participants in the *motivation* condition will receive the 'Get Motivated' module, which targets motivational processes, and consists of motivational interviewing-based counselling techniques. Participants will receive an interactive, fully automated activity each week, consisting of content-based motivational interviewing techniques [69].

In addition to receiving the 'Get Informed' and 'Get Motivated' modules, participants in the *action* condition will receive the 'Get Activated' module, which targets volitional processes, consisting of action planning, coping planning, and commitment techniques. Participants will receive interactive, fully automated activities each week, aiding them in setting a self-defined weekly MVPA goal, committing to that goal with i2be points, making action plans and coping plans to reach that goal, and making their own self-defined commitments outside of i2be [47, 70]. Furthermore, participants in the *action*

condition will receive the 'Get Energized' module, which targets automatic processes, and comprises mindfulness-based stress reduction and positive psychology techniques. Participants will receive four-minute audio clips of mindfulness-based stress reduction, and interactive, fully automated positive psychology exercises (Table 1) [48, 49, 51, 71].

Outcome measures

The primary outcome of this research project is weekly minutes of MVPA, as measured by an activity tracker worn on the wrist (Fitbit Inspire 2). Fitbit devices are well suited for the measurement of MVPA (and resting heart rate) in the context of MVPA interventions due to their relative accuracy [72]. Naturally, Fitbit-measured data is likely to be imperfect due to possibilities of missing or incomplete data arising from intentional (e.g. aversion to Fitbit device use) or unintentional non-compliance (e.g. forgetting to wear Fitbit device), and measurement error in data (e.g. imperfect measurement of MVPA).

Secondary outcomes consist of Fitbit-measured weekly average of daily resting heart rate, as well as self-reported body mass index, waist-hip ratio, cardiorespiratory fitness, and subjective well-being. The outcome measures of body mass index and waist-hip ratio will be combined into one overweight index by standardizing both measures and getting the average of these two standardized measures. Tertiary outcomes include self-reported motivation, intention, action planning, coping planning, commitment, affect, and stress. Control variables measured include self-reported trait self-control, habit, age, education, household composition, type of prior hypertensive pregnancy disorder, and whether the participant is currently pregnant or lactating (Table 2).

Implementation

A rolling recruitment and enrollment procedure will be used, initially aiming for a six week timeframe (September to November 2021), which may be extended depending on when the target sample size is met. The first participants are expected to complete the eight-week intervention in early December 2021. An invitation email containing a two-minute long introduction video and the participant information letter of the i2be study will be sent out to potential participants by health care professionals, in cases where recruitment is through the hospital, or the i2be research team, in cases where recruitment is through the patient organization. Patients interested in participating are directed to a short online questionnaire to assess eligibility based on study inclusion and exclusion criteria. Eligible patients are then asked to provide informed consent for participation, as well as their contact information. They will then receive an email containing the following information: that their Fitbit Inspire 2 will be sent to them by mail, a link to download the i2be app and the Fitbit app from the Google Play Store

Table 1. Weekly overview of behavior change techniques used in i2be.

| | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7 | Week 8 |
|---|---|---|---|---|--|--|--|--|
| Get Motivated Motivational Interviewing- Based Counselling | ldentifying Past Successes | Running Head Start Normalizing | Values Exploration | Importance Ruler Confidence Ruler | Hypothetical Thinking Goal Attainment Scaling | Query Extremes Looking Forward | Identifying Strengths | Recap of weeks 1-7 |
| Get Activated Action Planning, Coping Planning, and Commitment | Action Planning Commitment within and outside i2be | Action Planning Commitment within i2be Coping Planning | Action Planning Commitment within i2be Coping Planning | Action Planning Commitment within i2be Coping Planning | Action Planning Commitment within i2be Coping Planning |
| Get Energized Mindfulness- Based Stress Reduction Positive Psychology | Introduction to Mindfulness Three Good Things | Loving Kindness Kindness | Sensations Three Beautiful Things | Gratitude Gratitude | Humor Therapy Three Amusing Things | Breath Awareness Savoring | Validation Validation | Body Scan Power Posing |

Table 2. Schematic overview of data collection during the trial.

| Outcomes | Variables | Measurements | Baseline | Follow-up |
|-----------------------------------|---------------------------|---|----------|-----------|
| Primary Outcome | | | | |
| Objectively measured by Fitbit | Physical activity** | Moderate-to-vigorous intensity ✓ physical activity (MVPA) (min / week) | | ✓ |
| Secondary Outcomes | | | | |
| Objectively measured by Fitbit | Heart rate** | Week average of daily resting heart rate (beats / min) | ✓ | ✓ |
| Self-reported into app | Body mass index*** | Weight / length ² (kg / m ²) | ✓ | ✓ |
| | Waist-hip ratio*** | Waist circumference/ hip circumference | ✓ | ✓ |
| | Cardiorespiratory fitness | 1 mile Rockport walk test | ✓ | ✓ |
| | Subjective well-being | Satisfaction with Life Scale | ✓ | ✓ |
| Tertiary Outcomes | | | | |
| Self-reported into app | Motivation | The Behavioral Regulation in Exercise Questionnaire | ✓ | ✓ |
| | Intention | Own design based on Ajzen guidelines | ✓ | ✓ |
| | Action planning | Own design based on Sniehotta measure | ✓ | ✓ |
| | Coping planning | Own design based on Sniehotta measure | ✓ | ✓ |
| | Commitment | Own design | ✓ | ✓ |
| | Affect | Global Mood Scale | ✓ | ✓ |
| | Stress | Perceived Stress Scale | ✓ | ✓ |
| Control variables | | | | |
| Self-reported into app | Trait self-control | Brief Self-control Scale | ✓ | |
| | Habit | Habit Strength | ✓ | |
| | Age | Age (years) | ✓ | |
| | Education | English version based on ISCED 2011 Dutch version based on SOI 2016 | ✓ | |
| | Household composition | Living situation (Partner, children) | ✓ | |
| | Lactation status | Currently lactating (Yes / No) | ✓ | |
| | Pregnancy status | Currently pregnant (Yes / No; Due date) | √ | ✓ |
| | Type of disorder | Type of hypertensive pregnancy disorder | √ | |

Table 2 Continued

| Outcomes | Variables | Measurements | Baseline | Follow-up |
|-----------------------------|--------------------------|---|----------|---------------|
| Preferences | | | | |
| Self-reported into app | Voucher preference | Choice from three sports store vouchers | ✓ | |
| Stratification variables | | | | |
| Self-reported into app | Time since giving birth | < 12 months post-partum (Yes / No) | ✓ | |
| | MVPA | Average weekly minutes of MVPA in the past month (Low / Mid / High) | √ | |
| Process evaluation | | | | |
| Self-reported into app | Program acceptability | Component usability, appropriateness, engagement, appeal, satisfactions and dissatisfactions | | √ **** |
| Objectively measured by app | Program fidelity | Compliance with program | ✓ | ✓ |

^{*}Follow-up measurements immediately post-intervention, and at three and 12-months post-intervention.

(for Android smartphones) or App Store (for iPhones), and a Welcome Pack. The Welcome Pack will detail the technical setup necessary for participation (i.e., pairing the Fitbit app to the Fitbit device and the i2be app, syncing the Fitbit app weekly, using the Fitbit device, general i2be app structure).

When using the i2be app for the first time, participants will be asked to choose their preferred language (Dutch or English) and register. Subsequently, participants will be stratified and randomly allocated in-app to one of the three intervention conditions, as previously stated. Participants know that there are three versions of the app and that they are in one of them, but they do not know which one (i.e. Information, Motivation or Action). An up to two-week window is provided for technical setup before the baseline measurement. During this pre-baseline measurement period, participants have the option to watch the i2be introduction video, to have a wizard take them through the main functionalities of the app (left column under Onboarding in Figure 2), and have access to the general tabs of the app (Other Tabs in Figure 2). From the start of the baseline measurement, participants can log in to the app directly (right column under Onboarding in Figure 2), and from then onwards can access all of their allocation features (including the Home Tab in Figure 2). The eight-week intervention

^{**}Also measured weekly for the duration of the eight-week intervention.

^{***}Body mass index and waist-hip ratio are combined into one *Overweight index* by standardizing both measures and taking their average.

^{****}Only measured immediately post-intervention.

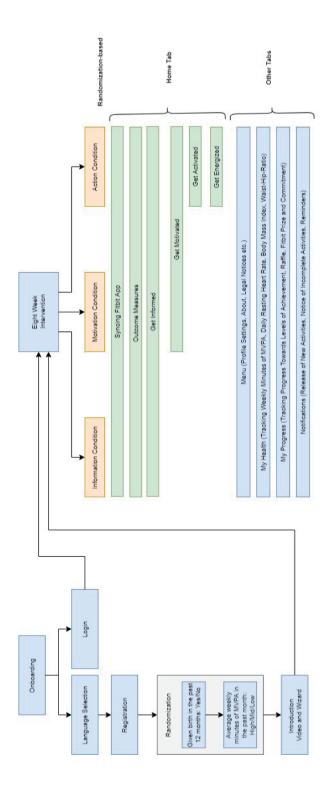


Figure 2: Allocation flowchart.

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period will start once the participant has completed their baseline measurement, i.e. completed the self-reported outcome measures, worn their Fitbit device for the baseline measurement week, and synchronized their Fitbit app at the end of that week. During the intervention period participants are expected to spend 15-30 minutes per week on module content. Furthermore, they are expected to spend an additional 15-30 minutes on completing outcome measurements at four time points, i.e. baseline, immediately post-intervention, and at three and 12 months post-intervention.

User interface

For all participants, the user interface of the i2be app shows a diverse range of women of different ethnic backgrounds and ages representative of the population, and uses female voice-overs in the introduction video and audio clips. Participants can find basic app functionalities, such as terms and conditions, under the Menu tab. The 'Get Informed', 'Get Motivated', 'Get Activated', and 'Get Energized' modules consist of interactive, fully automated activities each week, which will appear on the Home tab. Outcome measures to be filled in will also appear on the Home tab. Participants will be reminded weekly to sync the Fitbit app, also on the Home tab. The Notifications tab will announce the release of weekly activities, and reminders of weekly activities. Participants will be able to view their recent results of Fitbit-measured weekly minutes of MVPA and daily resting heart rate, and self-reported body mass index and waist-hip ratio under the My Health tab. They will also be able to track their progress related to i2be points under the My Progress tab (see *Persuasive technology elements* and *Gamification* below).

Persuasive technology elements

Two types of persuasive technology elements will be utilized by the i2be app: primary task support and dialogue support [57]. Not all elements will be present in all conditions, consistent with the study design. Primary task support involves reduction, personalization, and self-monitoring elements [57]. The reduction and personalization elements involve the self-setting of weekly MVPA goals. Some further personalized elements of the app include recaps of participants' past responses, the choice of when to receive a reminder of self-planned MVPA, and the option to commit to MVPA goals. The My Health and My Progress tabs both allow for self-monitoring. Dialogue support is provided to participants through reminders, suggestions, praise and rewards [57]. More specifically, participants receive a reminder of their action plan(s). Participants receive a reminder of their action plan(s) one hour prior to the planned MVPA by default (which they can adapt to a timing of their own liking). Participants receive automated praise for completing activities. Finally, participants will receive various rewards for participation (see *Gamification* below).

Gamification

For all participants, the completion of activities is linked to a virtual point system (i2be points), resulting in psychological rewards and tangible rewards. After every 100 i2be points accumulated, participants receive the psychological reward of progressing to the next level of achievement in-app (Bee Levels). The virtual i2be points are further used to qualify for tangible rewards. Participants enter into a weekly raffle for a self-selected sports store voucher (worth €25-30) under the condition that they earn the maximum i2be points for that week. Lastly, conditional on reaching a certain threshold of accumulated i2be points, participants can keep their Fitbit device at the end of the intervention

In addition to the psychological and tangible rewards available to all participants, participants in the *action* condition can choose to commit to their MVPA goal of that week, i.e. deposit some of their i2be points. If they achieve their MVPA goal for that week, their i2be points are returned to them, and they will also be eligible to take part in that week's raffle, conditional on their compliance with all other activities. However, if they do not achieve their MVPA goal for that week, they lose their deposited i2be points, and their eligibility for that week's raffle (Figures 2 and 3).

Sample size calculation

A meta-analysis of recent smartphone-based physical activity interventions found a small-to-medium average effect size (d = 0.31) on daily minutes of physical activity [73]. We carried out our sample size calculation for this study under the assumption that this average effect size is achieved both in testing the action condition against the information condition, and in testing the motivation condition against the information condition. Given this, we aim to recruit 630 participants to the trial with uniform randomization across conditions (i.e. 210 participants per condition). The average attrition rate in previous web-based physical activity interventions was 20% [74]. Such an attrition rate would leave us with a final total sample size of 504. Taking into account the potential maximum deviation from a 1:1:1 allocation ratio which may arise due to the stratified block randomization procedure, our intended sample size (N = 630) will give us sufficient statistical power (alpha = 0.05, power = 0.8) at our primary timepoint (immediately post-intervention) to detect effect sizes greater than or equal to the average effect size found in the meta-analysis (d = 0.31). The study will also be adequately powered to detect such effect sizes at the three and 12 months postintervention timepoints provided that overall attrition does not exceed 20% at those timepoints. This should be adequate to detect the effect size when testing each of the action and motivation conditions against the information condition. The effect size when testing the action condition against the motivation condition may be smaller than d =0.31, and thus we may be underpowered to detect this effect.

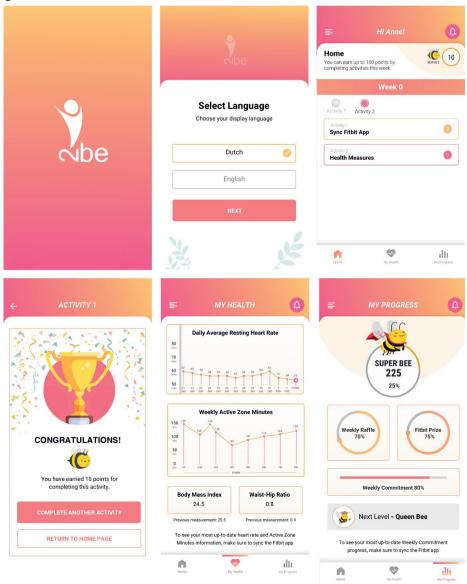


Figure 3: Look and feel of the i2be environment.

Data analysis plan

The primary analysis will be an available case analysis (i.e. participants with missing dependent variable data are excluded). Our primary outcome at each timepoint will be total minutes of MVPA for the full measurement week at that timepoint (e.g., for the immediately post-intervention timepoint, this is the 7 days immediately post-intervention) as measured by the Fitbit activity tracker.

Linear regression will be used to assess differences between groups at each timepoint. The first test of i2be is the difference between the action condition and the information condition to see whether our intervention as a whole is of value for the promotion of MVPA. Second, we will test the difference between the action condition and the motivation condition to gain insight into the added value of targeting volitional and automatic processes above targeting motivational processes to promote MVPA. Third. we will test the difference between the motivation condition and the information condition to produce an effect size value against which the main test of the efficacy of the i2be intervention can be benchmarked. Sensitivity analyses will be carried out to assess the robustness of results to the missing data strategy adopted by carrying out Intention-to-Treat (ITT) analyses using imputation methods (multiple imputation by chained equations [75], best-worst and worst-best analysis [76]), and when attrition is high and non-random by carrying out per-protocol analysis. To assess whether our intervention has differential effects across educational levels, subgroup analysis by educational level will be performed. Data analyses will be adjusted for control variables to decrease potential residual confounding after randomization, and to increase statistical power (see the supplementary file *Pre-analysis plan - Additional details*).

A process evaluation of the intervention will be performed immediately after the intervention, using program fidelity measures (i.e. user engagement statistics collected by the app such as how many people complete all module content and each individual module, and how the module completion rates change over time), and program acceptability measures (i.e. assessing self-reported component usability, appropriateness, engagement and appeal, and other satisfactions and dissatisfactions).

Data management

Data will be handled confidentially and stored in a pseudonymized manner. The identification key linking unique participant ID with personal data will be safeguarded and kept separate from deidentified research data. The identification key, informed consent forms, and deidentified research data will be archived for at least 10 years after completion of the study.

Fthics and dissemination

The study will adhere most strictly to all applicable legal, ethical, and safety provisions of the Netherlands and the EU. The study will be conducted in accordance with the principles of the Declaration of Helsinki [77]. The Medical Ethics Committee of the Erasmus MC has approved this study (MEC-2020-0981). Findings from the study will be presented at national and international scientific conferences. Furthermore, articles reporting on these findings will be submitted for publication in leading international

peer-reviewed scientific journals. Results will be communicated to the general public through general conferences, meetings, and newsletters.

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SUPPORTING INFORMATION

Pre-analysis plan - Additional details

Below are additional details to complement the description of the analysis plan given in the main protocol paper.

Overview

The analysis is divided into 4 categories as follows:

- Primary outcome analysis Weekly minutes of moderate-to-vigorous physical activity (MVPA)
- · Secondary outcomes analysis Health and wellbeing outcomes
- Mechanisms of action analysis
- MVPA analysis by education level subgroups

Please note the following:

- The time-points have been abbreviated as follows: M = Mid-intervention (week 5), P
 Post-intervention, 3m = 3 months post-intervention, 12m = 12 months post-intervention
- The treatment groups have been abbreviated as follows: Info = Information group,
 Mot = Motivation group, Act = Action group.
- All analyses described below use OLS regressions with heteroskedasticity-robust standard errors.
- The standard control variables referenced below are: age, trait self-control, habit, household composition, education, type of high blood pressure condition, pregnant at baseline (being pregnant is an exclusion criterion for enrolment in the trial; however, we control for the small possibility that participants may become pregnant between being enrolled in the trial and completing baseline measurements). Additionally, lactation status will be included as a control variable in the analysis of the Overweight Index dependent variable.
- Available case analysis will be used. This means that in each analysis, any participant
 with missing data for the dependent variable used in that analysis will be omitted
 from that analysis (wear-time cannot be tracked on a Fitbit; thus, in our analysis of
 weekly minutes of MVPA, we do not use a minimum Fitbit wear-time threshold to
 exclude participants from the analysis).
- To ensure that missing control variable data does not have a major impact on statistical power, we take the following approach with control variables:
 - Categorical control variables will be given an additional category 'missing' for participants who have missing data for that control variable.

- Numeric control variables will be encoded as categorical variables and each will have a missing' category for participants who have missing data for that control variable.
- These categorical variables are then dummy-coded for analysis.
- See Table 1 at the end of this document for details of the categories we specify for each control variable.
- Sensitivity analyses will be carried out to assess the robustness of results to the
 missing data strategy adopted. This will involve carrying out intention-to-treat
 analyses by imputing missing dependent variable values using the following methods:
 - Multiple imputation by chained equations [1]
 - Best-worst and worst-best sensitivity analysis [2]
 - In the case of high, non-random attrition, an additional sensitivity analysis will be carried out using a per-protocol analysis.
- Participants who become pregnant after the start of the trial are included in our main analysis (those who are pregnant at time of inclusion are excluded from the trial). However, we will also carry out three sensitivity analyses excluding participants from an analysis at a particular timepoint based on their pregnancy status. The three analyses will exclude those who are (i) pregnant, (ii) are in the second or third trimester of pregnancy, and (iii) are in the third trimester (in analyses at the 12-month post-intervention timepoint, it is possible that a participant that has become pregnant after the start of the trial has already given birth; thus, for the 12-month sensitivity analyses, we will also exclude any participant who is less than 3 months post-partum in these three sensitivity analyses).
- A rolling recruitment and enrolment procedure will be used, initially aiming for a six-week timeframe (September to November 2021), which may be extended depending on when the target sample size is met. The first participants are expected to complete the eight-week intervention in early December 2021.

1. Primary outcome analysis - weekly minutes of MVPA

| Outcome | Group comparisons | Time-points | Control variables |
|----------------|-------------------|---------------|------------------------------|
| Weekly minutes | Act v Info | M, P, 3m, 12m | - Baseline weekly minutes |
| of MVPA | Act v Mot | | of MVPA |
| | Mot v Info | | - Standard control variables |

Regression models:

| Group comparisons | Model |
|--------------------------|--|
| Act v Info Mot v Info | $y_t = \alpha_t + \beta_{1,t} Mot + \beta_{2,t} Act + \mathbf{X}' \varphi_t + \varepsilon_t$ |
| Act v Mot | $y_{t} = \alpha_{t} + \beta_{1,t} \ln fo + \beta_{2,t} Act + \mathbf{X}' \phi_{t} + \varepsilon_{t}$ |

Where subscript *t* denotes the time-period, *Info*, *Mot*, *Act* are indicators for the Information, Motivation and Action groups respectively, and *X* is the vector of control variables.

Within-individual analyses of how weekly minutes of MVPA evolves over time in each treatment group will also be carried out for descriptive purposes but will not be part of formal hypothesis testing.

2. Secondary outcomes analysis - Health and wellbeing outcomes

We test 4 health and wellbeing outcomes:

- Overweight index
 - We construct an *Overweight Index* using 2 measures of overweight (waist-hip ratio, BMI) by standardizing both measures and getting the average of these two standardized measures.
- Average weekly resting heart rate
- Cardiorespiratory fitness (CRF)
- Subjective well-being

| Outcome | Group comparisons | Time-points | Control variables |
|------------------------|-------------------|-------------|-------------------------|
| Overweight index | | P, 3m, 12m | - Baseline value of the |
| Average weekly resting | Act v Info | P, 3m, 12m | outcome variable |
| heart rate | | ., 5, . 2 | - Baseline weekly |
| | _ | | minutes of MVPA |
| Subjective well-being | Act v Mot | P, 3m, 12m | - Standard control |
| | | P, 3m, 12m | variables |
| | | | - Lactation status (in |
| | Mot v Info | | analysis of overweight |
| | | | index only) |

We will use a False Discovery Rate (FDR) procedure [3, 4] to control for testing multiple secondary outcomes. Both unadjusted and FDR-adjusted p-values will be presented when presenting the results from this analysis.

The regression models used will be the same as for the primary outcome analysis.

3. Mechanisms of action analysis

This analysis is exploratory, as distinct from confirmatory [5, 6].

Here we estimate treatment effects on the mechanism of action (MOA) variables.

We have 7 MOA variables. As per the Integrated Behavior Change (IBC) model shown in Figure 1 of the main protocol paper, our interventions target these MOA's as follows:

- Targeted by the Motivation and Action groups (*Get Motivated* module): Motivation, Intention
- Targeted by the Action group only (*Get Activated* and *Get Energized* modules): Action Planning, Coping Planning, Commitment, Affect, Stress

Our MOA analysis will focus on these relationships hypothesised by the IBC model, as outlined in the table below

| Outcome | Group comparisons | Time-points | Control variables |
|-----------------|--------------------------|-------------|------------------------------|
| Motivation | | | - Baseline value of the |
| Intention | (Mot+Act) v Info | | |
| | | | outcome variable |
| Action Planning | | | |
| Coping Planning | | P, 3m, 12m | - Baseline weekly minutes of |
| Commitment | Act v (Mot+Info) | | |
| Affect | | | MVPA |
| Stress | | | |
| | | | - Standard control variables |

Regression models:

| y ε {Motivation, Intention} | $y_t = \alpha_t + \beta_{1,t}MA + X'\phi_t + \varepsilon_t$ |
|---|---|
| y ϵ {Action planning, Coping planning, Commitment, Affect, Stress} | $y_t = \alpha_t + \beta_{1,t} Act + \mathbf{X}' \phi_t + \varepsilon_t$ |

Notation is the same as for the models described for the primary outcome analysis, and additionally *MA* is an indicator for being in either of the Motivation or Action groups).

Apart from the tests outlined above, we will also explore treatment effects on MOA variables not predicted by the IBC model.

4. MVPA analysis by education level subgroups

This analysis is exploratory. Subgroup analysis will be carried out by splitting the sample into two subgroups based on *education* as follows:

- · Less than higher education
- Higher education (the categories 'Bachelor or equivalent', 'Master or equivalent', 'PhD' are in the subgroup 2, while all other categories are in subgroup 1; all participants with missing data for education are excluded from this analysis).

We estimate heterogeneous treatment effects by adding *education* by treatment status interaction terms to the linear regression used for the primary outcome analysis.

| Outcome | Subgroups | Group comparisons | Time-points | Control variables |
|------------------------------|---|---------------------------------------|---------------|--|
| Weekly minutes of MVPA | 1. Less than higher education 2. Higher education | Act v Info Act v Mot Mot v Info | M, P, 3m, 12m | - Baseline weekly minutes of MVPA - Standard control variables (excluding education, as an education indicator variable is already included in the regression as a main effect variable) |

Regression models:

| Group comparisons | Model |
|--------------------------|--|
| Act v Info Mot v Info | $y_{t} = \alpha_{t} + \beta_{1,t} Mot + \beta_{2,t} Act + \beta_{3,t} educ + \beta_{4,t} Mot*educ + \beta_{5,t} Act*educ + \textbf{X}' \phi_{t} + \epsilon_{t}$ |
| Act v Mot | $y_t = \alpha_t + \beta_{1,t} \ln 6 + \beta_{2,t} + \beta_{3,t} = 0$ $y_t = \alpha_t + \beta_{1,t} \ln 6 + \beta_{2,t} + \beta_{3,t} = 0$ $y_t = \alpha_t + \beta_{1,t} \ln 6 + \beta_{2,t} + \beta_{3,t} = 0$ |

Notation is the same as for the models described for the primary outcome analysis, and additionally *educ* is an indicator for having a higher education.

See below a list of all control variables used in the various analyses in this study, with details of how we specify the categories for each variable.

The reference level for each variable for dummy-coding is highlighted in **bold**.

Table 1: Control variables – specification of categories.

| | Measure prior to specifying categories | Categories specified |
|---------------------------------------|--|--|
| Standard control variab | les used in all analyses | |
| Age | Integer value in range 18-65 | 18-24; 25-29; 30-34 ; 35-39; 40-44; 45-49; 50+; Missing |
| Trait self-control | Sum of ratings for each item (7 items, 5-point Likert scale) - range 7-35 | 7-13; 14-20; 21-27 ; 28-35; Missing |
| Habit | Sum of ratings for each item (17 items, 6-point Likert scale) - range 17-102 | 17-34; 35-51; 52-68 ; 69-85; 86-102; Missing |
| Household composition | Participant chooses one of: no partner-no children; partner-no children; no partner-with child(ren); partner- with child(ren). If with children, indicates number. | (A) No partner-no children; (B) Partner-no children; (C) Partner-1 child; (D) Partner-2 children; (E) Partner-3+ children; (F) No partner-1 child; (G) No partner-2+ children; (H) Missing |
| Education | Participant chooses one of: 1. None; 2. Less than primary education; 3. Primary education; 4. Lower secondary education; 5. Upper secondary education; 6. Post- secondary nontertiary education; 7. Short cycle tertiary education; 8. Bachelor or equivalent; 9. Master or equivalent; 10. PhD; 11. Unknown | 1. None; 2. Less than primary education; 3. Primary education; 4. Lower secondary education; 5. Upper secondary education; 6. Post-secondary nontertiary education; 7. Short cycle tertiary education; 8. Bachelor or equivalent; 9. Master or equivalent; 10. PhD; 11. Unknown; 12. Missing |
| Type of high blood pressure condition | Participant chooses one of: 1. Chronic hypertension; 2. Gestational hypertension; 3. Preeclampsia; 4. Eclampsia; 5. HELPP syndrome; 6. Other; | 1.Chronic hypertension; 2. Gestational hypertension; 3. Preeclampsia ; 4. Eclampsia; 5. HELPP syndrome; 6. Other; 7. Missing |
| Other control variables t | used in some analyses | |
| Lactation status | Participant chooses one of: 1. Yes; 2. No | 1. Yes; 2. No ; 3. Missing |
| Baseline weekly minutes of MVPA | Minutes of MVPA in week: integer value in range [0, ∞) | (1) < 20th percentile (2) 20th-39th percentile; (3) 40th-59th percentile ; (4) 60th-79th percentile; (5) >79th percentile; (6) Missing |
| Baseline resting heart rate | Resting Heart rate (average over a week): integer value in range [1, ∞) | (1) < 20th percentile (2) 20th-39th percentile; (3) 40th-59th percentile ; (4) 60th-79th percentile; (5) >79th percentile; (6) Missing |
| | | |

Table 1: Continued

| | Measure prior to specifying categories | Categories specified |
|--------------------------------|--|---|
| Baseline overweight index | Average of standardized measures of WHR and BMI: continuous value in range $(-\infty, \infty)$ | (1) < 20th percentile (2) 20th-39th percentile; (3) 40th-59th percentile ; (4) 60th-79th percentile; (5) >79th percentile; (6) Missing |
| Baseline CRF | mL/kg/min: continuous value in range (0, ∞) | (1) < 20th percentile (2) 20th-39th percentile; (3) 40th-59th percentile ; (4) 60th-79th percentile; (5) > 79th percentile; (6) Missing |
| Baseline subjective well-being | Sum of ratings for each item (5 items, 7-point Likert scale) - range 5-35 | 5-9; 10-14; 15-19; 20-24 ; 25-29; 30-35; Missing |
| Baseline motivation | Sum of ratings for each item (24 items, 5-point Likert scale) - range 24 to 120 | 24-47; 48-71; 72-95 ; 96-120; Missing |
| Baseline intention | Sum of ratings for each item (2 items, 7-point Likert scale) - range 2-14 | 1-2; 3-4; 5-6; 7-8 ; 9-10; 11-12; 13-14; Missing |
| Baseline action planning | Sum of ratings for each item (2 items, 7-point Likert scale) - range 2-14 | 1-2; 3-4; 5-6; 7-8 ; 9-10; 11-12; 13-14; Missing |
| Baseline coping planning | Sum of ratings for each item (2 items, 7-point Likert scale) - range 2-14 | 1-2; 3-4; 5-6; 7-8 ; 9-10; 11-12; 13-14; Missing |
| Baseline commitment | Sum of ratings for each item (1 item, 7-point Likert scale) - range 1-7 | 1; 2; 3; 4 ; 5; 6; 7; Missing |
| Baseline stress | Sum of ratings for each item (10 items, 5-point Likert scale) - range 10-50 | 10-19; 20-29; 30-39 ; 39-40; Missing |
| Baseline affect | Sum of ratings for each item (20 items, 5-point Likert scale) - range 20-100 | 20-39; 40-59; 60-79 ; 80-100 |

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CHAPTER 7

Moving from intention to behavior: a randomized controlled trial of an app-based physical activity intervention (i2be)

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ABSTRACT

Introduction

Physical activity interventions mostly fail to find meaningful long-term effects. A key factor in the failure of many interventions is likely an inadequate targeting of the theory-based processes that determine behavior. This study set out to address this limitation

Methods

We ran a randomized controlled trial (n=663) to test the efficacy of an app-delivered 8-week physical activity intervention, designed based on the integrated behavior change (IBC) model. Participants, women who had experienced a hypertensive pregnancy disorder in the past, were randomized to one of three conditions. The *Information* condition mimicked usual care, the *Motivation* condition targeted motivational processes with motivational interviewing-based counselling, while the *Action* condition targeted all three of the processes described by the IBC model: motivational, volitional and automatic, with motivational interviewing-based counselling, action planning, coping planning, commitment, positive psychology, and mindfulness-based stress reduction. Our primary outcome, weekly minutes of moderate-to-vigorous physical activity (MVPA), was measured by an activity tracker (Fitbit Inspire 2) provided to all participants. Treatment effects were estimated using linear regression on an available case basis (n=435).

Results

Relative to Information, neither Action nor Motivation had a significant effect immediately post-intervention on MVPA. Action worked better for those with low (below median) MVPA at baseline. A mechanism of action analysis showed that Action had a significant effect on motivational and volitional processes, but not on automatic processes. Program acceptability measures revealed that all intervention elements were positively perceived. Program fidelity measures showed that engagement with the intervention was reasonably high, and per-protocol analysis showed that results were largely similar when excluding those who didn't engage with the intervention.

Conclusion

There were several possible reasons for the absence of treatment effects: our study population had high mean MVPA at baseline; features present in all conditions may have crowded out the effect of behavior change techniques unique to Motivation and Action; the intervention activities may have been burdensome, limiting (cognitive or time) resources for additional physical activity; and the intervention may not have

7

adequately influenced automatic processes which the IBC model posits are crucial in determining physical activity. Non-engagement with the intervention was not an important reason for the lack of treatment effects.

Trial registration number: Netherlands trial register NL9329.

Keywords: Physical activity, behavior change, theory-based, evidence-based, mHealth.

INTRODUCTION

The WHO recommends that adults get at least 150 minutes of moderate physical activity, or 75 minutes of vigorous physical activity, or an equivalent combination of moderate-to-vigorous intensity physical activity (MVPA), each week [1]. Approximately 27% of people globally don't meet these guidelines [2]. Insufficient MVPA can have serious consequences for both physical and mental health, and has been estimated to cause 9% of premature deaths globally [3].

It is no surprise, then, that much research has been devoted to behavior change interventions promoting MVPA. Though many such interventions have been successful in producing small and short-term effects; large and long-term effects have generally proven elusive [4-6]. In many cases, an inadequate theoretical basis for the intervention likely plays a key role in the lack of success, while a limited linkage of evidence-based behavior change techniques to theoretical constructs is often another key flaw [7]. Evidence is mounting that theory-based health behavior change interventions are more effective [8-10] and subject to less variability in outcomes than interventions not based on theory [11].

Among theory-based interventions, many MVPA interventions are based on a prominent social cognition theory (e.g., protection motivation theory and theory of planned behavior) which describe only deliberative psychological processes [12-14]. Such interventions are often found to have strong effects on behavioral *intentions*, but not on *actual* behavior [15, 16]. This widens the *gap* between intention and behavior – the so-called *intention-behavior gap* [17, 18]. Such a gap – in economics often denoted as *time inconsistency* [19, 20] – can arise for various reasons. For instance, so-called limited attention may lead to an individual simply forgetting to act upon their intentions [21]. Alternatively, the opportunity costs of acting upon the intention may change (e.g., a better alternative becomes available) [22], or may be perceived to have changed (e.g., due to present bias) [23]. The intention-behavior gap has been the subject of a number of studies seeking to address it [24]. However, by only addressing deliberative processes, social cognition theories ignore automatic processes in decision-making that engender impulsive and habitual behavior and can directly influence behavior and bypass intentions [25, 26].

There is growing awareness that to maximize the probability of success, interventions should be based on theories that address both the intention-behavior gap and the multiple processes that govern action, including automatic processes. Dual-system theories incorporate two processes – deliberative and automatic [26-30]. The integrated

behavior change (IBC) model combines several well-known behavioral theories to incorporate the three key processes that it posits govern MVPA behavior. It incorporates two types of deliberative processes – motivational processes which influence preintentional mechanisms, and volitional processes that influence post-intentional determinants of behavior. It also incorporates automatic processes either bypassing intention-mediated mechanisms, or moderating the relationship between intention and behavior [14, 31, 32]. The IBC model has been successfully applied empirically to explain several health behaviors (e.g., MVPA, fat and sugar intake, sunscreen use) [33-41]. However, the use of the IBC model as the theoretical basis for interventions is still in its infancy [42].

To the best of our knowledge, this study is the first behavior change intervention, for any health behavior target, based on the IBC model. The details of the study design were detailed in the protocol paper for this study [43]. The intervention consisted of a combination of behavior change techniques from psychology and behavioral economics, namely motivational interviewing-based counselling, action planning, coping planning, commitment, positive psychology, and mindfulness-based stress reduction, which were systematically selected based on the IBC model (Figure 1), guided by evidence on the relationship between the techniques and theoretical variables [44-47], and evidence on the effectiveness of the techniques in spurring health behavior change [48-58].

A smartphone application, the *i2be* app, was developed to deliver the intervention using persuasive technology elements. Smartphone-based interventions provide many advantages compared to face-to-face interventions [59]: they may have lower costs, have potential for wider reach, are more flexible in terms of location and time of delivery, and have increased scalability [60-62]. Indeed, online interventions using persuasive technology elements have been shown to be more effective than interventions that lack such elements in increasing MVPA [61, 63] and in generating high user engagement [64, 65].

This intervention was tested with a sample of women (n=663) who had suffered a prior hypertensive pregnancy disorder and so have elevated risk for developing cardiovascular disease (CVD), meaning that insufficient MVPA for them is particularly risky [66]. Participants were randomized to one of three conditions: *Information*, *Motivation*, or *Action*. Information participants were given information on the relationship between MVPA, hypertensive pregnancy disorders and CVD risk, largely corresponding to the usual care offered to these women at the clinic. Motivation participants were additionally given motivational interviewing-based counselling

activities targeting motivational processes. Action participants were additionally given activities targeting motivational, volitional and automatic processes, namely motivational interviewing-based counselling, action planning, coping planning, commitment, positive psychology, and mindfulness-based stress reduction, and so targeted all three of the processes described by the IBC model.

A wrist-worn activity tracker (Fitbit Inspire 2) was used to measure our primary outcome, MVPA. Secondary health outcomes measured were resting heartrate (Fitbit-measured), body mass index (BMI), waist-hip ratio, cardiorespiratory fitness, and subjective wellbeing (all self-reported via the i2be app). Treatment effects were estimated using linear regression on an available case basis (n=435).

This study adds to the evidence base on interventions targeting MVPA by (i) conducting a relatively large randomized controlled trial (RCT) in a patient group at high risk for CVDs, (ii) employing three treatment arms based on the IBC model and delivering the interventions through a scalable mHealth application; (iii) linking theoretical constructs to evidence-based behavior change techniques traditionally used in psychology (e.g., action and coping planning; Mindfulness-Based Stress Reduction) and economics (e.g., commitment devices), and (iv) measuring our primary outcome using a Fitbit activity tracker. Additionally, to date only two other randomized controlled trials have attempted to reduce CVD risk in women with a prior hypertensive disorder of pregnancy [67], neither of which were based on health behavior theory or linked theoretical constructs to evidence-based behavior change techniques.

The results indicate that relative to Information, neither Action nor Motivation had a significant effect immediately post-intervention on MVPA or on secondary health outcomes in the overall sample. There were also no significant differences between Action and Motivation. The 95% confidence interval allows us to rule out any effect of Action compared with Information larger than 25 weekly minutes of MVPA. Those in Action who had low (below median) MVPA at baseline had significantly higher MVPA than Action participants who had high baseline MVPA.

Auxiliary analyses gave several clues for the lack of an average treatment effect in the overall sample. The Fitbit device, Fitbit app and basic version of the i2be app provided to all participants may have had a positive effect on MVPA and may have crowded out any potential treatment effects. The relatively high MVPA levels in the overall sample at baseline and throughout the intervention, accompanied by decreases in BMI we find across all conditions during the intervention, supports this claim. Moreover, while all intervention elements were revealed by a post-intervention process evaluation to have

been perceived positively by participants, the Fitbit was perceived as the most positive aspect of the intervention.

The high MVPA levels we see also points to our sample possibly consisting of a large number of participants who were highly physically active prior to signing up to the study. This may also have dampened treatment effects given that such participants had less room to improve. Further, the intervention was generally framed to encourage participants who had low physical activity levels, which may have discouraged highly active participants from becoming even more active.

Although there is no evidence of selection on observable personal characteristics, attrition rates were higher in Action relative to other groups. This suggests that the intervention activities may have been overly burdensome, which may also have hampered treatment effects. A mechanism of action analysis revealed that Action had a significant effect on motivational and volitional processes, but not on automatic processes, which may also have hampered treatment effects if it is automatic processes that are important for the gap between intentions and behavior. Program fidelity measures showed that engagement with the intervention was reasonably high, and per-protocol analysis showed that results were largely similar when excluding those who didn't engage with the intervention, showing that non-engagement was not an important reason for the absence of treatment effects.

This paper proceeds as follows: in the next section we describe the theoretical framework for the intervention, after that we describe participant recruitment and randomization, the experimental design, features of the i2be app, the estimation strategy, the results, and our conclusions.

Theoretical framework - the integrated behavior change model

As noted in the previous section, the IBC model integrates several theories in order to describe the three processes that it posits determine health behavior: motivational, volitional and automatic processes [32]. Social cognition and motivational theories are integrated into the model to describe motivational processes. More specifically, the IBC model incorporates the variables *intention* and *attitudes* from the theory of planned behavior and *intrinsic motivation* from self-determination theory [14, 68]. Dual-phase theories are integrated to model volitional processes by incorporating a *planning* variable [69, 70]. Automatic processes are modelled by incorporating variables such as *affect* and *habit* that relate to the non-conscious influences on behavior [26]. In designing our intervention, we developed three modules to target the three IBC model processes. The *Get Motivated* module included behavior change techniques that

targeted motivational processes, the *Get Activated* module included techniques that targeted volitional processes, while the *Get Energized* module targeted automatic processes (see Figure 1).

We also include *mechanism of action* variables in our theoretical framework, which are the theoretical variables through which our modules are hypothesized to act on the relevant processes. We hypothesize that Get Motivated will act on the motivational processes that determine MVPA via intrinsic motivation and intention, that Get Activated will work on volitional processes via action planning, coping planning and commitment, and that Get Energized will work on automatic processes via affect and stress.

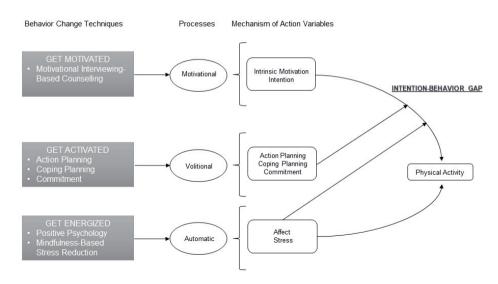


Figure 1: The integrated behavior change (IBC) model and the intention-behavior gap.

METHODS

Participant recruitment and randomization

Our study sample was made up of women who had suffered a hypertensive pregnancy disorder in the past. The prevailing hypothesis is that women who suffer from such disorders have latent CVD risk factors before becoming pregnant, and that the metabolic stress caused by pregnancy amplifies these risk factors and in turn triggers the disorders [71]. Such disorders, which include HELLP (Hemolysis, Elevated Liver enzymes, Low Platelet count) syndrome, preeclampsia, and eclampsia, are cardiometabolic risk factors for CVDs [72, 73]. For instance, preeclampsia sufferers have a

later-life CVD risk that is between two and eight times that of women who have had a normotensive pregnancy [74, 75].

There were several reasons for using this sample. First, the personal and public health benefits of an MVPA intervention may be higher for such women, given their increased CVD risk and given that insufficient MVPA is an important risk factor for CVDs [73, 76-78]. Second, these women may also be more motivated to participate in such an intervention because of their increased CVD risk. There may be an added motivation for new mothers (<12 months postpartum), who make up 15% of our sample, due to the fresh start effect [79]. Finally, once the pregnancy is over, women who have suffered a hypertensive pregnancy disorder usually do not have any physical constraints arising from or related to the disorder that limit their ability to participate in such an intervention (at least not until later-life, when their increased CVD risk may manifest itself), as other high-CVD risk individuals may have. Indeed, this last point means the results from a study with such women may be generalizable to other motivated, healthy adult women.

To participate in the study, a participant had to have suffered a prior hypertensive pregnancy disorder. We aimed to recruit 630 such participants in order to have enough statistical power (alpha = 0.05, power = 0.8) to detect a small-to-medium effect size on MVPA, which is the average effect found in a recent meta-analysis of smartphone-based MVPA interventions [80]. More detail on the power calculation can be found in our protocol [43].

Round one of recruitment was carried out with patients of the Follow-Up Pre-Eclampsia Outpatient Clinic (FUPEC) at the Erasmus Medical Centre (MC) in Rotterdam, which is the only clinic in the Netherlands providing cardiovascular follow-up care to women who have suffered severe preeclampsia [81]. Among sufferers of hypertensive pregnancy disorders, those who have suffered from preeclampsia, and especially severe preeclampsia, bear the highest CVD risk [74, 75]. Email invites were sent by the clinicians of FUPEC in October 2021 to the full population of over 1200 FUPEC patients for whom the clinic had email address information and who had consented previously to be contacted about research studies. In December 2021 and January 2022, the study was advertised to members of the HELLP foundation, the official Dutch patient organization for women who have suffered HELLP syndrome and/or preeclampsia, through their yearly webinar and patient magazine (exposure not known). At the end of January 2022, email invites were sent by the clinicians of FUPEC to over 900 Erasmus MC patients who had a prior hypertensive pregnancy disorder but were not patients of the FUPEC clinic. Recruitment was closed in February 2022 with 663 participants

recruited. 540 were FUPEC patients, another 50 were recruited through the HELLP foundation, while a further 73 were non-FUPEC Erasmus MC patients.

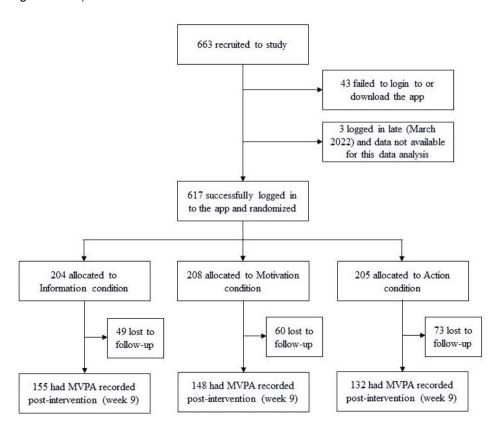
The recruitment procedure was the same for all three of these groups. The invite email contained a link to an online eligibility questionnaire which filtered out individuals who did not meet the inclusion criterion, and/or did meet at least one of the exclusion criteria. As noted, the inclusion criterion was having suffered a prior hypertensive pregnancy disorder. Exclusion criteria were being younger than 18 years of age, being pregnant, having given birth in the previous 3 months, having physical limitations preventing MVPA such as illness or injury, not being able to speak Dutch or English, and not owning a smartphone. Individuals who satisfied the inclusion criterion and none of the exclusion criteria then had to give informed consent and contact information in order to be registered as participants. Registered participants then received an email containing practical information about the study and the i2be app, a smartphone application developed for this study to deliver the intervention and gather outcome data. A Fitbit activity tracker was posted to the participant soon after registration. The baseline measurement week for a given participant began on the second Sunday after she logged into the app for the first time. This time delay was to allow for the delivery of the Fitbit device and technical set-up.

Once a participant downloaded and logged in to the app, she was randomized automatically by the app to one of three conditions - Information, Motivation or Action – using stratified permuted block randomization (variable block sizes of six or nine). Stratification was based on whether the participant had given birth in the previous 12 months, and on self-reported average MVPA per week in the past month. The probability of being allocated to a given condition was equal across conditions. The very left-hand column of appendix Figure A 1 shows the in-app flow when a participant first logged into the app.

Participants were not told to which condition they had been allocated, and were not given information about the content of the other conditions. However, given that each condition was distinguished by the in-app content presented to participants, it would be unreasonable to assume that they were completely blind to allocation. The allocation status data for each participant was held securely by the app developers, Avegen (a digital health company), from the moment of allocation and was not accessible by the research team until after a participant had completed the 8-week intervention and the first post-intervention outcome measurement week (week 9). As such the researchers were blinded to allocation until after a participant had completed week 9.

Of the 663 recruited, 43 never logged into the i2be app, and thus were not randomized to a study condition. See Figure 2 below. A further three were excluded from this analysis as they had not completed week 9 in time (due to a delay on their part in logging into the app after they had registered for the study). Just over 200 participants were randomized to each condition, with attrition by week 9 being 24% (49 participants) in Information, 29% (60 participants) in Motivation, and 36% (73 participants) in Action. Overall attrition by week 9 was 29% of those who logged into the app and 34% of those that were recruited to the study.

Figure 2: Participant recruitment flow.

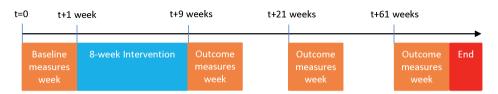


Experimental design

Study timeline

An eight-week intervention was delivered to participants via the i2be app. Sociodemographic characteristics and baseline values of outcome variables were measured via the app in the baseline week prior to the commencement of the intervention. Outcome variables were again measured in week 9 and will again be measured 12 weeks post-intervention (week 21) and 52 weeks post-intervention (week 61). MVPA was additionally measured in each week of the intervention (see the timeline of the study in Figure 3).

Figure 3: Study timeline.



Intervention conditions

Participants received weekly activity modules to complete in the app during the eightweek intervention period. The modules received depended on the condition a participant was in. A summary can be seen in Figure 4. Participants allocated to Information received the *Get Informed* module each week. This fully automated module provided relevant information on the relationship between MVPA, hypertensive pregnancy disorders and CVD risk in order to mimic the usual care provided to women at the FUPEC clinic. This module also served the purpose of encouraging Information participants to engage with the app, which was important given that all of our outcome measures were collected via the app.

Motivation condition participants also received the Get Informed module, and additionally received the *Get Motivated* module. This interactive and fully automated module targeted motivational processes and comprised of content-based motivational interviewing techniques, with new content made available to participants at the start of each intervention week [82]. See Table 1 for an overview of weekly content of the Get Motivated module, as well as the two other modules that we describe below (Get Activated and Get Energized). Full text of the content for each module are available from the first authors upon reasonable request.

Figure 4: Intervention conditions.

| Modules → | Get Informed | Get Motivated | Get Activated | Get Energised |
|-------------|--------------|----------------------|----------------------|----------------------|
| Groups ↓ | | | | |
| Information | ✓ | | | |
| Motivation | ✓ | ✓ | | |
| Action | ✓ | ✓ | ✓ | ✓ |

Action participants also received the Get Informed and Get Motivated modules, and additionally received two more interactive and fully automated modules – *Get Activated* and *Get Energized*. Get Activated targeted volitional processes and its content comprised of action planning, coping planning, and commitment techniques.[52, 83, 84]. In each intervention week, Get Activated prompted participants to make a goal for their MVPA minutes in that week, had the option to make a commitment to that goal using i2be points (points earned in the app for completing modules – see further details in the *Gamification* section), and were guided in making action plans to help them meet their goal. In weeks 1-4 participants were also guided in designing their own commitment devices, and in weeks 5-8 they were guided in making coping plans. Get Energized targeted automatic processes, and its content comprised of mindfulness-based stress reduction and positive psychology techniques, with new content available to participants in each intervention week [53, 54, 56, 85].

Through test runs, we estimated that it should take participants 15-30 minutes on a weekly basis to complete all modules during the intervention period, depending on what condition a participant was in. Modules in a given week could be completed in any order, and could be completed separately from each other at any time during the week. Additionally, if participants exited an incomplete module, their progress was saved and they could return to it later. Aside from some very basic tips on exercising in the Get Informed module, the modules did not provide examples of exercise sessions or programs that participants could do – it was left up to participants to decide themselves how best to accumulate MVPA minutes each week.

Outcome and control variables

Weekly minutes of MVPA was our primary outcome. This was measured using a wrist-worn activity tracker (Fitbit Inspire 2) given to each participant on enrolling in the study. Fitbit activity trackers are appropriate for this purpose as their MVPA measures are relatively accurate [86]. Having said that, there is still the possibility of missing data

Table 1: Weekly overview of behavior change techniques by i2be module.

| | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7 | Week 8 |
|---|---|---|---|---|---|--|-----------------------------------|-----------------------------------|
| Get Motivated | | | | | | | | |
| Motivational Interviewing- Based Counselling | Identifying past successes | Running head start; Normalizing | Values exploration | Importance ruler; Confidence ruler | Hypothetical thinking; Goal attainment scaling | Query extremes; Looking forward | Identifying strengths | Recap of weeks 1-7 |
| Get Activated | | | | | | | | |
| Action Planning | Action planning | Action planning | Action planning |
| Coping Planning | | | | | Coping planning | Coping planning | Coping planning | Coping planning |
| Commitment | Commitment with i2be points; Self-designed commitment | Commitment with i2be points; Self-designed commitment | Commitment with i2be points; Self-designed commitment | Commitment with i2be points; Self-designed commitment | Commitment with i2be points | Commitment with i2be points | Commitment with i2be points | Commitment with i2be points |
| Get Energized | | | | | | | | |
| Mindfulness- Based Stress Reduction | Introduction to mindfulness | Loving kindness | Sensations | Gratitude | Humor therapy | Breath awareness | Validation | Body Scan |
| Positive Psychology | Three Good Things | Kindness | Three Beautiful Gratitude Things | Gratitude | Three Amusing Things | Savoring | Validation | Power Posing |

harming overall data quality (e.g., if the participant does not wear the Fitbit all the time), and thus we exclude from our analysis of a particular endpoint week participants who have less than seven days of non-missing daily MVPA data for that endpoint week.

We also analyzed several secondary outcome variables. Using resting heartrate data obtained from the Fitbit, which has been shown to be relatively accurate [87], we analyzed the weekly average of daily resting heart rate. The i2be app was designed so that it could automatically pull MVPA and resting heartrate data directly from the Fitbit app.

Other secondary outcomes were self-reported by participants in the app: BMI, waist-hip ratio, cardiorespiratory fitness and subjective well-being [88-91]. We additionally measured a number of tertiary outcomes in order to facilitate a mechanisms of action analysis. These were self-reported in the app and include intrinsic motivation, intention, action planning, coping planning, commitment, affect, and stress [92-99]. We chose to measure affect and stress as well-defined proxies for the vague and hard to measure concept of state self-control [100]. The IBC model process to which each tertiary outcome relates can be seen in Figure 1.

Finally, we measured a number of control variables for use in regression analysis (also self-reported in the app): age, education, household composition, type of prior hypertensive pregnancy disorder, currently lactating, trait self-control, and habit [101-105]. Pregnancy status was also measured for sensitivity analyses. See Table 2: Schematic overview of data collection during the trial. for a schematic overview of data collection during the study. Full text of the questions used to elicit outcome and control variables are available from the first authors upon reasonable request.

Our primary endpoint weeks were week 9, week 21, and week 61, as well as, for MVPA only, the intervention midpoint (week 5). In this paper we present the results for week 5 and week 9 only, as data for week 21 and week 61 was not available at the time of writing.

Patient and public involvement

FUPEC clinic patients were involved in the design of the intervention and i2be app through a qualitative study which collected data on the mMealth intervention needs and preferences of these patients [106]. We also analyzed the perceived determinants of physical activity among these patients and mapped these determinants onto the three processes described by the IBC model [107]. Patients or members of the public were not involved in the carrying-out or reporting of this study.

Table 2: Schematic overview of data collection during the trial.

| Outcomes | Variables | Measurements | Baseline | Follow up* |
|-----------------------------------|---------------------------|---|----------|---------------|
| Primary Outcome | | | | |
| Objectively measured by Fitbit | Physical activity** | Moderate-to-vigorous intensity physical activity (MVPA) (min / week) | ✓ | ✓ |
| Secondary Outcomes | | | | |
| Objectively measured by Fitbit | Heart rate** | Week average of daily resting heart rate (beats / min) | ✓ | ✓ |
| Self-reported into app | Body mass index | Weight / length ² (kg / m ²) | ✓ | ✓ |
| | Waist-hip ratio | Waist circumference/ hip circumference | ✓ | ✓ |
| | Cardiorespiratory fitness | 1 mile Rockport walk test | ✓ | ✓ |
| | Subjective well-being | Satisfaction with Life Scale | ✓ | ✓ |
| Tertiary Outcomes | | | | |
| Self-reported into app | Motivation | The Behavioral Regulation in Exercise Questionnaire | ✓ | ✓ |
| | Intention | Own design based on Ajzen guidelines | ✓ | ✓ |
| | Action planning | Own design based on Sniehotta measure | ✓ | ✓ |
| | Coping planning | Own design based on Sniehotta measure | ✓ | ✓ |
| | Commitment | Own design | ✓ | ✓ |
| | Affect | Global Mood Scale | ✓ | ✓ |
| | Stress | Perceived Stress Scale | ✓ | ✓ |
| Control variables | | | | |
| Self-reported into app | Trait self-control | Brief Self-control Scale | ✓ | |
| | Habit | Habit Strength | ✓ | |
| | Age | Age (years) | ✓ | |
| | Education | English version based on ISCED 2011 Dutch version based on SOI 2016 | ✓ | |
| | Household composition | Living situation (Partner, children) | ✓ | |
| | Lactation status | Currently lactating (Yes / No) | ✓ | |
| | Pregnancy status | Currently pregnant (Yes / No; Due date) | ✓ | ✓ |
| | Type of disorder | Type of hypertensive pregnancy disorder | ✓ | |

Table 2: Continued

| Outcomes | Outcomes Variables Mea | | Baseline | Follow- up* |
|-----------------------------|--------------------------|---|----------|----------------|
| Preferences | | | | |
| Self-reported into app | Voucher preference | Choice from three sports store vouchers | ✓ | |
| Stratification variables | | | | |
| Self-reported into app | Time since giving birth | < 12 months post-partum (Yes / No) | ✓ | |
| | MVPA | Average weekly minutes of MVPA in the past month (Low / Mid / High) | ✓ | |
| Process evaluation | | | | |
| Self-reported into app | Program acceptability | Component usability, appropriateness, engagement, appeal, satisfactions and dissatisfactions | | √ *** |
| Objectively measured by app | Program fidelity | Compliance with program | ✓ | ✓ |

^{*}Follow-up measurements at week 9, week 21 and week 61.

Features of the i2be app

My Health and My Progress

Figure 5 shows examples of screens from the i2be app. In the *My Health* tab (bottom-middle of Figure 5), participants could see a graph of their Fitbit-measured weekly minutes of MVPA and daily resting heart rate since the start of the baseline week, and also see their self-reported BMI and waist-hip ratio. In the *My Progress* tab (bottom-right of Figure 5) all participants could see their i2be points and participation rewards progress (see *Persuasive technology elements* and *Gamification* below for details on i2be points) and Action participants could see their progress towards their weekly commitment. See Appendix 2 for details of the *Home* and *Notifications* tabs.

Persuasive technology elements

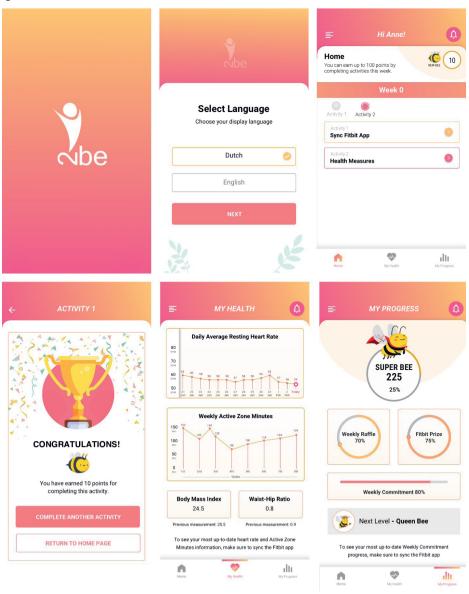
The i2be app made use of two different kinds of persuasive technology elements – primary task support elements and dialogue support elements [64]. The primary task support elements used were self-monitoring, personalization, and reduction [64]. All participants received self-monitoring elements via the My Health and My Progress tabs. Motivation and Action participants also received personalization elements by being able to see recaps of their responses to a number of modules. The Action participants

^{**}Also measured weekly for the duration of the eight-week intervention.

^{***}Only measured at week 9.

additionally received personalization elements through having a choice when to receive a reminder of their action plans and whether to commit to their MVPA goal or not, while they received both personalization and reduction by being able to set that goal. Dialogue support elements included praise, rewards, reminders, and suggestions [64]. When they completed modules, all participants were shown messages praising their efforts and were given i2be points and participation rewards (see Gamification below).

Figure 5: Look and feel of the i2be environment.



Action participants also received a reminder of the MVPA they had planned in their action plans shortly before the planned time.

Gamification

Participants in all conditions received in-app virtual points, called *i2be points*, for each module they completed. Each time a participant accumulated an additional 100 i2be points they progressed to the next *Bee Level*, giving them a psychological reward. i2be points could also lead to tangible rewards. If a participant earned all available i2be points in a given week, they were entered into a weekly raffle for a sports store voucher (€25-30). If a participant accumulated 300 i2be points, she earned the right to keep the Fitbit device after the study has ended. Hence, i2be points were used mainly to incentivize in-app module completion.

There was one way in which i2be points were used to incentivize MVPA. As part of the Get Activated activity module, each week action condition participants could deposit 40 of their accumulated i2be points to make a commitment to their weekly MVPA goal. The points were refunded to them if they reached their MVPA goal – otherwise they lost the points and consequently the possibility of entering that week's raffle. This feature of Action is somewhat akin to a self-funded deposit contract that has previously been shown effective in similar experiments [57, 58].

Estimation strategy

A pre-analysis plan was published as a supplementary file to the published protocol [43]. For our primary outcome, MVPA, as well as each of our secondary outcomes, we ran linear regressions to analyze week 9 differences between conditions in those outcomes. Note that for this analysis, BMI and waist-hip ratio were combined into a single standardized index, which we called the *overweight index*, rather than being analyzed separately, to reduce multiple hypothesis testing [108]. We also analyzed week 5 differences for MVPA. We did not analyze differences at week 21 or week 61 in this paper as the data is not yet available.

Our primary analysis was the test of the treatment effect on MVPA of our main intervention, Action, relative to Information. We also tested the effect of Action relative to Motivation to see if targeting all three processes of the IBC model leads to increased MVPA relative to just targeting motivational processes. We additionally tested Motivation relative to Information to give an effect size which would act as a benchmark against which the effect size in our main test (Action v Information) could be compared. We also ran baseline MVPA and education subgroup analyses.

Our main analyses were carried out on an available case basis, which means that

participants for whom dependent variable data was missing were excluded. Given that being pregnant at baseline was an exclusion criterion for our study, we also excluded four participants who reported not being pregnant at study sign-up and so were able to enroll, but turned out to be pregnant at the baseline measurement week. We carried out additional sensitivity analyses on a per-protocol basis, where we excluded participants who had low engagement levels with the intervention.

We also analyzed the change in outcome variables over time on a within-individual basis for descriptive purposes. Finally, we carried out a process evaluation of the intervention. This involved analyzing program fidelity measures (i.e., module completion rates), and program acceptability measures (i.e., satisfaction survey responses).

RESULTS

Sample characteristics and balance check

Table 3 below shows the baseline characteristics and outcome variable means of the full sample for whom data for the relevant variable is not missing. Our sample was 39 years of age on average. 66% had obtained a higher education (vocational education to university education in the Dutch system), for 32% the highest education obtained was mid-level (junior general secondary education to pre-university secondary education), while for 3% a lower education was the highest obtained (no primary school education to lower or preparatory secondary vocational education). 85% lived with a partner, and 95% had at least one child living in their household. 64% had experienced preeclampsia in the past, 56% had experienced HELLP, while 30% had experienced another hypertensive disorder of pregnancy. 15% had given birth in the previous 12 months. MVPA as measured by the Fitbit at baseline was almost 4 hours per week on average, well above the WHO recommended minimum of 2.5 hours per week. Average resting heartrate was 67, which is within the normal range for adults [109]. The average participant had a BMI of 26 and so is classified as overweight, and had a waist-hip ratio of 0.86 classifying her as obese [90, 91]. Cardiorespiratory fitness averaged 28 mL/kg/ min, below the median values for Dutch women aged 20 to 50, which range from 31 to 39 mL/kg/min [110]. Subjective wellbeing averaged 25.06, which is classified as a high level of well-being [111].

The table also provides means by treatment condition (rows 3-5) and p-values for tests of equality of means between conditions (rows 6-8). For the most part, randomization was balanced. The only significant difference was that Motivation consisted of significantly more lactating women than Information. We controlled for lactating at

baseline in our regression analysis of the overweight index, as lactation may help postpartum weight loss [112, 113].

Table 3: Sample characteristics.

| | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) |
|--------------------------|-------------------|----------------|------------------|-----------------|--------|--------|-------|-------|
| | Obser- vations | Full sample | Infor- mation | Motiv- ation | Action | l v M | IVA | ΜvΑ |
| Age | 579 | 38.83 | 39.04 | 38.95 | 38.49 | 0.905 | 0.474 | 0.542 |
| Lower education | 560 | 0.03 | 0.04 | 0.02 | 0.03 | 0.180 | 0.552 | 0.448 |
| Mid-level education | 560 | 0.32 | 0.29 | 0.32 | 0.35 | 0.511 | 0.233 | 0.586 |
| Higher education | 560 | 0.66 | 0.67 | 0.66 | 0.63 | 0.854 | 0.346 | 0.444 |
| Living with partner | 579 | 0.85 | 0.83 | 0.87 | 0.84 | 0.327 | 0.782 | 0.483 |
| Living with child(ren) | 579 | 0.95 | 0.96 | 0.96 | 0.94 | 0.840 | 0.240 | 0.324 |
| Prior preeclampsia | 551 | 0.64 | 0.69 | 0.62 | 0.63 | 0.152 | 0.269 | 0.750 |
| Prior HELLP | 551 | 0.56 | 0.56 | 0.57 | 0.54 | 0.851 | 0.780 | 0.636 |
| Other prior HP disorder | 551 | 0.30 | 0.26 | 0.32 | 0.32 | 0.261 | 0.242 | 0.952 |
| Lactating | 553 | 0.07 | 0.04 | 0.10 | 0.07 | 0.020* | 0.165 | 0.335 |
| Trait self-control | 513 | 22.29 | 22.02 | 22.65 | 22.20 | 0.240 | 0.723 | 0.379 |
| Habit | 475 | 59.93 | 60.27 | 59.51 | 60.02 | 0.588 | 0.856 | 0.721 |
| Self-report MVPA | 612 | 215.01 | 212.78 | 214.89 | 217.41 | 0.904 | 0.796 | 0.888 |
| <12 months postpartum | 612 | 0.15 | 0.14 | 0.15 | 0.15 | 0.844 | 0.717 | 0.867 |
| MVPA (Fitbit) | 480 | 236.13 | 227.01 | 261.74 | 220.03 | 0.131 | 0.705 | 0.067 |
| Resting Heartrate | 466 | 66.67 | 66.39 | 67.26 | 66.34 | 0.321 | 0.950 | 0.276 |
| ВМІ | 558 | 26.44 | 26.69 | 26.49 | 26.15 | 0.727 | 0.321 | 0.555 |
| Waist-Hip ratio | 489 | 0.86 | 0.86 | 0.86 | 0.85 | 0.766 | 0.652 | 0.429 |
| Cardioresp. Fitness | 339 | 28.44 | 28.44 | 31.01 | 25.59 | 0.396 | 0.387 | 0.066 |
| Subjective well-being | 515 | 25.06 | 24.60 | 25.43 | 25.14 | 0.184 | 0.375 | 0.647 |

Notes: Columns 2-5 shows means at baseline for those for whom we have the relevant baseline data, for full sample and each of the three conditions. Columns 6-8 show t-tests of equality of means between Information (I), Motivation (M) and Action (A). * p < 0.05, ** p < 0.01, *** p < 0.001. HP stands for hypertensive pregnancy.

Attrition

As noted in the *Participant recruitment and randomization* section (see also Figure 2), attrition was reasonably high at 34% of those recruited to the study and 29% of those randomized. Additionally, attrition rates were higher in Action (36%) than in Motivation (29%) or Information (24%). However, there is little evidence that attrition over the course of the intervention depended on observable personal characteristics. When we analyzed if attrition by week 9 had upset the balanced randomization between groups

we observed at baseline, we detected only one significant between-condition difference – in trait self-control between Information and Motivation. See Appendix Table A 1 for details. Additionally, when we analyzed if there had been changes on a within-group basis, we did not find significant differences between the mean characteristics of the baseline sample and week 9 sample for the full sample or within any of the three conditions. See Appendix Table A 2 for details.

Within-individual changes in outcomes MVPA

Figure 6 shows the evolution of MVPA over the course of the intervention, from the baseline week (week 0) through intervention weeks 1-8, and as far as week 9. We see that average MVPA for all conditions starts very high in the baseline week at approximately 4 hours per week (mean value for Information = 238 mins, Motivation = 256 mins, and Action = 238 mins), well above the WHO guideline level of 2.5 hours per week. MVPA declines for all conditions thereafter. This pattern of a spike in MVPA for all conditions on initial sign-up, followed by a decline, is often seen in RCTs testing MVPA interventions, even ones that find positive treatment effects on MVPA [21, 114]. By week 9, MVPA levels, though declined, are still well above 2.5 hours per week (mean value for Information = 195 mins, Motivation = 205 mins, and Action = 179 mins). What is important to note from this graph is that for much of the studied period, and especially in week 9, the mean MVPA of participants in Action was lower than that of participants in the other conditions. If we look at the change from baseline to week 9, the mean decline in MVPA was larger in absolute terms for Action than the other two conditions (mean change for Information = -40 mins, Motivation = -50 mins, and Action = -57 mins).

Secondary outcomes

Table 4 shows that average changes in secondary outcomes between the baseline week and week 9 generally went in a healthy direction (shown in green in the table). Most noteworthy is that BMI significantly decreases for all conditions by about 1% of the baseline value or 5% of a standard deviation. Subjective wellbeing also significantly increased for the full sample.

Figure 6: Weekly MVPA by treatment condition.

Notes: Graph shows average weekly MVPA (minutes) for sample of participants for whom MVPA data for each of weeks 0-9 is non-missing (n=427).

Table 4: Within-individual mean changes in secondary outcomes.

| | Resting heartrate | ВМІ | Waist-hip ratio | Cardio- respiratory fitness | Subjective well-being |
|--------------------------|----------------------|---------|--------------------|-----------------------------------|--------------------------|
| Full sample | | | | | |
| Baseline mean | 66.82 | 26.31 | 0.853 | 27.43 | 25.44 |
| Change in mean at week 9 | -0.37 | -0.26** | 0.000 | 4.09 | 0.68** |
| Information | | | | | |
| Baseline mean | 66.29 | 26.78 | 0.851 | 28.32 | 25.13 |
| Change in mean at week 9 | 0.04 | -0.24* | 0.006 | 5.37 | 0.88** |
| Motivation | | | | | |
| Baseline mean | 67.77 | 26.17 | 0.855 | 29.00 | 25.55 |
| Change in mean at week 9 | -0.79* | -0.29** | -0.001 | -0.10 | 0.37 |
| Action | | | | | |
| Baseline mean | 66.39 | 25.89 | 0.852 | 24.46 | 25.73 |
| Change in mean at week 9 | -0.38 | -0.24** | -0.007 | 6.68 | 0.73 |
| Observations | 374 | 336 | 266 | 175 | 286 |
| | | | | | |

Notes: Change in mean at week 9 is calculated as week 9 mean minus the baseline week mean. Tests of statistical significance are paired t-tests of equality of means between baseline mean and week 9 mean. Changes in mean in a "healthy" direction are in green font, changes in an "unhealthy" direction are in red. * p < 0.05, ** p < 0.01, *** p < 0.001

Primary analysis: Treatment effects using linear regression MVPA

In Figure 7 we can see the estimated treatment effects on MVPA at week 5 and week 9. We see no significant treatment effects for either Motivation or Action compared to Information. We also find no significant difference between Motivation and Action (see Appendix Table A 4). The 95% confidence interval allows us to rule out any effect of Action larger than 25 weekly minutes of MVPA compared with Information.

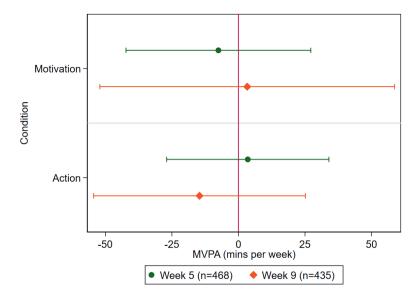


Figure 7: Treatment effects on MVPA relative to Information.

Notes: Linear regression of MVPA at week 5 and week 9 on indicators for being in Motivation and Action. Control variables are baseline week MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Graph shows treatment effect estimates with 95% confidence intervals. See Appendix Table A 3 for these results in tabular form.

Secondary outcomes

In Figure 8 we can see the estimated treatment effects on our secondary outcomes at week 9. We see no significant treatment effects for Motivation or Action compared to Information. Regressions on BMI and waist-hip ratio separately, not shown in Figure 8, also show no significant effects. We also see no significant difference between Motivation and Action (see Appendix Table A 6).

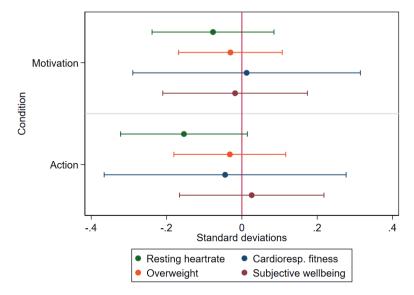


Figure 8: Treatment effects on secondary outcomes relative to Information.

Notes: Linear regression of standardized secondary outcomes at week 9 on indicators for being in Motivation and Action. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. The regression on *overweight* also controls for lactating. Graph shows treatment effect estimates with 95% confidence intervals. Sample sizes are 385 (resting heartrate), 284 (overweight), 216 (cardiorespiratory fitness), and 307 (subjective wellbeing). See Appendix Table A 5 for these results in tabular form.

Subgroup analysis

Although not included in our pre-analysis plan [43], we carried out some subgroup analyses by baseline MVPA level to get further insight into findings. Figure 9 shows the results of a regression including two interaction terms: (1) the interaction between the indicator for being in Motivation and an indicator for having low baseline week MVPA (i.e. MVPA in the baseline week at or below the median of 210 mins), and (2) the interaction between the Action indicator and the low baseline week MVPA indicator. We see evidence that Action worked much better for those with low baseline week MVPA: being in Action and having a low baseline week MVPA (action*low) led to an increase of over 70 minutes at week 5 and week 9, relative to being in the same condition and having high baseline week MVPA (action*high), which was statistically significant at week 5 and almost significant at week 9 (p=0.051).

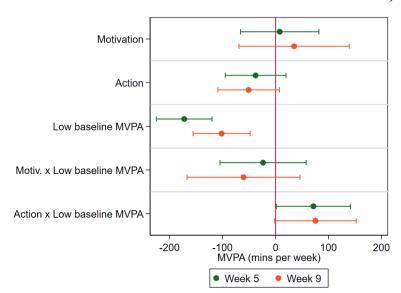


Figure 9: Treatment effects on MVPA relative to Information – baseline week MVPA interaction analysis.

Notes: Linear regression of MVPA at week 5 and week 9 on indicators for being in Motivation and Action, an indicator for having low baseline week MVPA (i.e., baseline week MVPA at or below the median (210 mins)), and interaction terms for the interactions of each of the Motivation and Action indicators with the low baseline week MVPA indicator. Control variables are baseline week MVPA, age, trait self-control, habit, household composition, education, type of prior hypertensive pregnancy disorder. Graph shows treatment effect estimates with 95% confidence intervals. See Appendix Table A 7 for these results in tabular form.

While this is strong evidence that action*low fared better than action*high, there is little evidence that action*low delivered treatment effects. The regression in Figure 10 shows that, when compared to those with low baseline week MVPA in Information, having low baseline week MVPA and being in Action leads to an insignificant increase of 25 (6) minutes at week 5 (9).

When compared to Motivation, in interaction analysis we see that Action also worked significantly better for low baseline week MVPA participants than for high baseline week MVPA participants (Appendix Table A 9) and that for those with low baseline week MVPA, being in Action led to a significant increase of 40 minutes in week 5 relative to being in Motivation (Appendix Table A 10). Note that as these baseline week MVPA subgroup analyses were not included in our pre-analysis plan, they are exploratory rather than confirmatory, and as such we don't apply multiple hypothesis corrections [115].

We also ran an education subgroup analysis, using an indicator variable for having lower/mid-level education, but we have no significant findings here (see appendix Table A 11 and Table A 12).

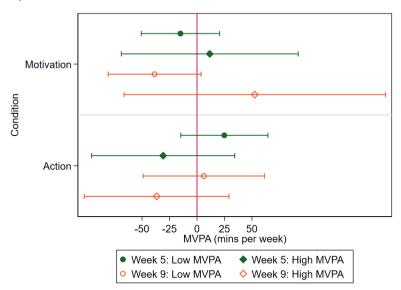


Figure 10: Treatment effects on MVPA relative to information – subsamples of low and high baseline week MVPA participants.

Notes: Linear regression of MVPA at week 5 and week 9 on indicators for being in Motivation and Action. Graph shows treatment effect estimates with 95% confidence intervals. Circle-shaped coefficient points represent estimates for sample of participants with baseline week MVPA at or below the median (210 mins). Diamond-shaped coefficient points represent estimates for sample of participants with baseline week MVPA above the median. Control variables are baseline week MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. See Appendix Table A 8 for these results in tabular form.

Mechanisms of action analysis

We see in Table 5 the results of our mechanism of action analysis. Motivation was ineffective, relative to Information, in influencing any of the mechanism of action variables. This is not so surprising for the variables proxying for volitional and automatic processes, as these were not targeted in Motivation, but it is surprising that the motivational interviewing-based counselling module was not effective in boosting intrinsic motivation or intentions. Action, however, significantly moved the motivational and volitional variables. While the coefficient estimates for Action's influence on automatic processes are all in the expected direction, they are insignificant. Action also significantly influenced the motivational and volitional variables in a healthy direction relative to Motivation, and the participants in Action also experienced significantly less stress and more positive affect than Motivation (see appendix Table A 14). As set out in our pre-analysis plan, these analyses were exploratory rather than confirmatory, and as such we don't apply multiple hypothesis corrections [115].

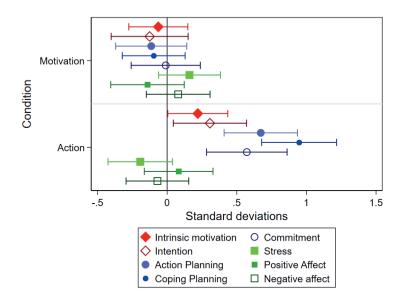


Table 5: Treatment effects on mechanisms of action variables relative to Information

Notes: Linear regression of standardized mechanism of action variables at week 9 on indicators for being in Motivation and Action. Control variables are baseline wek MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Graph shows treatment effect estimates with 95% confidence intervals. See Appendix Table A 13 for these results in tabular form.

Process evaluation

Program fidelity

Table 6 shows the compliance rates for each of the four program modules for non-attriters (i.e., non-missing value for week 9 MVPA). We see that compliance (i.e., completing at least 75% of a given module in at least 7 weeks of the 8-week intervention) was reasonably high across all modules, with approximately two in three participants who received Get Informed, Get Activated and Get Energized being "compliant" and almost 3 in 4 being compliant for Get Motivated. When we include attriters since baseline (Appendix Table A 15) patterns are largely similar, but compliance rates are obviously lower. When we estimate per-protocol treatment effects on MVPA (i.e. treatment effects for the sample who were compliant to Get Informed), we see no substantive change in our results (see appendix Table A 16). When we restrict our sample further to those who complied in all modules available to them, we also see no substantive change in results (see appendix Table A 17).

Table 6: Program compliers by module (sample of non-attriters).

| | Total | Compliers | Proportion of compliers |
|-----------------|-------|-----------|-------------------------|
| Get Informed | | | |
| Full Sample | 435 | 291 | 0.669 |
| Information | 155 | 113 | 0.729 |
| Motivation | 148 | 90 | 0.608 |
| Action | 132 | 88 | 0.667 |
| Get Motivated | | | |
| Motiv. & Action | 280 | 217 | 0.775 |
| Motivation | 148 | 122 | 0.824 |
| Action | 132 | 95 | 0.720 |
| Get Activated | | | |
| Action | 132 | 87 | 0.659 |
| Get Energized | | | |
| Action | 132 | 85 | 0.644 |
| | | | |

Notes: Sample is all those who have a non-missing week 9 value for MVPA. Compliance is defined as completing at least 75% of a given module in at least 7 weeks of the 8-week program.

Program acceptance

Figure 11 shows the results of the survey given to participants where they were asked to rate, on a scale from 1=Disagree to 5=Agree, the Fitbit and each of the i2be modules in terms of four key criteria: (1) "was easy to use", (2) "stimulated me to be physically active", (3) "helped me attain my physical activity goals", (4) "was appealing". The Fitbit and the modules all had a mean rating greater than three on all criteria, meaning they were rated positively on average. The Fitbit was rated highest or joint highest on each of the four criteria. Get Activated scored better than the other three modules on three of the four criteria, notably the two criteria directly related to increasing MVPA (helped attain goals and stimulated physical activity), but scored lowest on ease of use. In contrast, Get Energized scored lowest on those three criteria, but scored highly on ease of use. Qualitative data collected as part of this satisfaction survey will be used to perform thematic analysis to reveal patterns of user experience, as part of the long-term evaluation of the study.

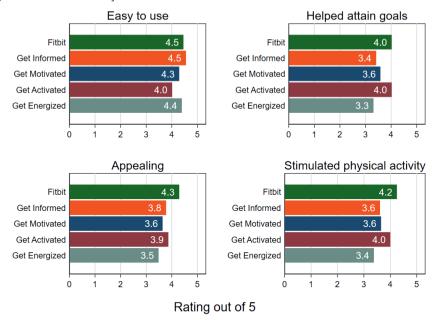


Figure 11: Satisfaction survey results.

Notes: Results of satisfaction survey given to participants in week 9. Shows mean rating on a scale of 1-5 given by participants to the Fitbit and each of the four i2be modules on four key criteria. Sample sizes are 370 (Fitbit), 351 (Get Informed), 215 (Get Motivated), 100 (Get Activated), and 100 (Get Energized).

DISCUSSION

Our main intervention, Action, was unsuccessful in increasing MVPA relative to Information. There is evidence, though, that Action worked better for those with low MVPA at baseline relative to those with high baseline MVPA. However, we find little evidence that this increased efficacy was enough to deliver treatment effects for this subgroup.

There are a number of possible reasons for the absence of treatment effects we find. First, the features of Information, which were also available to the other two conditions, may not have been an appropriate *usual care* benchmark. In particular, we may have underestimated the effect of the Fitbit device and app (increased self-monitoring, continuous prompts) and the basic version of the i2be app (continuous feedback via the My Health and My Progress tabs, reminders) on MVPA. These features are not generally provided as part of *usual care* to patients such as those in our sample. However, we needed to include them to be able to measure the participants' MVPA, and to ensure engagement of the control condition in order to be able to benchmark

any intervention effects. If the effect on MVPA of these features was strong, it may have crowded out any effect that may have otherwise arisen from the unique features of Motivation and Action.

Wearable physical activity trackers have been shown in some studies to increase shortterm physical activity levels [116]. We have noted that MVPA levels in all conditions. including Information, were high on average throughout the intervention, consistently higher than the WHO guideline level of 2.5 hours. MVPA was highest at baseline (approx. 4 hours), with 67% of participants exceeding 2.5 hours, compared to the 51% of Dutch female adults that self-report to do so [117]. In reality, the proportion of Dutch women reaching guideline levels might be much lower; studies from other countries. such as the US and UK, show that self-reported physical activity tends to be much higher than activity-tracker measured physical activity [118, 119]. Unfortunately, to our knowledge, similar data comparison studies of self-report and tracker-measured physical activity are not available for Dutch adults. This suggests that, at least at baseline and perhaps throughout the intervention. MVPA levels for our participants were higher than prior to enrolling in our study. Some suggestive evidence for the role of the Fitbit and My Health in such an increase, if it exists, is that during the baseline week, when MVPA was at its highest, participants were using the Fitbit and had access to My Health, but had not received any of the intervention modules Get Informed, Motivated, Activated or Energized yet. Indeed, our process evaluation shows that participants rated the Fitbit more positively than any of these intervention modules. Further, we see some positive movements in health outcomes across all conditions, most notably BMI, again consistent with increased MVPA levels relative to preenrollment

While an initial spike in physical activity for all groups, including control, is not uncommon in physical activity RCTs, perhaps due to Hawthorne effects, it seems plausible that the self-monitoring features of the "usual care" condition in our study may have amplified this effect, leading to a crowding out of treatment effects as previously mentioned. Some suggestive evidence to support the plausibility of such a crowding out effect is that in subgroup analysis, we find that Action worked much better for those with low baseline MVPA. A participant who experienced a strong effect on her baseline MVPA from the usual care conditions (to which all participants were exposed during and shortly before the week in which baseline MVPA was measured) had a higher probability of ending up in the high baseline MVPA subgroup than a participant on whom the usual care conditions didn't have a strong effect. It is plausible that Action worked better for those ended up in the low baseline MVPA subgroup because, on average, participants on whom the usual care conditions had a weaker effect and thus faced less crowding out were more likely to end up in this subgroup.

Second, the presence in our sample of a large number of participants who were highly physically active prior to signing up to this study may have had an impact on treatment effects. The high MVPA levels we see at baseline and across the intervention period suggest that we may have had a large number of such participants in our sample. Such participants have less room to improve than those with low physical activity levels. Additionally, in designing our intervention we had in mind that it should particularly target those most in need of increased MVPA (e.g., those who have lower MVPA prior to a study). For instance, we emphasized the WHO guidelines of 150 minutes per week when participants were setting a weekly goal in Get Activated. Setting this reference point may have been discouraging to highly active participants who regularly exceeded the 150 minute threshold, if it made them feel that they were doing "enough" or even "too much".

Additionally, if a highly active participant set their goal with only leisure time physical activity in mind (e.g., gym, jogging, tennis), but regularly did a lot of physical activity for occupational, domestic or transportation purposes (e.g., commuting, errands), she might find that her regular practical physical activity might be enough to achieve her goal (as in MVPA measurement, the Fitbit doesn't discriminate), meaning that the goal was ineffective in encouraging additional MVPA [120].

We see evidence that highly active participants may have played an important role: subgroup analyses show that Action worked better for the low baseline MVPA participants than the high baseline MVPA participants. This heterogeneity in response to interventions between low and high MVPA participants is a challenge for intervention studies, and indeed to overcome this some studies restrict recruitment to individuals with low MVPA levels [121, 122]. However, we did not exclude participants from joining the study based on how physically active they were because there is evidence that even for high MVPA individuals, increased physical activity can be beneficial in reducing CVD risk [123].

Third, we may have been slightly underpowered. Our power calculations were based on a final sample size of 504 [43]. Due to higher than anticipated attrition (34% vs. 20%), our final sample size was 435, which means our study may have been underpowered. However, the point estimates for treatment effects on MVPA are a decrease of 15 mins/week for Action relative to Information, and a minuscule increase of 3 mins/week for Motivation, which suggest that even for a larger sample we would not find positive significant treatment effects.

Fourth, the workload in Action, where participants had four activities to complete per week, may have been too high for some participants. Action had higher attrition rates

than the other two conditions, which may have been workload-related. If not all participants who found the workload overly burdensome attrited, then this may have dampened the effectiveness of Action, perhaps by reducing cognitive or time resources available for MVPA.

Fifth, the interventions may not have adequately impacted the IBC model processes they were designed to target. The mechanism of action analysis reveals that Action was successful in influencing motivational and volitional processes, but not automatic processes. Motivation was ineffective in influencing the motivational processes at which it was targeted. If automatic processes (e.g., stress, affect) are crucial in influencing physical activity, and in reducing the gap between intentions and behaviors as outlined in Figure 1, then this may at least partly explain the lack of treatment effects we find.

Sixth, the theoretical framework, the IBC model, on which we built the intervention may be inadequate. However, given that our Action failed to influence automatic processes, which the model predicts are important in MVPA behavior change, and that this is the first IBC model-based intervention and so we have no previous studies with which to compare our results, we cannot say much on the adequacy of the model. It is reasonably clear, however, that non-engagement with the intervention was not an important reason for the absence of treatment effects. Engagement was reasonably high, and per-protocol analysis where we exclude participants who had low engagement with the intervention shows similar results to our available case analysis.

Conclusion

We ran an RCT to test an app-delivered physical activity intervention with 663 women in the Netherlands who had suffered a prior hypertensive disorder of pregnancy. The intervention was designed based on the Integrated Behavior Change model, which describes physical activity as being determined by three processes: motivational, volitional, and automatic. The intervention was delivered through an app developed especially for this purpose – the i2be app. Participants were randomly allocated to one of three conditions – Information, which was meant to mimic usual care, Motivation, which targeted motivational processes, and Action, which targeted all three of the processes described by the IBC model.

We found that neither Action nor Motivation significantly increased MVPA or influenced secondary health outcomes in a healthy direction relative to Information. Action worked better for those with low baseline MVPA than those with high baseline MVPA. MVPA levels across all conditions were quite high over the course of the intervention, and BMI decreased in all conditions.

There are several possible reasons for the absence of treatment effects. On the basis of auxiliary analyses, our most plausible interpretation is that the participant workload of the intervention crowded out cognitive or time resources for additional physical activity, combined with the inability of the intervention to affect automatic processes thought to influence the intention-behavior gap. Additional possible explanations include that the "usual care" condition may have had a stronger than anticipated MVPA-encouraging effect, leading to a crowding out of any potential treatment effects of behavior change techniques that were unique to the treatment conditions, and that our intervention was not optimized for highly active participants, which may have made up a large portion of our sample. Non-engagement with the intervention was not an important reason for the lack of treatment effects.

To consider the generalizability of our findings, we examine List's SANS conditions in the context of this study [124]. In terms of selection, ours is, using the terminology of List, a framed field experiment, and as such participants selected into the study [125]. In terms of attrition, while overall attrition was relatively high at 34%, it was not selective on the basis of observables. In terms of naturalness, while participants were clearly aware that they were taking part in an experiment, the remotely-delivered app intervention was a natural one for our participants given the proliferation of health behavior apps now available, and the outcome, MVPA, was measured in a natural setting (their day-to-day environment). Finally, in terms of scalability, given the automated and remotely-delivered nature of the intervention with low variable costs, the app is well-suited to being scaled up. However, how scaling to a more general sample would affect results is not clear.

While we find no effect of our intervention on MVPA, we do not believe that this necessarily refutes the IBC model, or other multi-process models, as a wise foundation on which to build an intervention. Indeed, we believe that the more general principles which we followed in designing our intervention, namely having a clear theoretical foundation and matching theoretical variables to evidence-based behavior change techniques, can serve as a worthwhile guide for future intervention design.

Data management

Data was handled confidentially and stored in a pseudonymized manner. The identification key linking unique participant ID with personal data was safeguarded and kept separate from deidentified research data. The identification key, informed consent forms, and deidentified research data will be archived for at least 10 years after completion of the study.

Fthics and dissemination

The study adhered most strictly to all applicable legal, ethical, and safety provisions of the Netherlands and the EU. The study was conducted in accordance with the principles of the Declaration of Helsinki [126]. The Medical Ethics Committee of the Erasmus MC approved this study (MEC-2020-0981). Findings from the study have been and will be presented at national and international scientific conferences. Results will be communicated to the general public through general conferences, meetings, and newsletters.

Acknowledgements

In alphabetical order

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The i2be app was developed in collaboration with Avegen, a digital health company that aims to empower individuals to take control of their health and has specific expertise in the areas of cardiovascular health, maternal health, and individualized care.

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SUPPORTING INFORMATION

Appendix 1: Tables and figures

Table A 1: Between-condition attrition check – Test of differences in mean baseline characteristics of non-attritors between conditions.

| | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) |
|--------------------------|-------------------|----------------|------------------|-----------------|--------|--------|-------|-------|
| | Obser- vations | Full sample | Infor- mation | Motiv- ation | Action | I v M | IVA | ΜvA |
| Age | 429 | 39.28 | 39.41 | 39.63 | 38.75 | 0.795 | 0.456 | 0.313 |
| Lower education | 411 | 0.03 | 0.04 | 0.01 | 0.03 | 0.152 | 0.643 | 0.336 |
| Mid-level education | 411 | 0.30 | 0.27 | 0.31 | 0.31 | 0.516 | 0.560 | 0.961 |
| Higher education | 411 | 0.67 | 0.68 | 0.68 | 0.66 | 0.899 | 0.706 | 0.800 |
| Living with partner | 429 | 0.85 | 0.83 | 0.86 | 0.86 | 0.434 | 0.467 | 0.976 |
| Living with children | 429 | 0.95 | 0.95 | 0.96 | 0.93 | 0.787 | 0.446 | 0.307 |
| Preeclampsia | 417 | 0.63 | 0.65 | 0.58 | 0.65 | 0.205 | 0.950 | 0.238 |
| HELLP | 417 | 0.58 | 0.60 | 0.58 | 0.54 | 0.687 | 0.312 | 0.534 |
| Other HP disorder | 417 | 0.29 | 0.26 | 0.30 | 0.31 | 0.437 | 0.293 | 0.768 |
| Lactating | 420 | 0.08 | 0.05 | 0.10 | 0.08 | 0.113 | 0.245 | 0.689 |
| Trait self-control | 398 | 22.37 | 21.85 | 23.10 | 22.16 | 0.035* | 0.586 | 0.113 |
| Habit | 369 | 60.41 | 60.43 | 60.41 | 60.39 | 0.988 | 0.981 | 0.993 |
| Self-report MVPA | 435 | 217.29 | 207.48 | 226.37 | 218.61 | 0.339 | 0.588 | 0.716 |
| <12 months postpartum | 435 | 0.15 | 0.12 | 0.16 | 0.17 | 0.325 | 0.219 | 0.788 |
| MVPA(Fitbit) | 427 | 243.89 | 237.77 | 255.63 | 237.96 | 0.455 | 0.992 | 0.467 |
| Resting Heartrate | 416 | 66.63 | 66.16 | 67.13 | 66.60 | 0.275 | 0.610 | 0.538 |
| BMI | 420 | 26.15 | 26.33 | 25.95 | 26.19 | 0.520 | 0.819 | 0.701 |
| Waist-Hip ratio | 384 | 0.85 | 0.85 | 0.85 | 0.86 | 0.751 | 0.671 | 0.891 |
| Cardioresp. fitness | 286 | 28.66 | 28.21 | 30.71 | 26.82 | 0.383 | 0.626 | 0.189 |
| Subjective wellbeing | 395 | 25.18 | 24.58 | 25.74 | 25.22 | 0.094 | 0.362 | 0.461 |

Notes: Columns 2-5 shows means at baseline for those for whom we have the relevant baseline data, for full sample and each of the three conditions, and for whom have week 9 MVPA data (i.e., non-attritor). Columns 6-8 shows p-values from t-tests of equality of means between Information (I), Motivation (M) and Action (A). *p < 0.05, **p < 0.01, ***p < 0.01, ***p < 0.001. HP stands for hypertensive pregnancy.

 Table A 2: Within-condition attrition check – Test of differences between mean baseline characteristics of baseline sample (includes attritors) and week 9 sample (excludes attritors) by treatment condition.

| | Full Sample | le | | Information | uc | | Motivation | L. | | Action | | |
|-------------------------|-------------|--------|---------|-------------|--------|---------|------------|--------|---------|----------|--------|---------|
| | (1) | (2) | (3) | (4) | (5) | (9) | (7) | (8) | (6) | (10) | (11) | (12) |
| | Baseline | Week 9 | P-value | Baseline | Week 9 | P-value | Baseline | Week 9 | P-value | Baseline | Week 9 | P-value |
| Age | 38.78 | 39.22 | 0.343 | 39.04 | 39.41 | 0.642 | 38.95 | 39.63 | 0.384 | 38.36 | 38.57 | 0.802 |
| Lower education | 0.03 | 0.03 | 0.822 | 0.04 | 0.04 | 0.848 | 0.02 | 0.01 | 0.905 | 0.03 | 0.03 | 0.817 |
| Mid-level education | 0.32 | 0.30 | 0.484 | 0.29 | 0.27 | 0.791 | 0.32 | 0.31 | 0.854 | 0.35 | 0.31 | 0.475 |
| Higher education | 0.66 | 0.67 | 0.545 | 0.67 | 0.68 | 0.861 | 99.0 | 0.68 | 0.831 | 0.63 | 0.66 | 0.535 |
| Living with partner | 0.85 | 0.85 | 0.818 | 0.83 | 0.83 | 0.995 | 0.87 | 0.86 | 0.932 | 0.85 | 0.87 | 0.599 |
| Living with children | 0.95 | 0.95 | 0.835 | 96:0 | 0.95 | 0.636 | 96.0 | 96.0 | 0.997 | 0.93 | 0.93 | 966.0 |
| Preeclampsia | 0.65 | 0.63 | 0.550 | 69.0 | 0.65 | 0.514 | 0.62 | 0.58 | 0.501 | 0.64 | 0.65 | 0.776 |
| HELLP | 0.55 | 0.57 | 0.565 | 0.56 | 09.0 | 0.429 | 0.57 | 0.58 | 0.842 | 0.53 | 0.53 | 0.980 |
| Other HP disorder | 0:30 | 0.29 | 0.690 | 0.26 | 0.26 | 0.884 | 0.32 | 0:30 | 0.706 | 0.31 | 0.30 | 0.902 |
| Lactating | 0.07 | 0.08 | 0.716 | 0.04 | 0.05 | 0.655 | 0.10 | 0.10 | 0.933 | 0.08 | 0.09 | 0.674 |
| Trait self-control | 22.33 | 22.40 | 0.825 | 22.02 | 21.85 | 0.764 | 22.65 | 23.10 | 0.452 | 22.32 | 22.25 | 0.904 |
| Habit | 00.09 | 60.45 | 0.601 | 60.27 | 60.43 | 0.914 | 59.51 | 60.41 | 0.560 | 60.24 | 60.53 | 0.850 |
| Self-report MVPA | 214.78 | 217.2 | 0.825 | 212.78 | 207.48 | 0.774 | 214.89 | 226.37 | 0.547 | 216.65 | 218.35 | 0.932 |
| <12 months postpart. | 0.15 | 0.15 | 0.898 | 0.14 | 0.12 | 0.591 | 0.15 | 0.16 | 0.736 | 0.15 | 0.17 | 0.659 |
| MVPA(Fitbit) | 236.24 | 244.0 | 0.538 | 227.01 | 237.77 | 0.582 | 261.74 | 255.63 | 0.822 | 220.88 | 238.62 | 0.320 |
| | | | | | | | | | | | | |

Table A 2: Continued

| | Full Sample | a a | | Information | | | Motivation | | | Action | | |
|-------------------------|-------------|--------|---------|-------------|--------|---------|------------|--------|---------|----------|--------|---------|
| | (1) | (2) | (3) | (4) | (5) | (9) | (7) | (8) | (6) | (10) | (11) | (12) |
| | Baseline | Week 9 | P-value | Baseline | Week 9 | P-value | Baseline | Week 9 | P-value | Baseline | Week 9 | P-value |
| Resting Heartrate | 89.99 | 99.99 | 0.958 | 66.39 | 66.16 | 0.790 | 67.26 | 67.13 | 0.890 | 66.40 | 66.68 | 0.715 |
| BMI | 26.44 | 26.18 | 0.432 | 26.69 | 26.33 | 0.521 | 26.49 | 25.95 | 0.380 | 26.17 | 26.26 | 0.874 |
| Waist-Hip ratio | 0.86 | 0.85 | 0.691 | 0.86 | 0.85 | 0.653 | 0.86 | 0.85 | 0.622 | 0.85 | 0.86 | 0.599 |
| Cardioresp. fitness | 28.38 | 28.60 | 0.900 | 28.44 | 28.21 | 0.944 | 31.01 | 30.71 | 0.913 | 25.54 | 26.70 | 0.698 |
| Subjective wellbeing | 25.06 | 25.18 | 0.762 | 24.60 | 24.58 | 0.982 | 25.43 | 25.74 | 0.639 | 25.16 | 25.22 | 0.920 |
| Observations | 480 | 435 | | 169 | 155 | | 157 | 148 | | 154 | 132 | |

Motivation and Action respectively; columns (2), (5), (8), (11) shows the same only for participants who have non-missing values for MVPA at week 9 (i.e., non-attritors); Columns (3), (6), (9), (12) show the p-value for t-test of baseline mean = week 9 mean. * p < 0.05, ** p < 0.01, *** p < 0.001. In the final row, the total observations at Notes: Columns (1), (4), (7), (10) show the mean of each variable for all participants with non-missing values for that variable at baseline for the full sample, Information, baseline and week 9 for which MVPA data is not missing are shown. HP stands for hypertensive pregnancy.

Table A 3: Treatment effects on MVPA relative to Information

| | (1) | (2) | |
|------------|----------|----------|--|
| | Week 5 | Week 9 | |
| Motivation | -7.534 | 3.292 | |
| | (17.661) | (28.151) | |
| Action | 3.505 | -14.630 | |
| | (15.505) | (20.232) | |
| N | 468 | 435 | |

Linear regression of MVPA at week 5 (column (1)) and week 9 (column (2)) on indicators for being in Motivation and Action. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05. ** p < 0.01. *** p < 0.001

Table A 4: Effects on MVPA relative to Motivation.

| | (1) | (2) | |
|-------------|----------|----------|--|
| | Week 5 | Week 9 | |
| Information | 7.534 | -3.292 | |
| | (17.661) | (28.151) | |
| Action | 11.039 | -17.921 | |
| | (17.087) | (25.851) | |
| N | 468 | 435 | |

Linear regression of MVPA at week 5 (column (1)) and week 9 (column (2)) on indicators for being in Information and Action. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 5: Treatment effects on secondary outcomes relative to Information.

| | (1) | (2) | (4) | (5) |
|------------|----------------------|----------------------|-----------------------------------|-------------------------|
| | Resting heartrate | Over-weight Index | Cardio- Respiratory fitness | Subjective wellbeing |
| Motivation | -0.077 | -0.030 | 0.013 | -0.018 |
| | (0.082) | (0.070) | (0.153) | (0.098) |
| Action | -0.154 | -0.032 | -0.044 | 0.026 |
| | (0.086) | (0.075) | (0.163) | (0.097) |
| N | 385 | 284 | 216 | 307 |

Linear regression of standardized secondary outcomes at week 9 on indicators for being in Motivation and Action. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. The regressions in columns (2) also controls for lactating. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 6: Effects on secondary outcomes relative to Motivation.

| | (1) | (2) | (4) | (5) |
|-------------|----------------------|----------------------|-----------------------------------|-------------------------|
| | Resting heartrate | Over-weight Index | Cardio- Respiratory fitness | Subjective wellbeing |
| Information | 0.077 | 0.030 | -0.013 | 0.018 |
| | (0.082) | (0.070) | (0.153) | (0.098) |
| Action | -0.077 | -0.002 | -0.057 | 0.044 |
| | (0.083) | (0.068) | (0.185) | (0.103) |
| N | 385 | 284 | 216 | 307 |

Linear regression of standardized secondary outcomes at week 9 on indicators for being in the information and action conditions. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. The regression in column (2) also controls for lactating. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 7: Treatment effects on MVPA relative to Information – baseline MVPA interaction analysis.

| | (1) | (2) |
|----------------------------|------------|------------|
| | Week 5 | Week 9 |
| Motivation group | 7.832 | 34.955 |
| | (37.616) | (52.939) |
| | | |
| Action group | -37.635 | -50.796 |
| | (29.147) | (29.543) |
| | | |
| Low baseline MVPA | -172.425** | -101.882** |
| | (26.682) | (27.400) |
| | | |
| Motiv. x Low baseline MVPA | -23.602 | -60.445 |
| | (41.349) | (54.257) |
| | | |
| Action x baseline MVPA | 71.456* | 75.299 |
| | (35.545) | (39.104) |
| N | 427 | 427 |

Linear regression of MVPA at week 5 (column (1)) and week 9 (column (2)) on indicators for being in Motivation and Action, an indicator for having low baseline MVPA (i.e., baseline MVPA at or below the median (210 mins)), and interaction terms for the interactions of each of the motivation and action indicators with the low baseline MVPA indicator. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of prior hypertensive pregnancy disorder. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 8: Treatment effects on MVPA relative to Information – subsamples of low and high baseline MVPA participants.

| | Low baseline | MVPA | High baseline | MVPA |
|------------------|--------------|----------|---------------|----------|
| | (1) | (2) | (3) | (4) |
| | Week 5 | Week 9 | Week 5 | Week 9 |
| Motivation group | -15.076 | -38.605 | 11.601 | 52.600 |
| | (18.072) | (21.430) | (40.793) | (60.285) |
| Action group | 24.856 | 6.166 | -30.824 | -36.763 |
| | (20.090) | (27.994) | (33.012) | (33.378) |
| N | 215 | 215 | 212 | 212 |

Linear regression of MVPA at week 5 (columns (1) and (3)) and week 9 (columns (2) and (4)) on indicators for being in Motivation and Action. Sample in columns (1) and (2) is all participants with baseline MVPA at or below the median (210 mins), while sample in columns (3) and (4) is all participants above the median. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 9: Effects on MVPA relative to Motivation – Baseline MVPA interaction analysis.

| | (1) | (2) | |
|----------------------------|------------|------------|--|
| | Week 5 | Week 9 | |
| Action group | -45.467 | -85.751* | |
| | (34.509) | (50.459) | |
| Low baseline MVPA | -196.027** | -162.327** | |
| | (32.772) | (43.170) | |
| Action x Low baseline MVPA | 95.058* | 135.744* | |
| | (38.925) | (57.105) | |
| N | 427 | 427 | |

Linear regression of MVPA at week 5 (column (1)) and week 9 (column (2)) on indicators for being in the information and action conditions, an indicator for having low baseline MVPA (i.e., baseline MVPA at or below the median), and interaction terms for the interactions of each of the information and action indicators with the low baseline MVPA indicator. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Information control variable coefficients not shown. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001.

Table A 10: Treatment effects on MVPA relative to Motivation – subsamples of low and high baseline MVPA participants.

| | Low baseline | MVPA | High baseline | MVPA |
|------------------|--------------|----------|---------------|----------|
| | (1) | (2) | (3) | (4) |
| | Week 5 | Week 9 | Week 5 | Week 9 |
| Motivation group | 15.076 | 38.605 | -11.601 | -52.600 |
| | (18.072) | (21.430) | (40.793) | (60.285) |
| Action group | 39.932* | 44.771 | -42.425 | -89.363 |
| | (17.582) | (23.663) | (36.685) | (55.456) |
| N | 215 | 215 | 212 | 212 |

Linear regression of MVPA at week 5 (columns (1) and (3)) and week 9 (columns (2) and (4)) on indicators for being in the information and action conditions. Sample in columns (1) and (2) is all participants with baseline MVPA at or below the median (210 mins), while sample in columns (3) and (4) is all participants above the median., while sample in columns (3) and (4) is all participants above the median. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 11: Treatment effects on MVPA relative to Information – education interaction analysis.

| | (1) | (2) | |
|---------------------------|----------|----------|--|
| | Week 5 | Week 9 | |
| Motivation group | 9.368 | 4.531 | |
| | (23.580) | (25.983) | |
| | | | |
| Action group | 12.892 | -11.998 | |
| | (19.352) | (25.996) | |
| | | | |
| Lower/mid-level education | 6.559 | 48.741 | |
| | (28.889) | (31.839) | |
| | | | |
| Motiv. x lower/mid educ. | -47.763 | -4.766 | |
| | (38.624) | (57.056) | |
| | | | |
| Action x lower/mid educ. | -12.142 | -33.407 | |
| | (36.723) | (42.792) | |
| N | 444 | 411 | |

Linear regression of MVPA at week 5 (column (1)) and week 9 (column (2)) on indicators for being in the motivation and action conditions, an indicator for having at most a lower or mid-level education, and interaction terms for the interactions of each of the motivation and action indicators with the lower or mid-level education indicator. Control variables are baseline MVPA, age, trait self-control, habit, household composition, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 12: Treatment effects on MVPA relative to Information – subsamples of low/mid-level education and higher education.

| | Lower/Mid-level education | | Higher education | | |
|------------------|---------------------------|----------|------------------|----------|--|
| | (1) | (2) | (3) | (4) | |
| | Week 5 | Week 9 | Week 5 | Week 9 | |
| Motivation group | -45.059 | -44.730 | 6.012 | 3.289 | |
| | (29.232) | (56.396) | (25.796) | (25.510) | |
| Action group | -21.546 | -65.124 | 15.183 | -13.903 | |
| | (30.096) | (44.314) | (20.404) | (24.337) | |
| N | 149 | 134 | 295 | 277 | |

Linear regression of MVPA at week 5 (columns (1) and (3)) and week 9 (columns (2) and (4)) on indicators for being in the motivation and action conditions. Sample in columns (1) and (2) is all participants with at most lower or mid-level education, while sample in columns (3) and (4) is all participants with at higher education degree. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 13: Treatment effects on mechanisms of action relative to Information.

| | Motivational | | Volitional | | | Automatic | | |
|--------|------------------------------|----------------|-------------------------|---------------------|-----------------|-----------|-------------------------|-------------------------|
| | Intrinsic Motiv- ation | Inten- tion | Action Plan -ning | Coping Plan-ning | Comm- itment | Stress | Posi- tive Affect | Nega- tive Affect |
| Motiv. | -0.063 | -0.126 | -0.114 | -0.096 | -0.010 | 0.161 | -0.141 | 0.079 |
| | (0.108) | (0.140) | (0.130) | (0.115) | (0.126) | (0.113) | (0.134) | (0.116) |
| Action | 0.220* | 0.307* | 0.672** | 0.948** | 0.572** | -0.193 | 0.083 | -0.070 |
| | (0.109) | (0.134) | (0.134) | (0.137) | (0.147) | (0.117) | (0.125) | (0.114) |
| N | 298 | 309 | 305 | 300 | 310 | 291 | 296 | 306 |

Linear regression of standardized mechanism of action variables at week 9 on indicators for being in Motivation and Action. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 14: Effects on mechanisms of action relative to Motivation.

| | Motivational | | Volitional | | | Automatic | | |
|--------|------------------------------|----------------|-------------------------|---------------------|-----------------|-----------|-------------------------|-------------------------|
| | Intrinsic Motiv- ation | Inten- tion | Action Plan -ning | Coping Plan-ning | Comm- itment | Stress | Posi- tive Affect | Nega- tive Affect |
| Info. | 0.063 | 0.126 | 0.114 | 0.096 | 0.010 | -0.161 | 0.141 | -0.079 |
| | (0.108) | (0.140) | (0.130) | (0.115) | (0.126) | (0.113) | (0.134) | (0.116) |
| Action | 0.283* | 0.433** | 0.786** | 1.044** | 0.582** | -0.354** | 0.224* | -0.149 |
| | (0.120) | (0.144) | (0.140) | (0.138) | (0.146) | (0.118) | (0.123) | (0.117) |
| N | 298 | 309 | 305 | 300 | 310 | 291 | 296 | 306 |

Linear regression of standardized mechanism of action variables at week 9 on indicators for being in the information and action conditions. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 15: Program compliers by module – baseline sample.

| | Total | Compliers | Proportion |
|-----------------|-------|-----------|--------------|
| | | - | of compliers |
| Get Informed | | | |
| Full Sample | 480 | 301 | 0.627 |
| Information | 169 | 121 | 0.716 |
| Motivation | 157 | 91 | 0.580 |
| Action | 154 | 89 | 0.578 |
| Get Motivated | | | |
| Motiv. & Action | 311 | 223 | 0.717 |
| Motivation | 157 | 126 | 0.803 |
| Action | 154 | 97 | 0.630 |
| Get Activated | | | |
| Action | 154 | 92 | 0.597 |
| Get Energized | | | |
| Action | 154 | 85 | 0.552 |

Sample is all those who have a non-missing baseline value for MVPA. Compliance is defined as completing at least 75% of a given module in at least 7 weeks of the 8-week program.

Table A 16: Treatment effects on MVPA relative to Information – sample of Get Informed compliers.

| | (1) | (2) | |
|------------|----------|----------|--|
| | Week 5 | Week 9 | |
| Motivation | -25.461 | -19.211 | |
| | (23.133) | (25.015) | |
| Action | -4.405 | -11.186 | |
| | (19.154) | (22.433) | |
| N | 304 | 291 | |

Linear regression of MVPA at week 5 (column (1)) and week 9 (column (2)) on indicators for being in the motivation and action conditions. Sample is all those who completed at least 75% of the Get Informed module in at least 7 weeks of the 8-week program. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

Table A 17: Treatment effects on MVPA relative to Information – sample of all-module compliers.

| | (1) | (2) | |
|------------|----------|----------|--|
| | Week 5 | Week 9 | |
| Motivation | -37.909 | -28.091 | |
| | (23.710) | (24.496) | |
| Action | -11.855 | -1.128 | |
| | (23.864) | (27.020) | |
| N | 255 | 244 | |

Linear regression of MVPA at week 5 (column (1)) and week 9 (column (2)) on indicators for being in the motivation and action conditions. Sample is all those who completed at least 75% of each module available to them in at least 7 weeks of the 8-week program. Control variables are baseline MVPA, age, trait self-control, habit, household composition, education, type of high blood pressure condition. Standard errors in parentheses. * p < 0.05, ** p < 0.01, *** p < 0.001

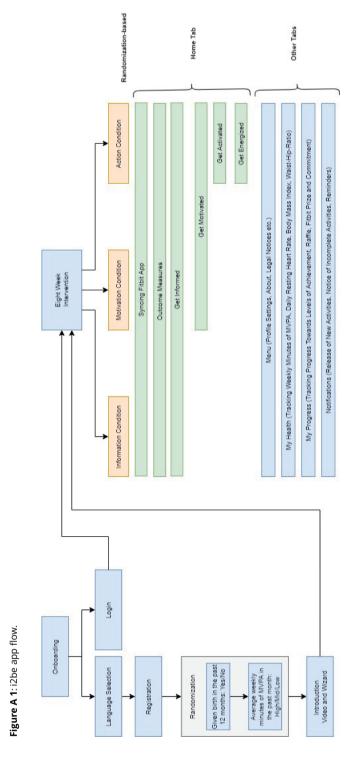
APPENDIX 2

i2be app - home and notifications

An overview of the functionalities and user flow of the i2be app can be seen in Appendix Figure A 1. The user flow on logging into the app for the first time is shown in the very left hand column, and has been described previously. Once logged into the app, the participant was brought to the *Home* tab, which showed the modules they had to complete in the current week. In weeks 0. 9. 21 and 61 they had an outcome measures module to complete. See an example of the Home tab in the top-right of Figure 5. In weeks 0-10, 21, 22, 61 and 62 they had to complete a module reminding them to sync the Fitbit app with their Fitbit device. In weeks 1-8 they had the activity modules relevant to their condition to complete (Get Informed, Get Motivated, Get Activated, and Get Energized). Modules could only be completed during the week to which they related and could not be edited in advance or retrospectively. Participants were, however, able to read back over module content and their own responses in those modules retrospectively. Modules in a given week could be completed in any order, and could be completed separately from each other at any time during the week. Additionally, if participants exited an incomplete module, their progress was saved and they could return to it later.

There were also a number of other tabs which all participants could navigate to from the Home tab. In the *Notifications* tab, participants could see notifications received informing them at the beginning of the week that the current week's modules were available and reminders later in the week to complete those modules. For participants in Action, they also received reminder notifications of their weekly action plans. These notifications were also received as push notifications directly to the home screen of the participant's phone. Details on the My Progress and My Health tabs are given in the *Features of the i2be app* section in the main text.

The user interface of the app utilized animated images of women from a diversity of ages and ethnic backgrounds. Female voice-overs were used in the introduction video and the audio clips.



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CHAPTER 8

Discussion

Developing mHealth interventions A practical guide

The current thesis set out to design, implement, and evalute a theory- and evidence-based mHealth intervention to decrease risk for a leading cause of mortality and disability worldwide: cardiovascular diseases (CVDs) [1]. Efforts to alleviate some of this burden are a global priority, as the number of people with CVDs and associated costs are only expected to grow in the future [2, 3]. Specifically, this thesis aimed to conduct an innovative intervention to reduce risk of CVDs through behavioral risk factors, such as insufficient physical activity, sedentary behavior, high fat intake, and high sugar intake [4-7], accompanying cardio metabolic risk factors, such as overweight, (abdominal) obesity, and high blood pressure [8], and psychosocial risk factors, such as stress and negative affect [9].

Individual-level interventions targeting behavioral, cardio metabolic, and psychosocial risk factors for CVDs are common worldwide [10]. Unfortunately, the effects of such interventions are generally too small and short-lived to achieve significant CVD risk reduction [10]. A hypothesized reason for these shortcomings is the limited extent to which interventions are based on, instead of being merely inspired by, health behavior theory [11-13]. Growing evidence suggests that theory-based interventions lead to larger effects in health contexts than non-theory-based interventions [14, 15]. Naturally, the quality of the theory used is vital: it has to incorporate up-to-date insights from the vast knowledge on behavior change that is already available; and preferably needs to have been found successful in predicting behavior at least observationally in previous studies. Interventions that are based on such a health behavior theory, and then systematically link theoretical constructs to evidence-based behavior change techniques, i.e., the active ingredients of behavior change interventions, are hypothesized to be most effective of all [11, 16]. Therefore, this thesis set out to design a theory- and evidence based intervention to reduce CVD risk.

Individual-level health promotion interventions that are based on theory are typically based on a prominent social cognition theory which describes behavior as the result of deliberative psychological processes [13]. While interventions based on such theories have generally been shown to be effective in changing behavioral intentions, they often stop short of changing actual behavior [17, 18]. A potential explanation for this shortcoming is that a substantial proportion of individuals intend to perform a health behavior of interest, but for various reasons fail to act on these intentions [19, 20]. A further limitation of interventions based on social cognition theories is that they overlook spontaneous or impulsive behavior that is the result of automatic processes, not directly under the conscious control or awareness of the individual [21, 22]. Researchers have therefore sought to identify potential ways to promote better enactment of intentions and account for automatic processes in behavioral interventions, and minimize this 'intention-behavior gap' [22, 23].

The insights from dual process theories might help to reduce the 'intention-behavior gap', as they account for two types of processes that govern action: automatic processes, by which behavior is determined by impulses and well-learned associations between context and action, and deliberative processes, by which action is determined by reasoned deliberation and the value attached to courses of action [22, 24-26]. Some integrated theories further differentiate between two types of deliberative processes that lead to behavior: pre-intentional (motivational) and post-intentional (volitional) processes, proposing that intention enactment is facilitated in the volitional phase by a planning process [27].

Behavioral scientists in both psychology and economics have been rapidly developing knowledge on the dual nature of cognitive processes that lead to health behavior, albeit from largely different perspectives: the two fields seldom conceptualize theoretical constructs in the same ways, with the same assumptions. Therefore, in preparation of the selection of a dual process theory to underlie our intervention, we have decided to compare the construct of self-control both theoretically as well as empirically in psychology and economics, presented in **chapters 2 and 3**.

To have the intervention resonate with its intended audience and thereby potentially increase intervention uptake and enhance behavior change and maintenance, one should assess the needs and preferences of the study population prior to the development of the intervention protocol [28]. For the same reason, the perceived relevance of the theoretical framework considered to serve as the basis of the intervention should be first assessed in the target population [29]. Qualitative studies are well suited for these tasks, given the broad and rich converging evidence that they provide. For these reasons, **chapters 4 and 5** adopted a qualitative approach to assess the needs and preferences and the perceived determinants of physical activity of the intended population of our subsequent intervention.

When it comes to the medium of interventions, web-based interventions have several advantages over face-to-face interventions: they are comparatively low cost, have a wide reach, and provide flexibility in intervention location and time [30, 31]. Access to web-based interventions may be further enhanced by delivering them via mobile phone optimized web browsers or dedicated mobile apps, also called mHealth [32]. mHealth interventions may provide an especially high social return in populations with an increased risk for CVDs later in life as these groups have much to gain from adopting healthier lifestyles [33-36]. Therefore, we decided to design and deliver an mHealth intervention tailored to the needs, preferences, and perceived physical activity determinants of a high CVD risk group, i.e., women with a prior hypertensive disorder of pregnancy. The study design, short-term effects, and process evaluation of the intervention are presented in **chapters 6 and 7**.

MAIN FINDINGS AND INTERPRETATION

First research question: How do theories and measures of self-control in psychology and economics relate to each other and to modifiable risk factors for CVDs?

Chapter 2 explored how self-control is conceptualized in the fields of psychology and economics by reviewing the literature on the theory and measurement of self-control, and by creating a common framework. To follow, chapter 3 explored how measures of trait self-control in the two fields relate to each other and to modifiable risk factors for CVDs.

Chapter 2

Chapter 2 presented a narrative review of the theory and measurement of self-control in psychology and economics to develop a common conceptual framework. Based on the reviewed literature, we were able to show that self-control can be conceptualized along three main characteristics: stability (trait versus state), process (impulsivity versus inhibition), and enactment (avoidance versus resistance). This framework highlights the multidimensional nature of self-control and will aid intervention researchers to select theories and measurements of self-control that are most appropriate for their health outcome of interest. While we were able to create a multidisciplinary conceptual framework of self-control, future empirical studies are warranted to shed light on the validity and practical application of this framework.

Chapter 3

In chapter 3, a cross-sectional study on the relationship between several measures of trait self-control, and their relationship with modifiable risk factors for CVDs was performed, using data from 4741 adults (18-65 years) participating in the Lifelines Cohort Study and the additional LIFESTYLE Study. We used several measures of trait self-control that are generally considered to capture inhibitory processes and several measures that capture impulsive processes. This chapter did not attempt to measure state self-control, a theoretical construct that thus far lacks empirically strong measures, as detailed in chapter 2.

In general, different measures of inhibition were moderately associated with each other, and several measures of inhibition and impulsivity related to each other moderately. Regression analysis that included all trait self-control and confounder variables showed that higher inhibition and impulsivity were associated with higher physical activity and lower sedentary behavior. Furthermore, higher inhibition was associated with lower fat and sugar intake and higher sleep quantity. Higher inhibition

and impulsivity were also associated with lower BMI. However, generally, inhibition was inconsistently related to cardio metabolic risk factors. The variance accounted for by trait self-control measures was small for all outcomes examined. Our findings support for the notion that trait self-control is a multidimensional construct, consisting of at least two dimensions, inhibition and impulsivity. We find both higher inhibition and impulsivity to be consistently associated with healthier outcomes, with inhibition having a stronger association overall. Our results indicate that both inhibition and impulsivity influence health independently and simultaneously. Intervention designers aiming to identify individuals at risk of an intention-behavior gap concerning physical activity, sedentary behavior, fat and sugar intake, and sleep, may want to use measures of trait inhibition. To better understand the causal relationships between the variables examined in the current study, longitudinal investigation of these associations is warranted in the future.

Second research question: What are the mHealth needs and preferences and the perceived physical activity determinants of a high CVD risk population?

Chapters 4 and 5 have assessed the needs and preferences of a population with an increased risk for CVDs later in life regarding the delivery of app-based cardiovascular health promotion. Further, the determinants of these participants physical activity were qualitatively assessed, and themes that emerged were used to examine the perceived relevance of a dual process theoretical framework.

More specifically, a population of women have who have experienced a hypertensive pregnancy disorder, severe preeclampsia, were selected for an mHealth intervention for several reasons. Firstly, health behavior interventions may provide an especially high social return in this population due to these women's increased CVD risk [33-36]. Second, these women are likely to be motivated to participate in a health behavior intervention due to the 'window of opportunity' that their new motherhood presents. Third, these women typically do not have any physical limitations that would prevent their participation in a health behavior intervention, as other patient groups with a high CVD risk might have. Finally, as these women's increased risk for CVDs is not likely to manifest until later in life, our findings may be generalizable to other motivated, young, and healthy women.

Chapter 4

In chapter 4 women who have experienced a hypertensive pregnancy disorder were asked about their needs: the extent to which they struggle to participate in cardiovascular health promoting behaviors, the extent to which they plan to make

positive changes to these behaviors, and the extent to which they are interested in participating in an app-delivered program targeting these behaviors. Second, these women's preferences regarding the delivery of app-based cardiovascular health promotion, i.e., their wishes regarding app content, functionalities, and interface, were examined

Women's primary need for health behavior promotion pertained to their fat and sugar intake and physical activity. Their next priority was to gain better means to manage their mental health. That the primary needs of women are closely linked to CVD risk emphasize the need for interventions that target these behaviors in this priority population [38, 39]. As a healthy lifestyle, such as engaging in physical activity, has been linked to improved mental health, future interventions could target multiple needs simultaneously [40-42]. Most women preferred the app-based intervention to include, in descending order: the tracking of health-related metrics, an interactive platform, the use of behavior change strategies, the provision of information, and personalization. Future app-based programs aimed to improve cardiovascular health in women with prior severe preeclampsia would benefit from including such elements in their delivery [43-45].

Chapter 5

In chapter 5, the perceived determinants of these women's physical activity were qualitatively assessed, and the themes that emerged were used to examine the relevance of a dual process theoretical framework. Participants perceived a wide range of facilitating and hindering factors to impact their physical activity. Thirteen themes emerged from the qualitative analysis, which were matched to four overarching themes: motivational processes (future health, perceived ability, attitude, future reward or regret, physical appearance, doing it for others), volitional processes (scheduling, planning), automatic processes (affect, stress), and environmental factors (time constraint, social support, physical environment). These themes had reasonable correspondence with the overarching motivational, volitional, and automatic processes described in the integrated behavior change model [46]. In addition, our results indicate that this model could be extended with future reward or regret [47-49] and environmental factors [50-52]. In combination with evidence from previous observational studies [53-61], the results of our study suggest that the integrated behavior change model may be a suitable theory-base for physical activity interventions in women with prior severe preeclampsia.

Third research question: How to design, implement, and evaluate theory- and evidence-based cardiovascular mHealth promotion?

Chapter 6 presented the study design of an app-delivered theory- and evidence-based intervention to reduce CVD risk, tailored to the needs, preferences and perceived physical activity determinants of women with a prior hypertensive disorder of pregnancy. Subsequently, chapter 7 analyzed the short-term efficacy, program acceptability, and program fidelity results of this intervention.

Chapter 6

The efficacy of an eight-week intervention was tested using a three-condition randomized controlled trial (RCT) delivered through a purpose-built app, the i2be app, in women with a prior hypertensive pregnancy disorder. The intervention was based on the integrated behavior change model, which outlines the motivational, volitional, and automatic processes that lead to physical activity. Following stratification on baseline factors, participants were randomly allocated to one of three conditions – the information condition, which was meant to mimic usual care, the motivation condition, which targeted motivational processes, and the action condition, which targeted all three of the processes described by the integrated behavior change model. The primary outcome was weekly minutes of moderate-to-vigorous physical activity, as measured by an activity tracker (Fitbit Inspire 2). Secondary outcomes included weekly average of Fitbit-measured daily resting heart rate, and self-reported BMI, waist-hip ratio, cardiorespiratory fitness, and subjective well-being. Tertiary outcomes included selfreported variables representing motivational, volitional, and automatic processes. Outcome measures were assessed at baseline, immediately post-intervention, and will be assessed at 3 and 12 months post-intervention. A process evaluation was performed based on program fidelity and acceptability measures immediately after the intervention. Efficacy was determined by available case analysis, and the mechanisms by which the behavior change techniques were hypothesized to lead to physical activity were tested

Chapter 7

We ran an RCT to test an app-delivered physical activity intervention with 663 women in the Netherlands who had suffered a prior hypertensive disorder of pregnancy. This chapter presents the first short-term efficacy (immediately post-intervention) and program acceptability and fidelity results. The action condition was unsuccessful in increasing physical activity relative to the information condition (usual care) or the motivation condition. We found some tentative evidence that the action condition worked better for those with low physical activity at baseline – arguably the group that has most to gain from such interventions. There are several possible reasons for the

lack of effect we find for the full sample. Physical activity levels in all conditions. including information (i.e., the control condition), were highest at baseline (approximately 4 hours per week), with 67% of participants exceeding 2.5 hours. In comparison, 51% of Dutch female adults self-reports to exceed 2.5 hours of physical activity per week [62]. In reality, the proportion of Dutch women reaching guideline levels might be much lower: studies from other countries, such as the US and UK, show that self-reported physical activity tends to be much higher than activity-tracker measured physical activity [63, 64]. Unfortunately, to our knowledge, similar data comparison studies of self-report and tracker-measured physical activity are not available for Dutch adults. Moreover, Fitbit-measured physical activity at baseline was also higher than self-reported physical activity over the last month. These findings suggests that, at least at baseline and perhaps throughout the intervention, the physical activity levels of participants were higher than prior to enrolling in the study. We identified health promoting changes in outcomes across all conditions, most notably BMI, consistent with this hypothesis. A possible cause of such potential change in physical activity could have been the features of the information condition, which were also available to the other two conditions, therefore possibly not having been an appropriate usual care benchmark. In particular, we might have underestimated the effect of the Fitbit device and app and the basic version of the i2be app on physical activity, which might have crowded out effects that may have otherwise arisen from the behavior change techniques included in the motivation and action conditions. Further, the lack of success of the action condition to significantly influence automatic processes may also have played an important role in the overall lack of effect, since the IBC model hypothesizes these processes to be influential in the intention-behavior gap regarding physical activity.

METHODOLOGICAL CONSIDERATIONS

What is self-control and why is it relevant for interventions?

Comprehensively capturing self-control is a challenging task given the infamously scattered nature of the topic both within and across fields of research. Chapter 2 presented a conceptual framework of self-control in terms of theories and measures of the construct in the fields of psychology and economics. Although self-control is a crucial concept in health promotion, the ambiguity of its conceptualization hampers progress in understanding its role in behavioral change. The current conceptual framework shows several similarities as well as important differences in concepts of self-control between the two disciplines, contributing to a more precise conceptualization of self-control. The empirical usefulness of the framework should

be evaluated in future studies. Chapter 3 set out to assess the empirical value of differentiating between the inhibition and impulsivity dimensions of trait self-control. However, it did not attempt to measure state self-control, as the measurement of this construct is still in its infancy, as detailed in chapter 2. The decision to only used wellestablished measures of trait self-control has both strengths and weaknesses. The central role of trait self-control in engaging in health promoting behaviors is virtually uncontested [65, 66], and the validity and reliability of measurement instruments capturing this construct are generally considered high [67-72]. However, trait selfcontrol is less of a feasible target for interventions than state self-control because it is relatively stable across situations and time. Instead, social-cognitive variables that mediate its effects, such as motivation, are easier to change. Because of its stable nature, measures of trait self-control may be used to identify individuals who would likely have difficulties in converting their healthy intentions into behavior [65, 66]. Our study identifies to some extent how dimensions of trait self-control (impulsivity versus inhibition) relate to modifiable risk factors for CVDs, which may allow intervention designers to identify 'at-risk' individuals concerning their health outcome of interest, and subsequently tailor intervention content to these people's needs, such as provide them with the behavior change technique of planning.

Whose trait self-control and modifiable CVD risk factors did we assess?

Participation in (social) epidemiological studies have been on the decline in past decades. Deprived groups, such as ethnic minority groups, unemployed people, lower income and educational groups, and substance users, are generally underrepresented in most observational studies, allowing only for limited generalization of findings to these people. Such selection bias may be in part explained by language related issues, fear of stigmatization, a smaller trust in science, and lower volunteerism [73, 74]. It also needs to be mentioned that participation in the LIFESTYLE add-on questionnaires was low: 19% of participants that received an invitation filled in at least one of the questionnaires. These numbers are comparable to other add-on questionnaire studies among Lifelines participants [75], and are likely due to the fact that these people get several participant request per year through Lifelines, and are not paid or rewarded otherwise for participation. However, low participation does not have to mean selective participation [76]. In order to assess the magnitude of potential selection bias within our study sample presented in chapter 3, information on demographic and health characteristics were compared to those of the whole LIFESTYLE sample (including those with missing values on predictor and confounder variables), as well as the general Lifelines Cohort (A1). These results showed that our study population was different from the whole LIFESTYLE sample as well as the general Lifelines Cohort on some of the examined variables, such as the likelihood of having been born in the Netherlands and self-rated health. However, the size of these differences were small, for example 95% of the general Lifelines Cohort, 97% of the whole LIFESTYLE sample, and 98% of our study sample having been born in the Netherlands; and 88%, 90%, and 92.5% of these groups having self-rated good to excellent health, respectively. The general Lifelines Cohort has been deemed to be broadly representative of the population in the North of the Netherlands on socioeconomic characteristics, lifestyle, diseases, and general health [77].

Who can we generalize our findings on mHealth needs and preferences to?

Several limitations should be kept in mind before generalizing our results presented in chapter 4. Most of our study population was highly educated, limiting the extent to which we can assume our findings to apply to all socioeconomic groups in terms of needs and preferences regarding mHealth promotion. Health apps are proliferating rapidly - there are now more than 350,000 available for download [78]. A prerequisite of health app use is owning a smartphone: about half of the world's population [79] and 84% of the Dutch population meets this criterion [80]. Over half of all Dutch women already use health apps, primarily to monitor their health behaviors, with another quarter before being open to using one in the future [81]. However, given that the prevalence of mobile phone use for health purposes generally shows an educational gradient, special attention needs to be paid to not inadvertently increase health inequalities with mHealth [82]. Furthermore, as our population self-selected from an outpatient clinic specialized in the cardiovascular follow-up and risk management of women with prior severe preeclampsia, these women may have had a higher awareness of their increased risk for CVDs than the average woman with prior preeclampsia. This could have led to different conclusions on the needs and preferences for mHealth promotion than a more general sample of women with a prior hypertensive disorder of pregnancy would have. Further, caution should be exercised when making generalizations based on our quantitative findings, i.e., regarding needs, due to the limited sample size of the study relative to most quantitative studies. Due to the predominantly qualitative nature of the survey, inclusion of participants was stopped after data saturation was reached on all qualitatively assessed topics, at a sample of 35 participants. While this is a sizable sample compared to similar qualitative studies (e.g., [83-85]), and even though qualitative studies can provide excellent in-depth converging evidence on complex issues, they do not have the characteristics of robust quantitative methods such as generalizability and reproducibility.

What is physical activity and how can we target it in interventions?

The definition and measurement of physical activity in chapters 6 and 7 of this thesis carries several consequences. We have decided not to exclude participants with moderate to high physical activity at baseline, as other studies have done [86], because some evidence suggests that there is a dose response relationship between the cardiovascular health benefits and physical activity, even though most gain is to be made for individuals inactive or low on activity at baseline [87]. Presenting the recommended physical activity guidelines of 150 minutes of physical activity per week. in combination with the tracking of activity with the Fitbit, both elements present in the usual care condition, may have inadvertently discouraged individuals with higher levels of physical activity to become even more active, thus flattening out the effect of intervention elements that differed between the groups. In addition, future studies need to assess prior activity tracker ownership to be able to give a longer onboarding period to participants that have not owned an activity tracker before to let novelty effects wear off prior to the baseline physical activity measurement of the intervention. Furthermore, while the general focus of our intervention content was on increasing leisure time physical activity, our method of assessing physical activity, i.e., a Fitbit that does not differentiate between leisure time, occupational, domestic, or transportation physical activity, left us in the dark about the domain of physical activity that our participants engaged in [88]. That we found health improvements across all conditions may suggest that a substantial amount of the activity captured in our study was not occupational [89]. Future studies could increase the 'naturalness' of their intervention by explicitly encouraging leisure time, domestic as well as transportation physical activity, and could try to tease out the domain of activity captured in their study by collecting data on the length, timing and location of participants' physical activity bouts. A final issue pertaining the measurement of physical activity concerned the possibility of erroneous data presented in chapter 7. Fitbit-measured data is likely to be imperfect due to possibilities of missing or incomplete data arising from intentional (e.g., aversion to Fitbit device use) or unintentional non-compliance (e.g., forgetting to wear Fitbit device), and measurement error in data (e.g., imperfect measurement of physical activity). On the other hand, when weighing the pros and cons regarding accuracy. ability to predict health outcomes, and price, the Fitbit seems a good alternative to self-report [90] and other consumer-grade and research grade trackers [91] for purposes as the current intervention.

How can we design an adequate usual care condition?

A central issue in chapters 6 and 7 pertains to how the control condition was defined. Ideally, in clinical contexts, control conditions should be neutral enough to be considered 'usual care', engaging enough to retain participants that get assigned to

that condition, and able to measure the outcomes of the study. In our mHealth intervention, we have designed the usual care condition content with these aspects in mind. In our intervention, all participants received usual care, treatment one received additional content, and treatment two received further content on top of that. Therefore, all participants received app-delivered information on topics related to physical activity, such as the relationship with hypertensive pregnancy, as well as recommendations on how to warm-up, cool-down, and lower risk of injury, largely corresponding to the usual care offered to women with prior hypertensive pregnancy disorders. However, we may have underestimated the effect of the this usual care condition, in combination with the Fitbit device and Fitbit app (that is necessary to pull the data from the Fitbit). The self-monitoring fostered by these basic elements, particularly the opportunity to keep an eye on Fitbit-measured minutes spent on moderate and vigorous physical activity, could be considered an intervention in and of themselves [16, 92]. These elements may have crowded out effects that may have otherwise arisen from the behavior change techniques included in the motivation and action conditions. That program acceptability measures showed that all intervention elements were found helpful in increasing physical activity and pleasant by participants, and our suspicion that baseline physical activity levels may have already been inflated by the features of the usual care condition, suggest that the general elements of our intervention may be useful for behavior change, if not suitable as control content.

How can we measure and influence automatic processes?

A challenge of chapters 3, 5, 6 and 7 concerns the measurement and targeting of automatic processes. Automatic processes such as stress and affect are thought to influence behavior without deliberation of the individual, or even beyond the awareness of the individual. Stress and affect were selected as proxies for state self-control - a theoretical construct that thus far lacks empirically strong measures, as detailed in chapter 2 - as these constructs emerged as important perceived predictors of physical activity in chapter 5. It is possible that other automatic variables, such as fatigue or cue awareness, would have been better proxies for state self-control. However, this would not have solved the more general issue that participating in a study requires deliberative thought, which means that self-reported data collected on automatic processes reflect individuals' perceptions and experiences. Whether or not participants are aware of, or have access to, processes that are automatic and are purported to affect behavior beyond their awareness is an open question [93]. Empirical investigations find comparable validity between using self-reported versus physiological measures of automatic processes (most prominently, implicit association tests), with physiological measures showing less variability of effect size [94]. Future studies should weigh the value of the added participant burden of using physiological measures and choose

measures of automatic processes accordingly in their study. In chapter 7, the lack of success of the action condition to significantly influence automatic processes, i.e., audio clips of mindfulness-based stress reduction, and interactive, fully automated positive psychology exercises [95-98] were not able to change stress and affect, may explain the overall lack of intervention effect we find. That is, assuming that these automatic processes were captured by the measures we used, and that automatic processes are indeed influential in the intention-behavior gap regarding physical activity.

Was the integrated behavior change model a suitable theory base?

The intervention presented in this thesis was the first completed intervention to be based on the integrated behavior change model, and also the first mHealth intervention to target CVD risk reduction in women with a prior hypertensive pregnancy disorder. Due to this novelty and accompanying lack of studies to compare our results to, it remains possible that the integrated behavior change model was not suitable as a theoretical framework for our intervention. However, given that our intervention failed to influence automatic processes, which the model predicts are important in physical activity behavior change, we do not have evidence on the adequacy of the model. Using a qualitative methodology in chapter 5 allowed us to explore the multiple decisionmaking processes that impact physical activity in women with prior severe preeclampsia, which has contributed to a more comprehensive understanding of the complexity of influences on this behavior in this group. Albeit providing us with converging evidence on the suitability of the integrated behavior change model as the theory-base of our subsequent intervention, quantitative testing of our model could have given additional insights and could have pointed to potential weaknesses prior to application in the intervention. While we did not find an effect of our intervention on physical activity, we do not believe that this refutes the integrated behavior change model, or other multi-process models, as a wise foundation on which to build interventions. A potential way for future studies to enhance the effectiveness of their physical activity intervention based on the integrated behavior change model would be to address theoretical variables beyond those currently described in the model, such as the ones we have identified in chapter 5. They could consider extending the model with the motivational processes of future reward or regret, which have been previously identified as a potential determinant of physical activity [47-49, 99]. Furthermore, they could target the environmental factors of time constraint, social support, and physical environment [50-52, 99], thereby also addressing broader concerns about targeting only individual level determinants of health behavior in interventions. Indeed, it is widely recognized in the field of public health that individual behavior shapes and is shaped by the (social) environment reciprocally, on multiple levels, from micro environments such as the family, to macro level, such as society [100]. We acknowledge that, as most public health

challenges, the reduction of CVD risk is too complex to be adequately understood and addressed from single, individual level analyses [101]. Therefore, future studies aiming to further our findings would benefit from viewing individuals in the context of their larger social units and contribute to the creation of environmental conditions that support sustainable behavior change. Given our findings in chapter 7, self-monitoring may also be a suitable extension of the integrated behavior change model.

What were the causes and consequences of attrition and engagement in our intervention?

For the interpretation of the results presented in chapter 7 it was necessary to consider the possibility of selective engagement and attrition by treatment conditions of the RCT. Attrition was higher in the action condition relative to the other two conditions, and app engagement by the non-attriters in the action condition was lower. This suggests that the intervention activities in this condition may have been burdensome, leading to disengagement and attrition. The workload was highest in the action condition, with four activities to complete per week. Pilot testing of the app suggested that completing all four activities would take a maximum of 60 minutes per week. Each activity could be completed independently of each other, i.e., one could spend four times (maximum) 15 minutes per week on completing content. Program acceptability measures assessing helpfulness in increasing physical activity and general pleasantness do not clearly explain increased attrition and non-compliance in the action condition: the module presented in this condition that targeted volitional processes, Get Activated, was the highest rated (4 out of 5), while the module aiming to change automatic processes, Get Energized, was the lowest rated (3.6 out of 5) of all app modules. However, when we estimate treatment effects with per-protocol samples (compliers), we see no substantive change in results, suggesting that lack of engagement was not the main driver of our lack of effects. Attrition was also not selective on basis of observables, i.e., self-reported baseline physical activity, age, trait self-control, habit, household composition, education, and type of high blood pressure condition. Further analyses will be able to reveal if among non-attriters those higher on app engagement were lower on physical activity. If so, it could be possible that working through the app content was a competing task, i.e., taking away time and other resources from, physical activity. In this case, the long-term follow up of the study that will take place at 3 and 12 months post-intervention, while no intervention content is delivered, could show a stronger effect of the physical activity encouraging skills that the participants have acquired during the content-delivering period of the intervention. Observing the higher than anticipated attrition in our study [76, 102, 103], the question arose whether our study was simply underpowered - however, the point estimates for treatment effects on physical activity suggest that even for a larger sample we would not have found

significant treatment effects. Finally, in terms of scalability, given the automated and remotely-delivered nature of the intervention with low variable costs, the app presented in the current thesis is well-suited to being scaled up. However, whether applying the full intervention in another population would achieve effects, benchmarked against our usual care condition, is not clear.

RECOMMENDATIONS FOR FUTURE RESEARCH

Base interventions on theory- and evidence

Behavioral interventions should be based on a promising theory (i.e., solidly based on previous knowledge and preferably previously found successful to explain behavior in at least observational studies). Then, whether found successful or unsuccessful in influencing behavior, changes in the (carefully modelled interrelations between) theoretical constructs pre and post can point towards explanations of the mechanisms behind intervention elements. The critical evaluation of theories and measures remains vital - revisions should be made to them as needed as part of a continuous research cycle of improvement. Ideally, when proposing (updated) theories, researchers should describe how to measure theoretical constructs therein to aid the future applicability of theory in practice. To have the intervention content resonate with its intended audience, the needs and preferences of the study population and the perceived relevance of the planned intervention foundation should be assessed prior to the finalization of the intervention protocol. Once a theory is selected to form the basis of an intervention, evidence-based behavior change techniques should be matched to its central theoretical variables in a systematic manner. The selection of techniques should be guided by taxonomies of behavior change techniques, evidence syntheses examining the association between these techniques and theoretical variables, and research showing the efficacy of these techniques in changing health behavior.

Apply behavior change techniques at the clinic

Results from the current thesis provide entry points for improving lifestyle counseling at the clinic for women with prior severe preeclampsia, and for other types of lifestyle interventions that health care practitioners may use to promote cardiovascular health. Our findings suggest an appreciation of patients of existing support and a wish for additional support from healthcare professionals in leading a healthy lifestyle. The provision of information, as well as more interventional counselling techniques, were requested by patients in our studies. For example, the scheduling described by our participants can be likened to temptation bundling, i.e., linking an action one wants to do with an action one needs to do, e.g. watching a movie only after doing some muscle

strengthening exercises [104], and commitment, i.e., pre-committing oneself to healthy behavior by ways of financial or social investment, e.g., purchasing a gym membership or making arrangements to go jogging with a friend [105]. Planning techniques were also found useful by the patients in our study [106]. Given these techniques' apparent relevance and relative simplicity, health care providers could aid their patients in the self-management of their disease by informing them of these and similar behavior change techniques. To not add to the burden of clinicians, techniques could be delivered via dedicated mHealth channels. Delivering lifestyle counseling online could not only aid patients in leading healthy lifestyles, but could also leave more time for sensitive topics during face-to-face counselling.

GENERAL CONCLUSION

The general aim of this thesis was threefold. Firstly, it aimed to design an innovative theory- and evidence-based mHealth intervention to reduce CVD risk. Second, it set out to implement it in a manner that resonates with its intended audience. Third, it aimed to evaluate the short-term effects of the resulting intervention. Taken together, the studies presented in the current thesis provide insight into both the theory and practice of delivering cardiovascular mHealth promotion.

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Developing mHealth interventionsA practical guide

Below we provide practical tips on how to design, implement, and evaluate mHealth interventions, based on both the strengths and weaknesses of the current thesis.

DON'T UNDERESTIMATE THE TASK

- Think of matters of data processing and transfer as early as possible: additional laws apply to data resulting from mHealth interventions (and health (behavior) trackers).
- Expect that you will need the help of developers and designers, and a year or more to develop an mHealth intervention.
- Expect several feedback rounds with Google Play and the Apple Store before your app becomes available for download: they perform their own quality checks.





KNOW YOUR AUDIENCE

- Consider the competition: participants may already be using other online solutions, and may have little patience for technological issues such as longer loading times and an inconvenient layout.
- Consider those that are relatively new to technological solutions: have a 'wizard' take new users through the most important elements of the intervention, and keep all features intuitive.
- When defining your population, consider that apps are released per country.

DESIGN AN ATTRACTIVE APP

- Design a user interface that shows a diverse range of people of different ethnic backgrounds and ages representative of the population, and use relatable voice-overs in any videos and audio clips.
- Utilize persuasive technology elements, for example provide participants with the option to self-set goals, to choose when to receive reminders, to commit to goals, and to self-monitor their own (health-related or other) progress.
- Use gamification, by for example linking the completion of intervention elements to a virtual point system resulting in psychological and tangible rewards
- The timeframe for when intervention elements can be completed should be as flexible as possible to reduce participant burden.

CHOOSE YOUR CONTENT WELL

- Consider ensuring that the content of the app is available in a widely-spoken language, such as English, to aid the scaling up of the intervention in the future.
- Intervention content should be interactive and fully automated to increase participant interaction and reduce researcher burden.
- Keep intervention content as short as possible: less fits on a smart phone screen than you would think.
- If using a control condition, design it to be as similar to participants' natural (phone) activities as possible, to encourage the engagement and retention of participants, and to allow for the measurement of the variables assessed in the study.



USE OUTCOME MEASURES WISELY

- Consider the trade-off between precision, costs and burden when choosing a measurement device: using health (behavior) trackers is more accurate, costly, and burdensome (data processing) for researchers than self-report questionnaires, but are arguably less burdensome to use for participants.
- If providing participants with a health (behavior) tracker, give a longer onboarding period to participants who have not owned a tracker before to let novelty effects wear off prior to the baseline measurement of the intervention.





LEARN AS MUCH AS POSSIBLE

- Administer program fidelity measures during the study: automatically capture compliance with elements of the intervention.
- Administer program acceptability measures directly after the study, such as self-report questions of mHealth component usability, appropriateness, engagement and appeal, and other satisfactions and dissatisfactions.



APPENDICES

Summary

Samenvatting

Acknowledgements

About the author

PhD portfolio

Curriculum vitae

SUMMARY

The current thesis set out to design, implement, and evalute a theory- and evidencebased mHealth intervention to decrease risk for a leading cause of mortality and disability worldwide: cardiovascular diseases (CVDs). Specifically, this thesis aimed to conduct an innovative intervention to reduce risk of CVDs through behavioral risk factors, such as insufficient physical activity, accompanying cardio metabolic risk factors, for example overweight, and psychosocial risk factors, such as stress, Growing evidence suggests that interventions based on high-quality behavioral theory (i.e. that incorporates up-to-date insights from the vast knowledge on behavior change that is already available and has been found successful in predicting behavior at least observationally in previous studies) may lead to larger effects in health contexts than non-theory-based interventions. Interventions that are based on such a health behavior theory and then systematically link theoretical constructs to evidence-based behavior change techniques are hypothesized to be most effective of all. Therefore, this thesis set out to design a theory- and evidence based intervention to reduce CVD risk. Individual-level health promotion interventions that are based on theory are typically based on a prominent social cognition theory which describes behavior as the result of deliberative psychological processes. While interventions based on such theories have generally been shown to be effective in changing behavioral intentions, they often stop short of changing actual behavior. The insights from dual process theories might help to reduce this 'intention-behavior gap', as they account for both automatic processes and deliberative processes.

In preparation of the selection of a dual process theory to underlie our intervention, we have decided to compare the construct of self-control both theoretically as well as empirically in psychology and economics, presented in **chapters 2 and 3**. Chapter 2 presented a narrative review of the theory and measurement of self-control in psychology and economics to develop a common conceptual framework. Based on the reviewed literature, we were able to show that self-control can be conceptualized along three main characteristics: stability (trait versus state), process (impulsivity versus inhibition), and enactment (avoidance versus resistance). This framework highlights the multidimensional nature of self-control and will aid intervention researchers to select theories and measurements of self-control that are most appropriate for their health outcome of interest. In chapter 3, a cross-sectional study on the relationship between several measures of trait self-control, and their relationship with modifiable risk factors for CVDs was performed. We used several measures of trait self-control that are generally considered to capture inhibitory processes and several measures that capture impulsive processes. In general, we found both higher inhibition and

impulsivity to relate to more healthy behavior, less unhealthy behavior, and some healthier cardio metabolic outcomes, with inhibition showing these patterns for more outcomes than impulsivity. However, not all findings, especially those concerning cardio metabolic outcomes, showed consistent patterns, and the variance accounted for by trait self-control measures was small for all outcomes examined. Our results indicate that both inhibition and impulsivity influence health independently and simultaneously.

Chapters 4 and 5 adopted a qualitative approach to assess the needs and preferences and the perceived determinants of physical activity of the intended population of our subsequent intervention. In chapter 4 women who have experienced a hypertensive pregnancy disorder were asked about their needs: the extent to which they struggle to participate in cardiovascular health promoting behaviors, the extent to which they plan to make positive changes to these behaviors, and the extent to which they are interested in participating in an app-delivered program targeting these behaviors. Second, these women's preferences regarding the delivery of app-based cardiovascular health promotion, i.e., their wishes regarding app content, functionalities, and interface, were examined. Women's primary need for health behavior promotion pertained to their fat and sugar intake and physical activity. Their next priority was to gain better means to manage their mental health. That the primary needs of women are closely linked to CVD risk emphasize the need for interventions that target these behaviors in this priority population. As a healthy lifestyle, such as engaging in physical activity, has been linked to improved mental health, future interventions could target multiple needs simultaneously. Most women preferred the app-based intervention to include, in descending order; the tracking of health-related metrics, an interactive platform, the use of behavior change strategies, the provision of information, and personalization. In chapter 5, the perceived determinants of these women's physical activity were qualitatively assessed, and the themes that emerged were used to examine the relevance of a dual process theoretical framework. Participants perceived a wide range of facilitating and hindering factors to impact their physical activity. Thirteen themes emerged from the qualitative analysis, which were matched to four overarching themes: motivational processes (future health, perceived ability, attitude, future reward or regret, physical appearance, doing it for others), volitional processes (scheduling, planning), automatic processes (affect, stress), and environmental factors (time constraint, social support, physical environment). These themes had reasonable correspondence with the overarching motivational, volitional, and automatic processes described in the integrated behavior change (IBC) model. In addition, our results indicate that this model could be extended with the motivational process of future reward, or regret and environmental factors.

The study design of the resulting intervention is presented in **chapter 6**, while its shortterm effects and process evaluation are presented in **chapter 7**. The efficacy of the eight-week intervention was tested using a three-condition randomized controlled trial (RCT) delivered through a purpose-built app, the i2be app, in women with a prior hypertensive pregnancy disorder. The intervention was based on the IBC model, which outlines the motivational, volitional, and automatic processes that lead to physical activity. Following stratification on baseline factors, participants were randomly allocated to one of three conditions - the information condition, which was meant to mimic usual care, the motivation condition, which targeted motivational processes. and the action condition, which targeted all three of the processes described by the IBC model. The primary outcome was weekly minutes of moderate-to-vigorous physical activity, as measured by an activity tracker (Fitbit Inspire 2). Secondary outcomes included the weekly average of Fitbit-measured daily resting heart rate, and selfreported BMI, waist-hip ratio, cardiorespiratory fitness, and subjective well-being. Tertiary outcomes included self-reported variables representing motivational, volitional, and automatic processes. Outcome measures were assessed at baseline, immediately post-intervention, and will be assessed at 3 and 12 months post-intervention. A process evaluation was performed based on program fidelity and acceptability measures immediately after the intervention. Efficacy was determined by available case analysis, and the mechanisms by which the behavior change techniques were hypothesized to lead to physical activity were tested. The action condition was unsuccessful in increasing physical activity relative to the information condition (usual care) or the motivation condition. We found some tentative evidence that the action condition worked better for those with low physical activity at baseline - arguably the group that has most to gain from such interventions.

There are several possible reasons for the lack of effect we find for the full sample. Physical activity levels in all conditions, including information (i.e., the control condition), were unusually high: they were highest at baseline (approximately 4 hours per week), with over two thirds of participants exceeding 2.5 hours per week. Fitbit-measured physical activity at baseline was higher than self-reported physical activity over the last month. These findings suggests that, at least at baseline and perhaps throughout the intervention, the physical activity levels of participants might have been higher than prior to enrolling in the study. We identified health promoting changes in outcomes across all conditions, most notably BMI, consistent with this hypothesis. A possible cause of such potential change in physical activity could have been the features of the information condition, which were also available to the other two conditions, therefore possibly not having been an appropriate usual care benchmark. In particular, we might have underestimated the effect of the Fitbit device and app and the basic version of

the i2be app on physical activity, which might have crowded out effects that may have otherwise arisen from the behavior change techniques included in the motivation and action conditions. Further, the lack of success of the action condition to significantly influence automatic processes may also have played an important role in the overall lack of effect, since the IBC model hypothesizes these processes to be influential in the intention-behavior gap regarding physical activity.

SAMENVATTING

Dit proefschrift beschrift het ontwerp, de implementatie en de evaluatie van een op theorie en bewijs gebaseerde mHealth-interventie gericht op het verminderen van risico op een wereldwiid belangriike oorzaak van sterfte en morbiditeit: hart- en vaatziekten (HVZ). In het bijzonder had dit proefschrift tot doel een innovatieve interventie uit te voeren om het risico op HVZ te verminderen door beïnvloeding van gedragsrisicofactoren, zoals onvoldoende lichamelijke activiteit, gerelateerde cardio-metabole risicofactoren, bijvoorbeeld overgewicht, en psychosociale risicofactoren, zoals stress. Er zijn steeds meer aanwijzingen dat interventies die zijn gebaseerd op hoogwaardige gedragstheorieën (d.w.z. theorieën die up-to-date inzichten bevatten uit de uitgebreide bestaande kennis over gedragsverandering en die in eerdere studies succesvol zijn gebleken in het voorspellen van gedrag) kunnen leiden tot grotere effecten in gezondheidscontexten dan interventies die niet op theorie zijn gebaseerd. Interventies die gebaseerd zijn op een dergelijke gezondheidsgedragstheorie en vervolgens systematisch theoretische constructies koppelen aan evidence-based technieken voor gedragsverandering, worden geacht het meest effectief te zijn. Daarom werd in dit proefschrift getracht een op theorie en bewijs gebaseerde interventie te ontwerpen om het risico op HVZ te verminderen. Interventies voor gezondheidsbevordering op individueel niveau die op theorie zijn gebaseerd, zijn meestal gegrond op een prominente sociale cognitie theorie die gedrag beschrijft als het resultaat van wilskrachtige psychologische processen. Hoewel interventies op basis van dergelijke theorieën over het algemeen effectief zijn gebleken in het veranderen van gedragsintenties, blijven deze vaak achter bij het veranderen van feitelijk gedrag. De inzichten uit twee systemen (dual process) theorieën kunnen helpen om deze zogenaamde 'intentie-gedragskloof' te verkleinen, aangezien ze zowel wilskrachtige processen als automatische processen verklaren.

Ter voorbereiding op de selectie van een geschikte dual process theorie hebben we besloten om het construct van zelfbeheersing zowel theoretisch als empirisch te vergelijken in de psychologie en de economie, zoals gepresenteerd in de hoofdstukken 2 en 3. **Hoofdstuk 2** presenteerde een beschrijvende review van de theorie en meting van zelfbeheersing in psychologie en economie om een gemeenschappelijk conceptueel kader te ontwikkelen. Op basis van de beoordeelde literatuur konden we aantonen dat zelfbeheersing kan worden geconceptualiseerd aan de hand van drie hoofdkenmerken: stabiliteit (eigenschap versus toestand), proces (impulsiviteit versus remming) en uitvoering (vermijding versus weerstand). Dit framework benadrukt de multidimensionale aard van zelfbeheersing en zal interventieonderzoekers helpen bij het selecteren van theorieën en meetinstrumenten van zelfbeheersing die het meest geschikt zijn voor hun gezondheidsuitkomst van belang. In **hoofdstuk 3** werd een

cross-sectioneel onderzoek uitgevoerd naar de relatie tussen verschillende maten van zelfbeheersing als eigenschap en hun relatie met te modificeren risicofactoren voor HVZ. We gebruikten verschillende maatstaven voor zelfbeheersing waarvan algemeen wordt aangenomen dat ze remmende processen vastleggen, en verschillende maatstaven die impulsieve processen vastleggen. Over het algemeen vonden we dat zowel hogere remming als impulsiviteit verband houden met meer gezond gedrag, minder ongezond gedrag, en enkele gezondere cardio-metabole uitkomsten, waarbij remming deze patronen laat zien voor meer uitkomsten dan impulsiviteit. Niet alle bevindingen, vooral die met betrekking tot cardio-metabole uitkomsten, vertoonden echter consistente patronen, en de variantie die wordt verklaard door zelfbeheersing maatinstrumenten was klein voor alle onderzochte uitkomsten. Onze resultaten geven aan dat zowel remming als impulsiviteit de gezondheid onafhankelijk van elkaar, gelijktijdig beïnvloeden.

In de hoofdstukken 4 en 5 werd gekozen voor een kwalitatieve benadering om de behoeften en voorkeuren en de ervaren determinanten van lichamelijke activiteit van de beoogde populatie van onze daaropvolgende interventie te beoordelen. In hoofdstuk 4 werden vrouwen die zwangerschapshypertensie hebben doorgemaakt, gevraagd naar hun behoeften: de mate waarin ze moeite hebben om zich bezig te houden met cardiovasculair gezondheidsbevorderend gedrag, de mate waarin ze van plan zijn dit gedrag positief te veranderen, en de mate waarin ze geïnteresseerd zijn in deelname aan een app-gestuurd programma gericht op dit gedrag. Ten tweede werden de voorkeuren van deze vrouwen onderzocht met betrekking tot het ontwikkelen van app-gebaseerde cardiovasculaire gezondheidsbevordering, dat wil zeggen hun wensen met betrekking tot app-inhoud, functionaliteit en interface. De primaire behoefte van vrouwen aan bevordering van gezondheidsgedrag betrof hun vet- en suikerinname en lichamelijke activiteit. Hun volgende prioriteit was het verkrijgen van betere middelen om hun mentale gezondheid te kunnen onderhouden. Dat de primaire behoeften van vrouwen nauw verband houden met het risico op HVZ, benadrukt de behoefte aan interventies die gericht zijn op dit gedrag in deze populatie. Aangezien een gezonde levensstiil, zoals lichameliike activiteit, samenhangt met een betere geesteliike gezondheid, zouden toekomstige interventies zich op meerdere behoeften tegelijk kunnen richten. De meeste vrouwen gaven er de voorkeur aan dat de app-gebaseerde interventie, in aflopende volgorde, omvat: het volgen van gezondheidsgerelateerde statistieken, een interactief platform, het gebruik van strategieën voor gedragsverandering, het verstrekken van informatie, en personalisatie. In hoofdstuk 5 werden de ervaren determinanten van de lichamelijke activiteit van deze vrouwen kwalitatief onderzocht, en de thema's die naar voren kwamen werden gebruikt om de relevantie van een dual process theorie te onderzoeken. Deelnemers rapporteerden een breed

scala aan faciliterende en belemmerende factoren van lichamelijke activiteit. Dertien thema's kwamen uit de kwalitatieve analyse naar voren, die vervolgens werden gekoppeld aan vier overkoepelende thema's: motiverende processen (toekomstige gezondheid, waargenomen bekwaamheid, houding, toekomstige beloning of spijt, lichamelijke verschijning, het doen voor anderen), wilskrachtige processen (inroosteren, plannen), automatische processen (stemming, stress) en omgevingsfactoren (tijdsdruk, sociale steun, fysieke omgeving). Deze thema's kwamen redelijk overeen met de overkoepelende motiverende, wilskrachtige en automatische processen beschreven in het model voor geïntegreerde gedragsverandering (IBC model). Bovendien geven onze resultaten aan dat dit model kan worden uitgebreid met het motiverende proces van toekomstige beloning of spijt, en omgevingsfactoren.

De onderzoeksopzet van de resulterende interventie werd gepresenteerd in **hoofdstuk** 6, terwijl de korte termijn effecten en procesevaluatie werden gepresenteerd in hoofdstuk 7. De effectiviteit van de acht weken durende interventie werd getest met behulp van een gerandomiseerde gecontroleerde studie (RCT) met drie condities via een speciaal gebouwde app, de i2be-app, bij vrouwen met eerdere zwangerschapshypertensie. De interventie was gebaseerd op het IBC model, dat de motiverende, wilskrachtige en automatische processen beschrijft die leiden tot lichamelijke activiteit. Na stratificatie op baselinefactoren werden deelnemers willekeurig toegewezen aan een van de drie condities: de informatieconditie, die bedoeld was om de gebruikelijke zorg na te bootsen, de motivatieconditie, die gericht was op motiverende processen, en de actieconditie, die gericht was op alle drie door de IBC model beschreven processen. De primaire uitkomst was wekelijkse minuten matige tot zware lichamelijke activiteit, gemeten door een activity tracker (Fitbit Inspire 2). Secundaire uitkomsten omvatten het wekelijkse gemiddelde van door Fitbit gemeten dagelijkse hartslag in rust, en zelfgerapporteerde BMI, taille-heupverhouding, cardiorespiratoire conditie en subjectief welzijn. Tertiaire uitkomsten omvatten zelfgerapporteerde variabelen die motiverende, wilskrachtige en automatische processen vertegenwoordigen. Uitkomstmaten werden beoordeeld bij aanvang, onmiddellijk na de interventie, en zullen in de toekomst worden beoordeeld op 3 en 12 maanden na de interventie. Direct na de interventie werd een procesevaluatie uitgevoerd op basis van programmagetrouwheid en aanvaardbaarheid. De effectiviteit werd bepaald door available case analysis, en de mechanismen waarmee de gedragsveranderingstechnieken verondersteld werden te werken tot lichamelijke activiteit werden getest. De actieconditie slaagde er niet in lichamelijke activiteit te verhogen ten opzichte van de informatieconditie (gebruikelijke zorg) of de motivatieconditie. Wel vonden we enig voorlopig bewijs dat de actieconditie beter werkte voor mensen met een lage lichamelijke activiteit bij baseline - misschien wel de groep die het meeste baat heeft bij dergelijke interventies.

Er zijn verschillende mogelijke redenen voor het gebrek aan effect dat we vonden voor de volledige studiepopulatie. Lichameliike activiteitsniveaus in alle condities, inclusief de informatieconditie (dat wil zeggen de controleconditie), waren ongewoon hoog: ze waren het hoogst bij aanvang (ongeveer 4 uur per week lichamelijk actief), meer dan tweederde van de deelnemers was meer dan 2.5 uur lichamelijk actief per week. De door Fitbit gemeten lichamelijke activiteit bij aanvang was hoger dan de zelfgerapporteerde lichamelijke activiteit in de afgelopen maand. Deze bevindingen suggereren dat, in jeder geval bij aanvang en misschien tijdens de hele interventje, de niveaus van lichamelijke activiteit van de deelnemers mogelijk hoger waren dan voordat ze deelnamen aan het onderzoek. We constateerden gezondheidsbevorderende veranderingen in uitkomsten voor alle condities, met name BMI, in overeenstemming met deze hypothese. Een mogelijke oorzaak van een dergelijke potentiële verandering in lichamelijke activiteit kunnen de kenmerken van de informatieconditie zijn geweest, die ook beschikbaar waren voor de andere twee condities, en daarom mogelijk geen geschikte benchmark waren voor gebruikelijke zorg. Mogelijk hebben wij ook met name het effect van het Fitbit-apparaat en de app en de basisversie van de i2be-app op lichamelijke activiteit onderschat, waardoor effecten die anders zouden zijn voortgekomen uit de gedragsveranderingstechnieken in de motivatie- en actiecondities, kunnen zijn verdrongen. Verder kan het gebrek aan succes van de actieconditie om automatische processen aanzienlijk te beïnvloeden ook een belangrijke rol hebben gespeeld in het algehele gebrek aan effect, aangezien het IBC model veronderstelt dat automatische processen van invloed zijn op de intentie-gedragskloof met betrekking tot lichamelijke activiteit.

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ABOUT THE AUTHOR

Lili L. Kókai was born on the 24th of December, 1993, in Budapest, Hungary. She finished her BSc degree in psychology and sociology at the University of Sussex, Brighton, the UK, after which she finished her MSc degree in health and medical psychology at Leiden University, Leiden, and her MSc degree in public health epidemiology at the Netherlands Institute for Health Sciences, Rotterdam. After finishing her PhD at the Department of Public Health of the Erasmus Medical Center, Rotterdam, in the Smarter Choices for Better Health Erasmus Initiative, she will stay on in the second term of the same Initiative as a postdoctoral researcher.



PHD PORTFOLIO

PhD candidate: Lili L. Kókai

University: Erasmus University Rotterdam

Faculty: Erasmus Medical Center

Department: Public Health PhD period: 2018-2022

Promotors: Prof. dr. ir. A. Burdorf & Prof. dr. J. L. W. van Kippersluis

| | Year | ECTS |
|---|-----------|------|
| Post-initial master training MSc in Health Sciences - Public Health Epidemiology, NIHES, Erasmus MC | 2018-2020 | 70 |
| Seminars, workshops and masterclasses | | |
| Scientific Integrity Workshop, Erasmus MC | 2022 | 0.3 |
| Department of Public Health Research Seminars, | 2018-2022 | 3 |
| Erasmus MC | | |
| Social Epidemiology Section Meetings, Erasmus MC | 2018-2022 | 1 |
| STeLA Workshop: Science and Technology Leadership, | 2019 | 0.5 |
| Erasmus MC | | |
| BROK® Certificate, Erasmus MC | 2018 | 1.5 |
| BROK® Certificate renewal, Erasmus MC | 2022 | 1.5 |
| Biomedical Writing Course, Erasmus MC | 2021 | 1.5 |
| Community Project Workshops, Erasmus MC | 2019 | 0.5 |
| Limesurvey Workshop, Erasmus MC | 2018 | 0.5 |
| Endnote Workshop, Erasmus MC | 2018 | 0.5 |
| Systematic Search in Pubmed Workshop, Erasmus MC | 2018 | 0.5 |
| Patient Oriented Research Workshop, Erasmus MC | 2018 | 0.3 |
| Chronic Disease Self-Management (CDSMP) Leader Training, | 2018 | 4 |
| Erasmus MC | | |
| Convince your audience Workshop, EUR | 2019 | 0.5 |
| Personal Leadership Workshop, EUR | 2019 | 0.5 |
| Data Workshop, Lifelines | 2018 | 0.5 |
| Design and Branding Workshop, Avegen | 2020 | 0.5 |
| Technical Workshop, Avegen | 2020 | 0.5 |

| Teaching activities | | |
|---|-----------|---|
| MSc Thesis Supervisor of Marte van der Bijl, MSc Medicine, EUR | 2020 | 3 |
| Guest Lecturer, Introduction to Medical Psychology, | 2022 | 1 |
| MSc Health Sciences, EUR | | |
| Guest Lecturer, Honors Class, BSc Economics and Econometrics, EUR | 2021 | 1 |
| Tutor, Healthy City, BSc Health Policy and Management & Public Health, EUR | 2020 | 2 |
| Tutor, Community Project, BSc Medicine, EUR | 2020 | 2 |
| Facilitator, Intervision, MSc Health Sciences, EUR | 2022 | 2 |
| (Poster) presentations | | |
| International Conference on Ambulatory Monitoring of | 2022 | |
| Physical Activity and Movement, International Society for | | |
| the Measurement of Physical Behavior, Colorado, USA | | |
| Smarter Choices for Better Health Conference, EUR, Rotterdam | 2019 | |
| Physical and Mental Health Science Fair, Hungarian Embassy, | 2018 | |
| Den Haag | | |
| Committees | | |
| Societal Impact Committee, Smarter Choices for Better Health, EUR | 2022 | |
| Junior Researchers' Committee, Smarter Choices for Better Health, EUR | 2018-2021 | |
| Social Committee, Department of Public Health, Erasmus MC | 2018-2019 | |
| Societal impact | | |
| Interview EUR News Bulletin: Food impacts us in so many ways | 2019 | |
| Article in Tijdschrift Positieve Psychologie: | 2021 | |
| Vervul je potentiële (gezonde) zelf | | |
| Article in Vereniging voor Gezondheidseconomie Bulletin: | 2022 | |
| Multidisciplinair onderzoek naar preventie | | |
| Article in Inzicht Magazine: Gezonde leefstijl na PE/HELLP | 2021 | |
| Blog Smarter Choices for Better Health: Fulfilling one's potential (healthy) self | 2021 | |
| Blog Smarter Choices for Better Health: Societal impact | 2022 | |
| Establishing and maintaining Smarter Choices for Better Health | 2018-2022 | |
| media presence | | |

CURRICULUM VITAE

Research experience

Erasmus Medical Center, Rotterdam - Researcher

April 2021 - Present

Postdoctoral researcher in the Smarter Choices for Better Health Erasmus Initiative. Examining the extent to which the effectiveness of behavioral health interventions can be improved by tailoring to:

- individual-level needs and preferences, including psychological traits and states
- environmental-level contexts, such as economic, social, cultural, and institutional factors

Co-promotor of PhD candidate Dorien Beeres.

January 2018 - September 2022

PhD candidate in the Smarter Choices for Better Health Erasmus Initiative. Designing, implementing and analyzing:

- quantitative survey on the determinants of health behavior in the Lifelines cohort
- qualitative assessments in patient population of a future mHealth intervention
- randomized mHealth intervention aiming to increase physical activity and decrease cardiovascular risk.

Presenting at conferences, maintaining international collaborations.

Netherlands Institute for Health Sciences, Rotterdam - Researcher

September 2018 - July 2020

MSc thesis: Self-control and modifiable risk factors for cardiovascular disease in the Lifelines cohort.

Leiden University, Leiden-Researcher trainee

September 2016 - July 2017

MSc thesis: Health-related possible selves and behaviors in university students.

University of Sussex, Brighton, UK – Researcher trainee

September 2012 - July 2016

Research assistant on PhD project: Applying technology and performing arts to improve children's self-concept; aiding set-up, conduct and analysis, e.g. participant observation, transcribing interviews.

BSc psychology thesis: Saving lives while restricting freedoms: an international study of reactance towards organ donation policies.

BSc sociology thesis: Concealed liberation: how the burkini as a site of debate influences the positioning of muslim women in the west.

University of Amsterdam, Amsterdam - Researcher trainee

September 2015 - July 2016

Research assistant on PhD project: Cross-cultural differences in affective communication styles; aiding analysis, e.g. conducting thematic analysis.

Research assistant on MSc project: Information dissemination in groups; aiding set-up and conduct, e.g. recruiting and scheduling participants, coordinating group experiment in lab.

Central European University, Budapest, Hungary — Researcher trainee

July 2013 - July 2015

Research assistant on several PhD projects: Three summers at the department of cognitive science's VisionLab; aiding study set-up and conduct, e.g. scheduling participants, coordinating experiments in lab.

Teaching experience

BSc Medicine, EUR, Rotterdam - Facilitator motivational interviewing

February 2023

Facilitating motivational interviewing training.

MSc Health Sciences EUR, Rotterdam - Facilitator intervision

February - June 2022

Facilitating reflection on research-related challenges.

MSc Health Sciences EUR, Rotterdam—Lecturer medical psychology

February 2022 - February 2023

Presenting about health behavior intervention development, implementation and evaluation.

BSc Economics and Econometrics EUR, Rotterdam— Lecturer honors class

November 2021

Presenting about health behavior intervention development, implementation and evaluation.

MSc Medicine EUR, Rotterdam - Thesis supervisor

September 2020 - January 2021

Supervising thesis, from survey design to qualitative analysis, on physical activity determinants in women with a prior hypertensive disorder of pregnancy.

BSc Health Policy and Management EUR & Public Health Erasmus Medical Center, Rotterdam — Tutor healthy city

February - March 2020

Tutoring (interactive) lectures, debates, working groups, and assignments about improving health through collective measures.

BSc Medicine EUR, Rotterdam – Tutor community project

January - February 2020

Tutoring (interactive) lectures, debates, working groups, and assignments about optimizing prevention.

Clinical experience

Graduate Mental Health Placement, Bali and Java, Indonesia — Psychologist trainee

September - October 2017

Planning and conducting activity sessions at psychiatric facilities, rehabilitation centers, addiction centers, schools and orphanages.

Leiden University, Leiden – Psychologist trainee

March - May 2017

Planning and conducting counseling sessions using psychodiagnostic tools, e.g. screening, case formulation, agenda setting, therapeutic techniques, and SOAP report.

Middin, Den Haag – Psychologist trainee

February 2017 - January 2018

Conducting activity sessions at psychiatric facility.

Expat Nest, Den Haag – Psychologist trainee

June - August 2017

Preparing internal documents for the management and operation of counseling service, writing mental health-related content for website.

Graduate Mental Health Placement, Panadura, Sri Lanka — Psychologist trainee

May - June 2016

Planning and conducting activity sessions at psychiatric facilities, rehabilitation centers, addiction centers, schools and orphanages.

Education

2018-2020

 $Post-initial\ MSc\ Public\ Health\ Epidemiology,\ Netherlands\ Institute\ for\ Health\ Sciences,$

Rotterdam 2016-2017

MSc Health and Medical Psychology, Leiden University, Leiden

Distinction: Cum laude

2012-2015

BSc Psychology with Sociology, University of Sussex, Brighton, UK

Distinction: First class honors

2014-2015

BSc Study Abroad Year Psychology, University of Amsterdam, Amsterdam

Publications

October 2022

Needs and preferences of women with prior severe preeclampsia regarding app-based cardiovascular health promotion. Published at BMC Women's Health.

April 2022

Perceived determinants of physical activity among women with prior severe preeclampsia: a qualitative assessment. Published at BMC Women's Health.

January 2022

Moving from intention to behaviour: a randomised controlled trial protocol for an app-based physical activity intervention (i2be). Published at BMJ Open.

