Study Protocol

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Effects of an Active Choice Intervention on Physical Activity Intentions and Behaviour among Physically Inactive Adults: A Four-Arm Web-Based Experiment

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Title

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Names protocol contributors

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Abstract

- **Background**: This web-based experimental study aims to ascertain whether promoting an active (i.e. conscious, autonomous and explicit) choice process about physical activity results in better behavioural outcomes (e.g. physical activity) and psychological outcomes (e.g. physical activity intention) compared to promoting a passive choice process in physically inactive adults.

- **Methods**: Participants will be randomized to one of four groups. The active choice groups (GA and GA+) will read the national physical activity guideline, and complete exercises in which they will weigh advantages and disadvantages of physical activity, consider personal values, and identify barriers. The GA+ group will be supplemented with action and coping planning exercises. The passive choice groups (G and GI) will receive the guideline; group GI will additionally receive information about possible advantages and disadvantages and barriers to physical activity. Behavioural and psychological outcomes will be assessed at the first measurement (T1) and follow-up (T2). Intergroup differences will be examined by regression analyses. In addition, we will conduct sensitivity analyses and a process evaluation.

- **Trial registration**: retrospectively registered

Keywords

Inactive Adults, Active choice, Decision making, Web-based intervention, Intention, Physical activity

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	Effects of an Active Choice Intervention on Physical Activity Intentions and Behaviour among Physically Inactive Adults: A Four-Arm Web-Based Experiment
Trial registration {2a and 2b}.	https://clinicaltrials.gov/. Retrospectively registered.
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Author details {5a}	Lorraine L. Landais[a], Olga C. Damman[a], Judith G.M. Jelsma[a], Evert A.L.M. Verhagen[a,b], Danielle R.M. Timmermans[a] [a] Amsterdam UMC, Vrije Universiteit Amsterdam, Department of Public and Occupational Health, Amsterdam Public Health research institute, Amsterdam, The Netherlands [b] Amsterdam Collaboration on Health & Safety in Sports, Department of Public and Occupational Health, Amsterdam Movement Sciences, Amsterdam UMC, Vrije Universiteit Amsterdam, Amsterdam, The Netherlands
Name and contact information for the trial sponsor {5b}	N/A
Role of sponsor {5c}	N/A

Introduction

Background and rationale {6a}

Interventions that promote physical activity among inactive adults (i.e. adults not engaging in at least 150 minutes of moderate-intensity aerobic physical activity per week [1]) generally show small effects, and effects usually diminish over time [2]. Intervention outcomes may be improved if interventions would support individuals in making a more active choice about their physical activity behaviour. Previous studies in the field of choice architecture and behavioural economics have shown that the way a choices are presented influences individuals' decisions [3, 4]. In this field, the term 'active choice' is usually used to refer to explicit compulsory choices without a default option [5-7]. We use a broader conceptualisation; by 'active choice' we mean a conscious, autonomous and explicit choice in which an individual actively weighs the advantages and disadvantages of choice options, considers his/her values, and thinks about specific personal goals, possible barriers to achieve those goals, and possible ways to cope with those barriers. This operationalisation shows similarities with components from different approaches, including Acceptance and Commitment Therapy (ACT) [8], the Disconnected Values Model (DVM) [9], and Mental Contrasting with Implementation Intentions (MCII) [10]. Health-promoting interventions based on these approaches appear to be effective in increasing physical activity [11-13] and physical fitness [14, 15].

Promoting active choices may improve intervention outcomes for multiple reasons. Firstly, it has been demonstrated that providing individuals with a choice – instead of telling them more directly what to do – increases perceived autonomy, which is associated with higher intrinsic motivation and greater behavioural persistence [16, 17]. Secondly, choices that align with people's individual values increase satisfaction about the choice and commitment toward the chosen option, which may induce greater behavioural persistence as well [6, 18, 19]. People regularly prioritize social and work-related values, leaving little time for physical activity [20]. Decision aids and motivational interviewing are examples of tools that may support individuals in clarifying their values and in resolving ambivalence between the value of 'health' and conflicting values, such as social and work-related values [21, 22].

Thirdly, promoting active choices likely empowers people to make more *informed* choices, as an active choice process encourages people to weigh advantages and disadvantages associated with choice options and to make a value-congruent choice [23, 24]. Whether individuals can actually make informed choices depends on multiple factors, including the quality of educational information/ decision support and individuals' own information-processing motivation and skills [25].

A fourth advantage of an active decision-making process is that spelling out personal goals – by planning when, where and how goal-directed behaviour will be performed (i.e. 'action planning') –increases the likelihood of goal-attainment and sustained behaviour change [26]. Such action plans, or 'implementation intentions', are formulated as 'if-then plans' in which a specific situational context (i.e. the 'if' component) is linked with a goal-directed cognition or behaviour (i.e. the 'then' component) [27]. A meta-analytic review showed that action planning is more effective in changing physical activity behaviour if individuals also plan how they will cope with potential barriers (i.e. 'coping planning') [28].

In the current web-based experimental study, we will compare the effect of promoting an active choice process versus a passive choice process about physical activity on behavioural outcomes (e.g. physical activity behaviour, perceived increase in physical activity) and psychological outcomes (e.g. physical activity intention, commitment) among physically inactive adults.

Objectives {7}

To ascertain whether promoting an active (i.e. conscious and autonomous) choice process about physical activity results in better behavioural outcomes (e.g. physical activity) and psychological outcomes (e.g. physical activity intention) compared to promoting a passive choice process in physically inactive adults. Moreover, our aim is to gain a better understanding of the active choice process, including the importance that inactive adults attach to different values and to advantages and disadvantages of physical activity.

Trial design {8}

Pre-test post-test four-arm (1:1:1:1) parallel design

Methods: Participants, interventions and outcomes

Study setting {9}

Web-based study conducted in the Netherlands among members of an online panel of research agency *Flycatcher Internet Research*.

Eligibility criteria {10}

Inclusion criteria: Adults who engage in low levels of physical activity (i.e. are physically active for at least 30 minutes on <5 days a week *and* engage in <150 minutes of physical activity in total throughout an average week)

Exclusion criteria: Pregnant women, wheelchair users and individuals who could not walk a minimum of 100 meters.

Who will take informed consent? {26a}

Participants eligible for inclusion will be informed about the study and data storage. Participants will subsequently be asked to provide (online) informed consent; if they provide consent (by clicking a button), they continue to the study.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

N/A

Interventions

Explanation for the choice of comparators {6b}

The comparison group (group G) will only receive information about the national physical activity guideline, because this was expected to result in a passive choice process about physical activity.

Intervention description {11a}

Group GA+: Participants will receive a web-based intervention consisting of the national physical activity guideline and several assignments to promote a very active choice process. Assignments include: completing a decision balance sheet; indicating the importance of personal values and the time, effort and energy spent on these personal values; action planning; identifying barriers to physical activity; coping planning.

Group GA: Participants will receive a web-based intervention consisting of the national physical activity guideline and several assignments to promote an active choice process. Assignments include: completing a decision balance sheet; indicating the importance of personal values and the time, effort and energy spent on these personal values; identifying barriers to physical activity.

Group GI: Participants will receive web-based information about the national physical activity guideline, pros and cons of physical activity, and possible barriers to physical activity, to promote a somewhat passive choice process.

Each group will receive the intervention at the first measurement (T1), after completing the IPAQ questionnaire.

Criteria for discontinuing or modifying allocated interventions {11b}

N/A

Strategies to improve adherence to interventions {11c}

N/A

Relevant concomitant care permitted or prohibited during the trial {11d}

N/A

Provisions for post-trial care {30}

N/A

Outcomes {12}

Primary outcomes:

Outcome	**Measurement**	**Time of measurement: First measurement (T1) or**

		follow-up (T2)
Intention	Intention to become more physically active (yes/no), assessed by a questionnaire item	T1
Physical activity	Physical activity levels (MET minutes per week), assessed by the short form of the International Physical Activity Questionnaire (IPAQ)	T1 and T2 (change from baseline)

Secondary outcomes:

Outcome	**Measurement**	**Time of measurement: First measurement (T1) or follow-up (T2)**
Sitting time	Sitting time (minutes per day), assessed by the short form of the International Physical Activity Questionnaire (IPAQ)	T1 and T2 (change from baseline)
Perceived increase in physical activity	Participants' perception of an increase in physical between baseline and follow-up (assessed by a questionnaire item)	T2
Intention strength	Participants' intention strength toward becoming more physical active (assessed by a questionnaire item)	T1 and T2
Active choice	Degree to which an active choice is made; a composite score of 9 items on a scale of 1 - 5	T1
Autonomous choice	Degree to which an autonomous choice is made; 2 items on a scale of 1 - 10	T1
Commitment	Commitment to become more physically active; 1 item on a scale of 0 - 10	T1 and T2
Self-efficacy	Self-efficacy to become more physically active; 2 items on a scale of 1 - 10	T1 and T2
Satisfaction	Degree of satisfaction with one's plan to become/ not become more physically active; 1 item on a scale of 1 - 10	T1
Alignment of choice with personal values	Extent to which one's plan to become/ not become more physically active corresponds with what one considers important; 1 item on a scale of 1 - 10	T1
Perceived advantages and disadvantages of physical activity	Open-ended questions about the perceived advantages and disadvantages of one's current physical activity behavior, and of increasing physical activity	T1
Value of health	Importance of the value 'health', and the time, effort and energy spent on health; both on a scale of 1 to 10	T1
Values influencing	The extent to which the following values impact one's	T1

physical activity	physical activity levels on a scale of 1 to 10: responsibility, achievement, pleasure, family, friendships, balance.	
Plans to change physical activity	Open-ended questions about the preferred kind of physical activity, frequency, location, days and start date.	
Perceived barriers to physical activity	Open-ended question asking about perceived barriers to physical activity	T1
Plans to cope with perceived barriers	Open-ended questions about the ways one could cope with each perceived barriers	T1
Factors supporting physical activity	Question about the factors that supported or would support physical activity. Multiple choice question.	T2
Barriers to physical activity	Question about the barriers that hindered physical activity in the past two weeks. Multiple choice question.	T2

Participant timeline {13}

First measurement (T1): Eligible participants will first complete the short form of the IPAQ; subsequently, each group will receive the intervention (either GA+, GA, GI, or G). Post-intervention, participants will be asked to complete a questionnaire that assesses most outcomes (see Outcomes {12}).

Second measurement (T2): Approximately two weeks after the first measurement, participants will be invited to the follow-up measurement: a short questionnaire (see Outcomes {12}).

Sample size {14}

The study is powered to detect a 12% difference in 'Intention to become more physically active' (proportion 'yes' versus 'no') post-intervention (T1) between group G and group GA+ (see Intervention) using an alpha level of .05 and a statistical power of 80%. This means that 182 participants are required per group. Consequently, at follow-up (T2) – assuming a dropout rate of 33% – we would be able to detect a difference of 598 MET minutes per week between group G and group GA+, as well as a 15% difference regarding the percentage of participants that would be 'moderate/high active' versus 'low active'.

Recruitment {15}

The research agency will invite all panel members (n = 9395) by e-mail to participate. If needed, a few reminders will be sent by e-mail to panel members to achieve adequate enrolment.

Assignment of interventions: allocation

Sequence generation {16a}

Participants will randomly be assigned to one of four experimental groups by the research agency,

Concealment mechanism {16b}

Random allocation will be done by the computer.

Implementation {16c}

Research Agency Flycatcher will randomly assign panel member to one of the four groups.

Assignment of interventions: Blinding

Who will be blinded {17a}

Trial participants will be blind to the group they are assigned to; they will not be informed about the other groups.

Procedure for unblinding if needed {17b}

N/A.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Self-reported physical activity and sitting time will be measured using the short form of the International Physical Activity Questionnaire (IPAQ) which has been shown to have reasonable reliability and validity. The questionnaire assesses time spent in vigorous intensity activities (e.g. heavy lifting or fast bicycling), moderate intensity activities (e.g. carrying light loads or doubles tennis) and walking for at least ten minutes over the last seven days, in addition to time spent sitting. Following IPAQ analysis guidelines, metabolic equivalents (METs) were used to calculate MET-minutes per week for each type of physical activity. All cases for which the sum of vigorous and moderate activity and walking is greater than 960 minutes (16 hours) will be excluded from analysis. Moreover, responses of <10 minutes will be recoded ‘zero’. A combined total physical activity MET-minutes per week score will be computed by summing the vigorous, moderate and walking MET-minutes per week scores. A dichotomization will also be made: the ‘Low’ category from the analysis guidelines will be compared with a combination of the categories ‘Moderate’ and ‘High’ (i.e. three or more days of vigorous-intensity activity of at least 20 minutes per day, or five or more days of moderate-intensity activity and/or walking of at least 30 minutes per day, or five or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum total physical activity of at least 600 MET-minutes/week). Although maximum values for sitting time are not specified in IPAQ guidelines, we will exclude cases with ≥1200 minutes (20 hours) of daily sitting time from analysis.
We will assess perceived increase in physical activity by asking participants at T2 whether they have changed their physical activity behaviour in the past two weeks (yes/no) and, if so, what they have changed. Based on their answers, we will categorize participants as ‘more physically active’ or as ‘less physically active/no change’. The remaining outcomes will be assessed by questionnaire items.

Plans to promote participant retention and complete follow-up {18b}

Participants will receive reminders to participate by e-mail. Participants who discontinue T1 and participate in T2 will be asked at the end of the follow-up questionnaire to provide a reason for not finishing T1.

Data management {19}

Anonymized SPSS-files with the collected data will be provided by the research agency. These files will be stored at Amsterdam UMC for 15 years (participants will be informed about this).

Confidentiality {27}

The SPSS files will be anonymized by research agency Flycatcher. Only the research team will be allowed access to participant's data.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/A

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Statistical analyses will be performed in SPSS for Windows version 26. Differences in physical activity (MET-mins per week), sitting time, intention strength, active choice, autonomous choice, commitment, self-efficacy, satisfaction and alignment of choice with personal values between group GA+, group GA, and group GI and group G (comparison group) will be assessed using linear regression analyses; logistic regression analyses will be used to analyse the effects on physical activity (moderate/high vs. low), perceived increase in physical activity and intention. The four groups will be dummy coded and used as independent variables in all analyses. For outcomes measured at both T1 and T2, we will use the T2 outcome as dependent variable and adjust for the T1 outcome (covariate). Participants who do not complete T1 will be excluded from analyses. Outliers (i.e. values exceeding 1.5 interquartile ranges below the 25th percentile or above the 75th percentile) in IPAQ data will be excluded from analysis. A significance level (alpha) of 0.05 was used. Outcome variables heavily skewed to the right will be log transformed for the regression analyses to meet the assumption of normal distribution.

Interim analyses {21b}

N/A

Methods for additional analyses (e.g. subgroup analyses) {20b}

We will conduct multiple sensitivity analyses. In the first set of sensitivity analyses, we will examined possible confounding by age and possible effect modification by gender, educational level and health condition on our primary outcome measures (physical activity and intention), as previous literature suggests an association between these sociodemographic variables and physical activity behaviour [36-39]. We will use a liberal significance level (alpha = 0.10) for interaction terms. In case of confounding or effect modification on the primary outcome measures, we will additionally analyse possible confounding or effect modification on the remaining outcome measures. In case of confounding, we will adjust for the confounder in the analyses. In case of effect modification, we will analyse the results for each subgroup of the effect modificator (again by regression analyses).

In the second set of sensitivity analyses, we will combine group G with group GI and group GA with group GA+, and compared their effects on all outcome measures.

In the third set of sensitivity analyses, we will conduct all main analyses without the participants in group GA+ who do not complete the action and coping planning assignments because they do not want to become more physically active.

Fourthly, we will conduct a sensitivity analysis for physical activity (MET-minutes per week) in which we will exclude all participants who physical or mental health conditions that severely hinder physical activity, including illness, pain, and depression.

Finally, we will conduct exploratory analyses on (a) perceived advantages and disadvantages of physical activity; (b) the value of ‘health’, as well as the experienced discrepancy between the ‘importance of health’ and the ‘time, effort and energy spent on health’; (c) other values influencing physical activity; (d) individual plans to increase physical activity; (e) perceived barriers to physical activity, and plans to cope with those barriers; (f) factors that supported or hindered physical activity between T1 and T2.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Pairwise deletion will be used for missing data.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

We plan to make all data available during publication, e.g. via clinicaltrials.gov.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

Research team CHOiCE of the AmsterdamUMC, Department of Public and Occupational Health, will coordinate and steer the trial. This team consists of five researchers who meet bimonthly.

Composition of the data monitoring committee, its role and reporting structure {21a}

Research agency *Flycatcher Internet Research* (www.flycatcher.eu) will collect and monitor the data. After collecting the data, the research agency will send the data to the CHOiCE research team (Amsterdam UMC). Flycatcher Internet Research is an independent research agency with no competing interests.

Adverse event reporting and harms {22}

N/A

Frequency and plans for auditing trial conduct {23}

N/A

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

N/A; retrospectively registered trial.

Dissemination plans {31a}

Publication in a scientific journal.

Trial status

Protocol version 2 (retrospectively registered), 29-06-2021. Start recruitment: September 4, 2020. End of recruitment: October 9, 2020. Trial status: completed.

Abbreviations

N/A Not applicable*; IPAQ* International Physical Activity Questionnaire

Declarations

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Authors' contributions {31b}

All authors contributed to the conceptualization of the study and to the development of the intervention and questionnaire. LL analysed the data and drafted the manuscript. All authors interpreted the data. JJ checked the quantitative analyses as well as the qualitative coding. JJ, OD, EV and DT critically reviewed and edited drafts of the manuscript. All authors approved the final manuscript.

Funding {4}

No external funding was received for this research.

Availability of data and materials {29}

We will provide public access to the anonymized final dataset, e.g. via clinicaltrials.gov.

Ethics approval and consent to participate {24}

In accordance with local regulatory guidelines and standards for human subjects' protection in the Netherlands (Medical Research Involving Human Subjects Act), our study was exempted from review by the medical research ethics committee of Amsterdam UMC (2020.142). All participants provided informed consent.

Consent for publication {32}

Not applicable.

Competing interests {28}

The authors declare that they have no competing interests.

Authors' information (optional)

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