i2be: a randomized controlled trial protocol for an app-based physical activity intervention

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28866

Source
NTR

Brief title
i2be

Health condition

None

Sponsors and support

Primary sponsor: Smarter Choices for Better Health Erasmus Initiative (Erasmus University Rotterdam)
Source(s) of monetary or material Support: Smarter Choices for Better Health Erasmus Initiative, Erasmus Trustfonds

Intervention

Outcome measures

Primary outcome

The primary outcome is objectively measured weekly minutes of moderate-to-vigorous

physical activity.

Secondary outcome

Secondary outcomes include objectively measured (resting) heart rate and self-reported physiology measurements (body mass index, waist-hip-ratio, cardiorespiratory fitness), as well as subjective well-being.

Study description

Background summary

Physical activity is an important determinant of cardiovascular health. Therefore, health behavior interventions targeting physical activity are highly warranted. Most interventions have limited and short-term effects, likely because they fail to bridge the intention-behavior gap. The current study will test a dual system theory- and evidence-based e-health intervention, and additionally, provide important insight into the contribution of volitional and automatic processes in bridging the intention-behavior gap and achieving sufficient and sustained physical activity.

The effectiveness of the intervention will be tested using a three-arm randomized controlled trial implemented through an app. The intervention is based on the integrated behavior change model, describing physical activity as the result of motivational, volitional, and automatic processes. The study design will allow insight into the contribution of volitional and automatic processes in bridging the intention-behavior gap.

Following i2be app registration and stratification on baseline factors, participants will be randomly allocated (1:1:1) in-app to the control group, treatment 1, or treatment 2. The control group receives the module ‘Get Informed’ consisting of usual care, i.e. knowledge provision. In addition to the module ‘Get Informed’, treatment 1 receives the module ‘Get Motivated’ (targeting motivational processes), consisting of the behavior change technique (BCT) of motivational interviewing-based counselling. In addition to the modules ‘Get Informed’ and ‘Get Motivated’, treatment 2 receives the module ‘Get Activated’ (targeting volitional processes), consisting of the BCTs of action planning training and reminders, coping planning training, and commitment training, and the module ‘Get Energized’ (targeting automatic processes), consisting of the BCTs of mindfulness-based stress reduction and positive psychology. Engagement with the fully automated app is incentivized through primary task support, dialogue support, and psychological and tangible rewards.

The primary outcome is objectively measured weekly minutes of moderate-to-vigorous physical activity. Secondary outcomes include objectively measured (resting heart rate) and self-reported physiology measurements (body mass index, waist-to-hip-ratio, cardiorespiratory fitness), as well as subjective well-being. Tertiary outcomes include self-reported mechanism of action variables in order to assess the mechanisms underlying the

effects of BCTs. Objectively measured outcomes will be captured by a Fitbit device (Fitbit Inspire 2), and all other outcomes measures will be self-reported into the i2be app. Outcome measures will be assessed at baseline, immediately post-intervention, at 3 months follow-up, and at 12 months follow-up. Weekly minutes of moderate-to-vigorous physical activity will additionally be assessed at the intervention midpoint. Effectiveness will be determined by a modified intention-to-treat analysis.

i2be has been 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. Avegen was responsible for the programming of the app, and the name, logo and branding of the app.

Study objective

The main test of i2be is the test between treatment 2 versus control, expecting higher weekly minutes of moderate-to-vigorous physical activity in the former. Second, we will test the difference between treatment 2 and treatment 1, expecting higher weekly minutes of moderate-to-vigorous physical activity in the former. Third, we will test the difference between treatment 1 and control, expecting higher weekly minutes of moderate-to-vigorous physical activity in the former.

Study design

Outcome measures will be assessed at baseline, immediately post-intervention, at 3 months follow-up, and at 12 months follow-up.

Intervention

Intervention duration is 8 weeks. All participants use the i2be app and their Fitbit device, and receive the module ‘Get Informed’ consisting of usual care (standard treatment).

In addition to receiving standard treatment, treatment 1 receives the module ‘Get Motivated’ (targeting motivational processes), consisting of the behavior change technique (BCT) of motivational interviewing-based counselling.

In addition to receiving standard treatment and the module ‘Get Motivated’, treatment 2 receives the module ‘Get Activated’ (targeting volitional processes), consisting of the BCTs of action planning training and reminders, coping planning training, and commitment training. Furthermore, treatment 2 receives the module ‘Get Energized’ (targeting automatic processes), consisting of the BCTs of mindfulness-based stress reduction and positive psychology.

Contacts

Public
Erasmus MC
Lili Kókai

0649267173
Scientific
Erasmus MC
Lili Kókai

0649267173

Eligibility criteria

Inclusion criteria

In order to be eligible for participation in the trial, a participant must have experienced a hypertensive disorder of pregnancy (e.g. preeclampsia, eclampsia, HELLP syndrome) in the past.

Exclusion criteria

Exclusion criteria for enrollment into the trial are: <18 years of age, pregnant at time of inclusion, <3 months post-partum, physical limitation preventing physical activity (e.g. illness, injury, surgery, rehabilitation), no working knowledge of Dutch or English language, no possession of a smartphone, and unwillingness to use a Fitbit device and the Fitbit and i2be apps.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-09-2021
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
On completion of the trial, and after the publication of the results, researchers who provide a methodologically sound proposal can request individual deidentified participant-level data from the corresponding author for those participants who have provided informed consent for sharing of data.

Ethics review

Positive opinion

Date:	09-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9329

Register	ID
Other	Medical Ethics Committee Erasmus MC : MEC-2020-0981

Study results

Summary results
Study protocol will be submitted to a scientific journal.