

Using "IF-THEN" plans to increase physical activity

Submission date 04/06/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/06/2019	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/09/2022	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Implementation intentions (i.e., making if-then plans) are effective at changing behaviour. However, despite many studies showing this effect there are few studies that have been conducted on large samples and for more than a short term follow up. The aim of this study is to test the effectiveness of using two different interventions (standard volitional help sheet and single situation volitional help sheet) at increasing physical activity in comparison to a control group.

Who can participate?

UK adults who are capable of engaging in physical activity

What does the study involve?

Participants complete a series of questionnaires about their physical activity and are then randomly allocated to one of the three groups. The standard volitional help sheet includes a list of situations when people might not want to be physically active (e.g., If I'm tempted not to be physically active when I'm under a lot of stress) and a list of solutions to overcoming these (e.g., then I will make myself do some physical activity anyway because I know I will feel better afterward). Participants are asked to draw a line from the situations that are relevant to them to their chosen solutions. They can create as many situation and solution pairs as they want. The single situation volitional help sheet includes a stem but not a specific situation (e.g., If I'm tempted not to be physically active...) and a list of solutions to overcoming this (e.g., then I will make myself do some physical activity anyway because I know I will feel better afterward). Participants are asked to draw a line from the stem to them to their chosen solutions. They can create as many pairs as they want. The control group includes the same list as the standard volitional help sheet but people are asked just to tick situation and solutions that are relevant to them. After 6 months participants are asked the same physical activity questions to see if the intervention has increased their physical activity and also find who it will work best for.

What are the possible benefits and risks of participating?

The benefits of participating are that participants may increase their physical activity. There are no risks of participating.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
May 2019 to June 2020

Who is funding the study?
Tesco (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

2019-7332-10682

Study information

Scientific Title

Using "IF-THEN" plans to increase physical activity

Study objectives

Current study hypothesis as of 18/10/2019:

1. The two conditions that complete a volitional help sheet (standard VHS and single situation VHS) will report greater physical activity and lower sedentariness at follow up than the control condition
2. Increases in physical activity/reductions in sedentariness will be associated with improved subjective well-being
3. The VHS interventions will be most effective for those who have developed high habits, awareness of standards, self-monitoring, self-regulatory effort, capabilities, opportunities and motivations to increase physical activity and are currently not meeting health behaviour guidelines (including physical activity, smoking, alcohol consumption and diet)

Previous study hypothesis:

1. The two conditions that complete a volitional help sheet (standard VHS and single situation VHS) will report greater physical activity and lower sedentariness at follow up than the control condition

2. Increases in physical activity/reductions in sedentariness will be associated with improved subjective well-being
3. The VHS interventions will be most effective for those who have high habits, awareness of standards, self-monitoring, self-regulatory effort, capabilities, opportunities and motivations to increase physical activity and are currently not meeting health behaviour guidelines (including physical activity, smoking, alcohol consumption and diet)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/06/2019, University Research Ethics Committee at the University of Manchester (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL; 0161 275 2206/2674; research.ethics@manchester.ac.uk), ref: 2019-7332-10682

Study design

Three-arm randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Physical activity

Interventions

Participants complete a series of questionnaires about their physical activity and are then randomly assigned to one of the three conditions:

1. The standard volitional help sheet includes a list of situations when people might not want to be physically active (e.g., If I'm tempted not to be physically active when I'm under a lot of stress) and a list of solutions to overcoming these (e.g., then I will make myself do some physical activity anyway because I know I will feel better afterward). People are asked to draw a line from the situations that are relevant to them to their chosen solutions. They can create as many situation and solution pairs as they want.
2. The single situation volitional help sheet includes a stem but not a specific situation (e.g., If I'm tempted not to be physically active...) and a list of solutions to overcoming this (e.g., then I will make myself do some physical activity anyway because I know I will feel better afterward).

People are asked to draw a line from the stem to them to their chosen solutions. They can create as many pairs as they want.

3. The control condition includes the same list as the standard volitional help sheet but people are asked just to tick situation and solutions that are relevant to them.

After 6 months participants are asked the same physical activity questions to see if the intervention has increased their physical activity and also find who it will work best for.

Intervention Type

Behavioural

Primary outcome measure

1. Physical activity is measured using the Sport England: Short active lives questionnaire and the IPAQ at baseline and 6 months follow up
2. Sedentary behaviour is measured using a sedentary behaviour questionnaire at baseline and 6 months follow up

Secondary outcome measures

1. Capability, opportunity and motivation (based on COM-B model) is measured using the COM questionnaire at baseline and 6 months follow up
2. Habit is measured using the self-reported habit index (automaticity scale) at baseline and 6 months follow up
3. State self-regulation is measured at baseline and 6 months follow up (Sniehotta, F. F., Scholz, U., & Schwarzer, R. (2005). Bridging the intention-behavior gap: Planning, self-efficacy, and action control in the adoption and maintenance of physical activity. *Psychology & Health*, 20, 143–160. <http://dx.doi.org/10.1080/08870440512331317670>)
4. Daily smoking, weekly alcohol consumption and daily fruit and vegetable intake measured using three questions at baseline and 6 months follow up
5. Subjective well-being measured using the Office of National statistics measure of wellbeing at baseline and 6 months follow up

Overall study start date

01/05/2019

Completion date

28/02/2020

Eligibility

Key inclusion criteria

UK adults who are capable of engaging in physical activity

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

3000

Total final enrolment

3085

Key exclusion criteria

1. Children
2. People who are not capable of engaging in physical activity
3. People not based in the UK

Date of first enrolment

08/07/2019

Date of final enrolment

16/08/2019

Locations**Countries of recruitment**

United Kingdom

Study participating centre

YouGov will be distributing the questionnaires via its online platform

United Kingdom

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Sponsor information**Organisation**

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Sponsor type

University/education

ROR

Funder(s)

Funder type

Industry

Funder Name

Tesco

Results and Publications

Publication and dissemination plan

The researchers will share all documents used in the study, statistical analysis plan and data on OSF. Planned publication in a high impact peer-reviewed journal

Intention to publish date

28/02/2021

Individual participant data (IPD) sharing plan

The data will be shared via OSF. However, people can contact Dr Tracy Epton (epton.tracy@gmail.com). The data will be available for 10 years, data will be freely available for anyone who wishes to use it. Consent from participants was obtained. The data will be fully anonymised.

The statistical analysis plan has been uploaded as an additional file (added 31/10/2019)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		29/10/2019	31/10/2019	No	No