

Trial Description

Title

A randomized controlled trial to evaluate the efficacy of time- and routine-based cues on habit formation

Trial Acronym

HABIT

URL of the trial

<https://www.ewi-psy.fu-berlin.de/einrichtungen/arbeitsbereiche/gesund/forschung/HABIT-Website-201902081.pdf>

Brief Summary in Lay Language

Habits are behaviors that persons carry out spontaneously, usually without any externally imposed commands. There is consensus in applied health and social psychology research that it helps individuals to acquire new healthy habits when they associate their intended behavior with a regularly occurring cue. Such a cue could be an object, situation, time point, or a routine. The key to successful habit formation is to repeat the behaviour consistently when the cue is encountered (e.g., eat a yoghurt with fruits while watching the daily news). Initially, the performance of the new behaviour might require a lot of effort and willpower. Over time, as behaviors are repeated in a consistent setting (e.g., at the same time of day) they then start to be carried out with less thought and much more efficiently as control of the behaviour transfers to cues in the environment. These cues can activate a nearly automatic response: a habit. This online-based daily diary study aims to compare habit formation for a self-selected healthy nutrition behaviour (e.g., eat a yoghurt with fruits) in individuals who (i) plan to repeatedly perform their desired at a specific time of the day (i.e., time-based cue) or (ii) plan to carry out the behaviour in response to an existing daily routine (i.e., routine-based cue). Participants of both groups are asked to plan and carry out their intended nutrition behavior in response to their self-selected cue every day for 12 weeks. To assess how successful participants enact their intended behavior and how much time they need to build a habit, participants are asked to fill in short daily questionnaires and three longer questionnaires.

Brief Summary in Scientific Language

This trial is an online-based, two-arm, randomised, controlled trial (intensive longitudinal study design) with healthy adults from the general population, comparing habit formation for a self-selected eating behavior in individuals who form an action plan based on a routine-based cue vs. individuals prompted to form an action plan based on a time-based cue. After responding to the baseline assessment (T1), individuals will be randomized to the intervention arm (i.e., routine-based cue) or the control arm (i.e., time-based cue). Completing the intervention will take about 5 minutes for both intervention groups. Individuals are followed up at 4 (T2), 8 (T3), and 12 (T4) weeks after the baseline assessment. Participants will also be asked to respond to a short daily questionnaire over 12

weeks (D0-D84). The primary outcome is automaticity (as an indicator of habit strength; daily assessments) for the self-selected eating behavior. The secondary outcome is plan enactment, that is, the enactment of the self-selected eating behaviour (daily assessments).

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00016720**
 - Date of Registration in DRKS: **2019/02/14**
 - Date of Registration in Partner Registry or other Primary Registry: [---]*
 - Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
 - Ethics Approval/Approval of the Ethics Committee: **Approved**
 - (leading) Ethics Committee Nr.: **226/2018** , **Ethikkommission der Freien Universität Berlin, Fachbereich Erziehungswissenschaft und Psychologie, Habelschwerdter Allee 45**
14195 Berlin, Deutschland
- <https://www.ewi-psy.fu-berlin.de/einrichtungen/kommissionen/kommissionen/ethik->**

Secondary IDs

Health condition or Problem studied

- Free text: **non-clinical population, problems with self-regulation**

Interventions/Observational Groups

- Arm 1: **Intervention Group 1**
 - **Participants were asked to choose a healthy eating behaviour that they would like to make into a habit**
 - **Criteria for the selection of the intended behavior: behaviour had to be one that participants i) did not already do and one that (ii) could be performed in response to a salient daily routine (routine-based cue)**
 - **Criteria for the selection of the cue: cue had to be an existing routine (i) that**

occurred every day (ii) and only once a day

- **Action planning for the self-selected nutrition behavior**
- **Prompt to carry out the self-selected behaviour in the same context (e.g., at breakfast) every day for 12 weeks**
- **Prompt to create a reminder by writing down the desired behavior and cue**

■ **Arm 2: Intervention Group 2**

- **Participants were asked to choose a healthy eating behaviour that they would like to make into a habit**
- **Criteria for the selection of intended behavior: behaviour had to be one that participants i) did not already do and one that (ii) could be performed daily in response to a specific time of day (time-based cue)**
- **Criteria for the selection of cue): a time-based cue (e.g., 7:00 pm)**
- **Action planning for the self-selected nutrition behavior**
- **Prompt to carry out the self-selected behavior at the same time of day (e.g., 7 pm) every day for 12 weeks**
- **Prompt to create a reminder by writing down the desired behavior and cue**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Changes in automaticity (up to three months after baseline assessment), Automaticity will be measured daily over the duration of the study (D0-D84), Measurement: Self-Report Behavioral Automaticity Index (SRBAI; Gardner et al., 2012; Thurn et al., 2014)

Secondary Outcome

Changes in plan enactment (up to three months after baseline assessment): Plan enactment (i.e. enactment of intended behavior in response to planned personal cue) will be measured daily over the duration of the study (D0-D84), Measurement: Self-report plan enactment (Lally et al., 2010)

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- other **Freie Universität Berlin, Universität/E-Mail-Verteiler**
- other **Medical School Berlin, Universität/E-Mail-Verteiler**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/02/18**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Sufficient knowledge of the German language to understand and complete the questionnaires and the intervention material

Exclusion criteria

Insufficient knowledge of German to complete the questionnaire and intervention, no vision impairment, younger than 18

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/06/02**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.