Trial Description

Title

Contenance: A randomized controlled trial to evaluate the efficacy of a mobile intervention on healthy smartphone use

Trial Acronym

Contenance

URL of the trial

https://www.notlessbutbetter.com

Brief Summary in Lay Language

The smartphone is our daily companion and very useful when it comes to managing a variety of daily tasks. However, previous research showed that many persons report problematic forms of smartphone use. To support persons to better control their smartphone use, programs were developed (e.g., apps) which allow persons to plan smartphone time-outs (e.g., to be offline from 8-9 pm on day X). As another approach to support persons in their smartphone use, mental training programs promote personal resources such as understanding one's smartphone-related values, setting of personal goals, and forming healthy smartphone habits. This study aims to examine the effectiveness of a newly developed mental training app for healthy smartphone use.

In this app-based study, a sample of adults who were randomly assigned to an intervention group (mental training) or control group (self-selected daily time-outs of one hour) are investigated. Participants in both groups receive a baseline questionnaire which is followed by app-based daily exercises (duration: ca. 1-5 min per day) over 20 days. After these 20 days, they receive two further questionnaires at the following day (21st day after the start of the study) as well as 3 weeks later (42nd day). When working on the questionnaires, persons respond to questions on (among others) their problematic smartphone use and well-being.

Brief Summary in Scientific Language

Since the launch of the first iPhone in 2007 and the release of further smartphone models, specific forms of how persons use their smartphone were observed such as problematic smartphone use that is increasingly becoming a challenge for health care systems (van Velthoven, Powell, & Powell, 2018). Empirical findings show links of problematic smartphone use with depression, anxiety, stress (Elhai, Dvorak, Levine, & Hall, 2017), forms of addiction (Wolniewicz, Tiamiyu, Weeks, & Elhai, 2017) and reduced psychological well-being (Tangmunkongvorakul et al., 2019). Recently, interventions were developed that aimed at improving smartphone use and were oftentimes provided as smartphone apps. Many interventions hereby focus on restricting persons' smartphone use by setting screen time limits (e.g. Curtaz, Hoppe, & Nachtwei, 2015; Stieger & Lewetz, 2018). However, resource-based, tailored interventions to foster psychological factors to, in turn, promote persons' healthier smartphone use were rather neglected. This

**randomized controlled trial aims at evaluating the effectiveness of a newly developed app-based psychological intervention to promote healthy smartphone use.
The sample consists of adults who complete an app-based baseline questionnaire (T1/D0) after giving their informed consent to participate in the study. Based on randomization into intervention or control group, participants receive daily, app-based brief exercises (duration: ca. 1-5 min per day) for the subsequent 20 days (D1-D20). The exercises in the intervention group include educational elements, impulse control exercises, habit exercises through planning, and exercises on psychological flexibility (particularly mindfulness, understanding of values and committed action). In the active control group, a daily smartphone time-out of one hour is planned for the following day (cf. Curtaz, Hoppe, & Nachtwei, 2015). After the intervention period (D1-D20), all participants are invited to complete two further questionnaires: One day after the last intervention day (T2/D21) and 3 weeks later (T3/D42). The primary outcome for evaluating the effectiveness of the intervention is the self-reported problematic smartphone use (T1, T2, and T3). The secondary outcome for evaluating the effectiveness of the intervention is self-reported well-being (T1, T2, and T3). It is assumed that persons of the intervention group (vs. active control group) show improvements in their problematic smartphone use and well-being following the intervention.**

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017606**
- Date of Registration in DRKS: **2019/08/09**
- 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.: **2019-14R1 , Ethikkommission der Humboldt Universität zu Berlin, Lebenswissenschaftliche Fakultät, Institut für Psychologie, Rudower Chaussee 18
12489 Berlin, Deutschland**

Secondary IDs

Health condition or Problem studied

- Free text: **non-clinical population, problems with and/or motivation to change own smartphone use**

Interventions/Observational Groups

- Arm 1: **Arm 1 (Intervention group)**

  Five consecutive modules with daily exercises (each ca. 1-5 min). Each module goes over 4 days (in sum: 20 days; D1-D20)

  1. Module: „Observe“, D1-D4
  1 exercise on psychoeducation: self-awareness, 2 exercises on mindfulness, 1 exercise on perception of impulses

  2. Module: „Reflect“, D5-D8
  1 exercise on psychoeducation: reflection of personal smartphone habits, 2 exercises on identification of situational and emotional smartphone trigger, 1 exercise on mindfulness use of social media

  3. Module: „Vision“, D9-D12
  1 exercise on understanding of values as well as smartphone-related goal setting, 1 exercise on value-related committed action, 2 exercises on mindfulness

  4. Module: „Plan“, D13-D16
  1 exercise on action planning and value-related committed action, 1 exercise on coping planning, 2 exercises on alternative behavioral responses in critical situations

  5. Module: „Support“, D17-D20
  1 exercise on habit formation: Design of the smartphone screen, 2 exercises on smartphone use in certain environments, 1 exercise on smartphone use in social situations
- Arm 2: **Arm 2 (Active control group)**

  Daily task: Form a plan on a smartphone time-out over one hour for the subsequent day

  From day to day, participants can choose a new time for their smartphone time-out (i.e., based on previous experiences with the time-out task and based on demands of the upcoming day)

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Changes in problematic smartphone use (up to 6 weeks following baseline assessment), PSU (Foerster, Roser, Schoeni, & Röösli, 2015), also measured at T1 (Baseline/Randomization), T2 (T1+3 weeks; after intervention period), and T3 (T1+6 weeks; follow-up)

Secondary Outcome

Changes in well-being (up to 6 weeks following baseline assessment), PERMA Profiler (Butler & Kern, 2016), measured at T1 (Baseline/Randomization), T2 (T1+3 weeks; after intervention period), and T3 (T1+6 weeks; follow-up)

Countries of recruitment

- DE **Germany**
- FR **France**
- PL **Poland**
- CH **Switzerland**
- NL **Netherlands**

Locations of Recruitment

- other **Freie Universität Berlin, Berlin**
- other **Humboldt Universität zu Berlin, Berlin**
- University Medical Center **Charité - Universitätsmedizin Berlin, Berlin**
- other **Universität Zürich, Zürich**

- other **Intranet of a German co-working space, Berlin**
- other **Social media and social media groups , [---]***

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/10/09**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

Ownership and use of a smartphone based on iOS; Sufficient knowledge of the English language to understand and complete the questionnaires and the intervention material

Exclusion criteria

No ownership and use of a smartphone based on iOS; Insufficient knowledge of the English language or vision impairment to understand and complete the questionnaires and the intervention material, <18 years

Addresses

- **Primary Sponsor**

  Team Impulskontrolltrainer: Contenance
  Ms. B. Sc. Christina Roitzheim
  Reuterstraße 97
  12053 Berlin
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **roitzhec at hu-berlin.de**
  URL: **[---]***
- **Contact for Scientific Queries**

Contact for Scientific Queries

Freie Universität Berlin, Fachbereich Erziehungswissenschaft und Psychologie, Arbeitsbereich Gesundheitspsychologie
Mr. Dr. Jan Keller
Habelschwerdter Allee 45
14195 Berlin
Germany

Telephone: **03083854906**
Fax: **[---]***
E-mail: **jan.keller at fu-berlin.de**
URL: **https://www.ewi-psy.fu-berlin.de/gesund**

■ **Contact for Public Queries**

Team Impulskontrolltrainer: Contenance
Ms. B. Sc. Christina Roitzheim
Reuterstraße 97
12053 Berlin
Germany

Telephone: **03083854906**
Fax: **[---]***
E-mail: **roitzhec at hu-berlin.de**
URL: **[---]***

■ **Collaborator, Other Address**

Universität Witten/Herdecke, Gesundheits-, Arbeits- und Organisationspsychologie
Ms. Prof. Dr. Theda Radtke
Alfred-Herrhausen-Str. 44
58455 Witten
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **Theda.Radtke at uni-wh.de**
URL: **[---]***

■ **Collaborator, Other Address**

Universität Zürich, Angewandte Sozial- und Gesundheitspsychologie
Mr. M. Sc. Konstantin Schenkel
Binzmühlenstrasse 14
8050 Zürich
Switzerland

Telephone: **[---]***

Collaborator, Other Address

Universität Zürich, Angewandte Sozial- und Gesundheitspsychologie
Mr. M. Sc. Konstantin Schenkel
Binzmühlenstrasse 14
8050 Zürich
Switzerland

Telephone: **[---]***
Fax: **[---]***
E-mail: **konstantin.schenkel at psychologie.uzh.ch**
URL: **https://www.psychologie.uzh.ch/de/bereiche/sob/angsoz.html**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Freie Universität Berlin / Profund Innovation
Kaiserswerther Str. 16-18
14195 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/12/09**

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.*