Trial Title: Smartphone Screentime Reduction improves mental health: A randomized clinical trial

Internal Reference Number / Short title: Digital Detox Study (DDS)

Ethics Ref: EK GZ 67/2021-2024
(submitted August 20, 2023, approved October 23, 2023)
Original Trial Protocol in German

Trial Registration Ref: https://osf.io/a9k76

(Trial registration November 8, 2023)

Original trial registration in English

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Sponsor/Funding: The study was financed by the department itself (no additional funding). The wearables were sponsored by the participating universities as well as from the state lower Austria.

Funder: No funding.

Chief Investigator Signature:

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1. KEY TRIAL CONTACTS

Chief Investigator	Prof. Dr. Christoph Pieh, MD Head of Department and Full Professor for Psychosomatic Medicine Department of Psychosomatic Medicine and Psychotherapy University Krems Dr. Dorrek Straße 30 +432732893/2530
Sponsor	University will sponsor the fitness tracker.
Funder(s)	N.a.
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2. LAY SUMMARY

The aim of this RCT is to evaluate the impact of digital detox on mental health in 18-29 yo students from Austria. Screen time (less than 2 hours per day) as well as social media use (less than 1 hour per day) should be reduced for a period of 3 weeks and the effects should be compared to a controlled group .

A sample of N > 96 should be recruited through newsletter, notices and advertising on social media. The inclusion criteria are more than 3 hours of screen time per day, primarily on social media, and no psychiatric illness for which they are being treated.

After informing and signed the consent form, the particpants have to download an App (ESMira®), which processes the whole study. The first step is to fill out sociodemographic data,smartphone usage and mental health questionnaires. After controlling for inclusion and exclusion criteria, ESMira will randomize into intervention (A) and controlled group (B).

The participants in the intervention group (A) should continue their social media use and smartphone screen time unchanged for the first 10 days (Baseline= t1.) After that, the participants should limit their use of social media, such as Instagram, TikTok, Snapchat, Facebook, or similar sites to one hour per day and the complete screen time under two hours per day. To comply with that, participants should use the limiter function of there smartphone or download an additional app. Screen time of the smartphone and the social media use will be tracked automatically or via uploading a screenshot. At the end of the intervention (t2), the mental health questionnaires will be collected again. Afterwards there are no further tasks for the participants in the intervention group (A), social media use is possible again without restrictions, screen time and social media use will be tracked until 3 month follow up (t3). During the study period participants will be asked to additionally wear a fitness tracker to measure daily movement as well as sleep behavior.

The controls group (B) will be asked to continue their social media use and screen time unchanged for 3 month, after that the will be asked to fill out the mental health questionnaires again.

Hypotheses

The primary hypothesis of the study is that mental health, particularly stress, depressive symptoms, and sleep quality will improve after the intervention (t2) compared to the control group as well as compared to baseline.

3. SYNOPSIS

Trial Title	Smartphone Screentime Reduction improves mental health: A randomized clinical trial
Internal ref. no. (or short title)	EK GZ 67/2021-2024
Trial registration	https://osf.io/a9k76
Sponsor	N.a.
Funder	N.a.
Clinical Phase	
Trial Design	Two group, not blinded, randomized controlled trial with a follow up.

Trial Participants	Healthy adults could participate if thes were 1) between 18 - 29 yo, 2) owning a smartphone and using it at least 3 h/d, and 3) no diagnosed or treated mental disorder, no ongoing psychotherapy or psychopharmaceutic therapy (self-report). Moderately elevated levels in mental health screening questionnaires were no exclusion criteria.		
Sample Size	With a small to medium effect size (Cohens d= 0.45; power .8, significance level < .05, icc = .05), significant results can be expected with a completed data set of minimum 40 people per group. Considering a drop-out rate of 20%, at least 50 people per group were recruited.		
Planned Trial Period	The total study period will be 12 weeks: Screening for eligibility, 10 days baseline phase, 3 weeks intervention, 6 weeks post intervention to follow-up		
Planned Recruitment period	Study protocol submission: August 20, 2023; Approval by Ethical committee October 23, 2023; Information on Social Media and notices at University; Registration November 8, 2023; Screening for Eligibility November 8-10, 2023		
	Objectives	Outcome Measures	Timepoint(s)
Primary	• Depressive Symptoms • Well-being • Stress • Sleep Quality	• Patient Health Questionnaire (PHQ-9) • World Health Organization well-being questionnaire (WHO-5) • Perceived Stress Questionnaire (PSQ-20) • Insomnia Severity Index (ISI)	T0, T1, T2
Secondary	• Problematic Smartphone Use • Disordered Eating • Body Appreciation • Anxiety	• Smartphone Addiction Scale (SAS-SV) • SCOFF • BAS-2 • GAD-7	T0, T1, T2
Intervention(s) •	The intervention is reducing smartphone screen time <2/h for 3 weeks. Smartphone screen time will be assessed weekly in both groups using the smartphones' built-in screen time measurements. Weekly, participants will be asked to upload a screenshot from their screen time from the previous week.		

4. BACKGROUND AND RATIONALE

The mental health of young people has significantly deteriorated in recent years. For example, in Austria in 2022, 73% of girls and 45% of boys suffered from moderate depressive symptoms (Haider et al., 2023). Other psychological symptoms were also very common, such as anxiety symptoms (57% in girls and 35% in boys) or sleep problems (34% in girls, 21% in boys) (Haider et al., 2023).

Although the causes of this trend are undoubtedly multifactorial and vary individually, daily smartphone use appears to have a particularly large impact (Humer et al., 2022). This is relevant because many countries, including Austria, are experiencing a rapid increase in daily smartphone use: According to the HBSC study, the average time spent on smartphones in 2022 was 5 hours per day, almost double what it was in 2018 (HBSC Study, 2022, HBSC Study, 2018). Additionally, there is at least a correlational relationship between screen time and mental health: a study of over 7000 young people showed that the likelihood of depressive symptoms increased up to 7 times with increasing smartphone use duration (Humer et al., 2022). Anxiety symptoms, sleep disturbances, disordered eating behavior, or stress also increased with increasing screen time, while life satisfaction and well-being decreased (Humer et al., 2022, Pieh et al., 2021). This demonstrates a stair-step effect: with each additional hour of daily screen time, the frequency of mental symptoms increases and well-being decreases (Humer et al., 2022).

A significant portion of daily screen time is due to the use of social media. These platforms are now an integral part of our daily lives, and their usage is increasing exponentially (Huang et al., 2018; Y. Sun et al., 2021). With the emergence of social media, the first scientific investigations into why we use social media were published (including Nadkarni et al., 2012). Excessive use of social media is associated with a variety of negative effects, such as decreased work performance (Kuss et al., 2014, Xanidis and Brignell, 2016), less healthy social relationships (Fox and Moreland, 2015, Müller et al., 2016), sleep problems (Koc & Gulyagci, 2013, Wolniczak et al., 2013), or lower life satisfaction (Blachnio et al., 2016, Hawi and Samaha, 2016).

More and more studies are highlighting the high addictive potential of social media (Sun et al., 2021). This seems to be present with most social media platforms, with TikTok (and presumably other short video formats) appearing to have particularly high addictive potential (Marengo et al., 2022).

This is consistent with earlier findings that reported a significant increase in boredom or craving (a term from addiction medicine describing intense desire for the addictive substance during withdrawal) when completely abstaining from social media for a week (Stieger et al., 2018). This study also showed that after just one week, there was no lasting change in usage behavior. After the intervention, participants resumed using social media as frequently as before (Stieger et al., 2018).

The reasons and causes for the intensive use of social media are certainly not fully understood. Activation of the brain's reward system through likes and positive interactions or the fear of missing out ("Fear of Missing Out" or FOMO) may repeatedly lead us to reach for our smartphones. But self-presentation, recognition, or "social comparison" can also play a role.

While social media can have advantages for entertainment, distraction, or contact with others, excessive use can lead to a range of negative consequences. In response, the term "Digital Detox" has emerged to emphasize the need for a conscious reduction in digital use.

5. OBJECTIVES AND OUTCOME MEASURES

Objective, Research Question, Procedure, and Design

The aim of the planned study is to reduce the screen time of healthy students in Austria over a period of 3 weeks and to investigate its impact on mental health.

Mental health indicators were evaluated in both groups at baseline, post-intervention, and at follow-up (t2). Participants will be informed weekly via App.

1. Main outcomes

Well-being (WHO-5): The validated German version of the World Health Organization well-being questionnaire (WHO-5) will be used.

Depressive symptoms (PHQ-9):Depressive symptoms will be assessed using the Patient Health Questionnaire (PHQ-9) in the validated German version.

Stress (PSQ-20): Stress will be assessed using the German version of the 20-item short-form of the Perceived Stress Questionnaire.

Sleep quality (ISI): Sleep quality will be assessed with the Insomnia Severity Index (ISI).

2. Additional outcomes

Problematic smartphone use (Smartphone Addiction Scale (SAS-SV)), anxiety symptoms (GAD-7), disordered eating (SCOFF), and Body Appreciation (BAS-2) will further be assessed.

Physical activity will be measured using a fitness tracker, as well as heart rate variability (HRV) and resting heart rate.

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Depressive Symptoms (PHQ-9) Well-Being (WHO-5) Stress (PSQ 20) Sleep quality (ISI)	• Patient Health Questionnaire (PHQ-9) • World Health Organization well-being questionnaire (WHO-5) • Perceived Stress Questionnaire (PSQ-20) • Insomnia Severity Index (ISI)	At Baseline, post-intervention and at Follow-up.
• Problematic Smartphone Use	• Smartphone Addiction Scale • SCOFF • BAS-2 • GAD-7	At Baseline, post-intervention and at Follow-up.

• Disordered Eating • Body Appreciation • Anxiety		

6. TRIAL DESIGN

This study is a randomized, controlled trial (RCT) with a follow-up. There is no blinding and a two parallel group design. In order to keep drop outs in the control group low, participants in the control group will be offered intervention after follow-up (cross over).

7. PARTICIPANT IDENTIFICATION

7.1. Trial Participants

Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the trial.
- Male or Female, aged 18 years or above (up to 29 yo).
- Health volunteer trial: be in good health (no diagnosed mental disorder, no ongoing medication or psychotherapy).

7.2. Exclusion Criteria

The participant may not enter the trial if ANY of the following apply:

- Diagnosed mental disorder
- Ongoing psychotherapy.
- Psychotropic drugs.
- Screen time daily less than 3 hours.

8. TRIAL PROCEDURES

8.1. Recruitment

Via social media, newsletter and notices at university.

8.2. Screening and Eligibility Assessment

The screening and eligibility assessment included sociodemographic data (age, gender), physical activity per week, statement about mental health disorders or therapy, as well as mental health indicators.

8.3. Informed Consent

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants. Participants have to sign must personally sign and date the Informed Consent form before participation

Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. The original signed form will be retained at the trial site.

8.4. Randomisation

Randomization will be processes through the ESMira® App. This App allows automatically randomization to one or the other group. After signing an informed consent form, participants joined the study in the ESMira18 app via QR-code. Randomization of ESMira is impervious to external influences.

8.5. Blinding and code-breaking

No blinding

8.6. Baseline Assessments

Main Outcomes:

- Patient Health Questionnaire (PHQ-9)
- World Health Organization well-being questionnaire (WHO-5)
- Perceived Stress Questionnaire (PSQ-20)
- Insomnia Severity Index (ISI)

Additional outcomes:

- Smartphone Addiction Scale
- SCOFF
- BAS-2
- GAD-7
- Physical activity (Fitness tracker).

8.7. Early Discontinuation/Withdrawal of Participants

Withdraw is possible at any time and without giving a reason. In case of withdrawal prior randomization, data won´t be replaced. In case of withdrawel after randomization, missing data will be estimated by maximum likelihood estimation.

8.8. Definition of End of Trial

The end of trial is the follow-up measurement.

9. TRIAL INTERVENTIONS

Screen time (less than 2 hours per day) as well as social media use (less than 1 hour per day) should be reduced for a period of 3 weeks and the effects should be compared to a controlled group. A sample of N > 96 should be recruited through newsletter, notices and advertising on social media. The inclusion criteria are more than 3 hours of screen time per day, and no psychiatric illness for which they are being treated. After informing and signed the consent form, the participants have to download an App (ESMira®), which processes the whole study. The first step is to fill out sociodemographic data,smartphone usage and mental health questionnaires. After controlling for inclusion and exclusion criteria, ESMira will randomize into intervention (A) and controlled group (B). The participants in the intervention group (A) should continue their social media use and smartphone screen time unchanged for the first 10 days (Baseline.) After that (t1), the participants should limit their use of social media, such as Instagram, TikTok, Snapchat, Facebook, or similar sites to one hour per day and the complete screen time under two hours per day. To comply with that, participants should use the limiter function of there smartphone or download an additional app. Screen time of the smartphone and the social media use will be tracked automatically or via uploading a screenshot. At the end of the intervention (t2), the mental health questionnaires will be collected again. Afterwards there are no further tasks for the participants in the intervention group (A), screen time and social media use is possible again without restrictions. Screen time and social media use will be tracked until 3 month follow up (t3). During the study period participants will be asked to additionally wear a fitness tracker to measure daily movement as well as sleep behavior. The controls group (B) will be asked to continue their social media use and screen time unchanged to follow-up, after that the will be asked to fill out the mental health questionnaires again. After follow up, control group (B) will be offered to participate at intervention to keep drop outs and missing values low.

10. SAFETY REPORTING

Particpants will be informed that discomfort, burdensome, withdrawal symptoms, or unrest might be possible during 3-week intervention period. They will receive an emergency phone number for a psychological support if the symptoms were too stressful.

11. STATISTIC ANALYSIS PLAN

We will use the statistic software IBM SPSS Statistics (IBM Corp., Armonk, NY, USA) to analyze the data. χ^2-Test and independent samples tests will be used to examine differences at baseline (t0) regarding age, gender, smartphone screen time, physical activity per week, and mental health indicators between the control and the intervention group.

To examine the effect of reduced smartphone screen time on the mental health indicators, repeated measurements ANOVAs (rm-ANOVA) will be applied. The primary hypotheses focuses on the difference between t0 (baseline) and t1 (post-intervention) between control group and intervention group (between group effect). In a secondary analysis, the follow-up time point (t2) will also be included.
Group allocation (control vs. intervention) will be the between-group factor, time will be the within-group factor (t0, t1, t2). Furthermore, a sub-group analysis (rm-ANOVA) will be applied of those, who strictly adhered to the 2h smartphone screen time limit during all three weeks.
In case of baseline group-differences in the mental health indicators, these variables will be added as a covariate in the rm-ANOVA. If the sphericity assumption will be violated, the Greenhouse-Geisser correction will be applied. In the post hoc tests, Bonferroni correction will be applied to adjust for multiple comparisons.
Missing values will be estimated with via maximum likelihood estimation.

11.1. Sample Size Determination

According to the power analysis 40 per group should finish the study per group, in case of 20% drop outs, a minimum of 96 participants should be included.

12. DATA MANAGEMENT

The whole data collection procedure will be carried out through the ESMira App. ESMira is a tool for running longitudinal studies (ESM, AA, EMA, ...) with completely anonymized communication with participants and data collection. The following validated and frequently used mental health questionnaire will be used: Wellbeing (WHO-5), Depressive Symptoms (PHQ-9), Anxiety (GAD-7), Stress (PSS-10), Sleep quality (ISI), Eating disorder (EAT-8; SCOFF), and body awareness (BAD-2). These questionnaires will be collected at baseline, after intervention and at follow up. During the study, a weekly measurement of well being (WHO-5), body awareness (BAD-2), and stress (PSS-10) will be performed. What is ESMira? It works without a steady internet connection. All functionality of studies are saved locally in the app and saved data are cached and will be uploaded as soon as there is an internet connection. Personal Feedback: Researcher can set up complex charts that will be automatically calculated out of participants' data. These statistics can be either personalised to the participants or calculated out of all participants' data. Completely anonymous: Each participant gets a random participant id under which all data is collected. ESMira does not collect any personal data at any time. Anonymous Chat: Participants can communicate with the researcher from within the app and stay completely anonymous while doing so. Additionally, researchers can send important messages to all participants of a study. Free and open source: ESMira is developed as a project at Karl Landsteiner University to be used for our own studies and published for the community to use completely free of charge. Find out more at: https://github.com/KL-Psychological-Methodology/ESMira

13. ETHICAL AND REGULATORY CONSIDERATIONS

13.1. Declaration of Helsinki

The Investigator will ensure that this trial is conducted in accordance with the principles of the Declaration of Helsinki.

13.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this trial is conducted in accordance with relevant regulations and with Good Clinical Practice.

13.3. Incentives

Participants can keep the fitness tracker after completing the study as an incentive.

14. FINANCE AND INSURANCE

14.1. Funding

No funding, however, the fitness tracker will be sponsored by University.