University for Continuing Education Krems

Study protocol

Digital Detox Study

A randomized controlled trial with two unblinded, parallel arms assessing the effect of reducing smartphone screen time on mental health

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1. Introduction

1.1. Background

The mental health of young people has deteriorated significantly in recent years. In 2022, as many as 73% of girls and 45% of boys in Austria suffered from moderate depressive symptoms (Haider et al., 2023). Other mental health symptoms were also very common, such as anxiety symptoms (57% among girls and 35% among boys) or sleep problems (34% among girls, 21% among boys) (Haider et al., 2023). Although the causes of this development are undoubtedly multifactorial and individually different, daily smartphone use seems to have a particularly large influence (Humer et al., 2022). This is relevant because in many countries, including Austria, there has been a rapid increase in daily smartphone use: According to the HBSC study, the average time spent on a smartphone in 2022 was 5 hours a day, almost twice as much as in 2018 (Felder-Puig et al., 2021). In addition, there is at least a correlative link between screen time and mental health: A study of over 7,000 young people showed that the probability of depressive symptoms increased up to sevenfold with increasing smartphone usage time (Humer et al., 2022). Anxiety symptoms, sleep disorders, disordered eating behavior, and stress also increased with increasing screen time, while quality of life and well-being were reduced (Humer et al., 2022, Pieh et al., 2021). A stepwise effect can be seen: With each additional hour of daily screen time, the frequency of psychological symptoms increases and well-being decreases (Humer et al., 2022).

A previous randomized controlled trial on the effect of smartphone use reduction on mental health in a relatively homogenous, sociodemographically advantaged, and healthy sample showed significant improvements in depression, well-being, stress, and sleep quality through a reduction in screen time (Pieh et al., 2025).

1.2. Purpose

The planned study aims to test this causal relationship in a larger and, above all, more diverse sample, and to make a more generalizable statement about the relationship. From a scientific point of view, the study offers the opportunity to examine the causality between smartphone use and psychological symptoms in a broader and more diverse sample and thus to test the generalizability of the previous results. From a social perspective, the findings can help to develop targeted prevention and intervention programs that aim to reduce screen time and promote mental health. At a time when digital devices are an integral part of everyday life, the study results could help to promote a more health-conscious relationship with technology and sustainably strengthen mental health.

2. Study objective

The aim of the Digital Detox study is to examine the effect of reduced smartphone use on mental health. The following primary research questions are addressed in the study:

- How does a three-week reduction in smartphone use affect the depressive symptoms of the participants?
- How does a three-week reduction in smartphone use affect the sleep quality of the participants?
- How does a three-week reduction in smartphone use affect the well-being of the participants?
- How does a three-week reduction in smartphone use affect the perceived stress of the participants?

2.1. Primary objectives

The primary objective of the study is to examine the effect of smartphone reduction on mental health parameters: depressive symptoms, well-being, stress, and sleep quality. The following primary hypotheses are tested:

- H1: Reducing smartphone use to ≤ 2 hours/day over 3 weeks leads to a difference in the depressive symptoms of the intervention participants before (t0) and after participating in the intervention (t1).
- H2: Reducing smartphone use to ≤ 2 hours/day over 3 weeks leads to a difference in the sleep quality of the intervention participants before (t0) and after participating in the intervention (t1).
- H3: Reducing smartphone use to ≤ 2 hours/day over 3 weeks leads to a difference in perceived stress of the intervention participants before (t0) and after participating in the intervention (t1).
- H4: Reducing smartphone use to ≤ 2 hours/day over 3 weeks leads to a difference in the well-being of the intervention participants before (t0) and after participating in the intervention (t1).
- H5: The reduction in smartphone use to ≤ 2 hours/day over 3 weeks led to a difference in depressive symptoms between the control and intervention groups at the post-intervention time point (t1).
- H6: The reduction in smartphone use to ≤ 2 hours/day over 3 weeks led to a difference in sleep quality between the control and intervention groups at the post-intervention time point (t1).
- H7: The reduction in smartphone use to ≤ 2 hours/day over 3 weeks led to a difference in perceived stress between the control and intervention groups at the post-intervention time point (t1).
- H8: The reduction in smartphone use to ≤ 2 hours/day over 3 weeks led to a difference in well-being between the control and intervention groups at the post-intervention time point (t1).

2.2. Secondary objectives

The secondary objective focuses on loneliness, craving, and physical activity. The following hypotheses are tested:

- H9: Reducing smartphone use to ≤ 2 hours/day over 3 weeks leads to a difference in the loneliness of the intervention participants before (t0) and after participating in the intervention (t1).
- H10: The reduction in smartphone use to ≤ 2 hours/day over 3 weeks led to a difference in loneliness between the control and intervention groups at the post-intervention time point (t1).
- H11: Reducing smartphone use to ≤ 2 hours/day over 3 weeks leads to a difference in the physical activity of the intervention participants before (t0) and after participating in the intervention (t1).
- H12: The reduction in smartphone use to ≤ 2 hours/day over 3 weeks led to a difference in physical activity between the control and intervention groups at the post-intervention time point (t1).
- H13: Reducing smartphone use to ≤ 2 hours/day over 3 weeks leads to a difference in craving of the intervention participants before (t0) and after participating in the intervention (t1).
- H14: The reduction in smartphone use to ≤ 2 hours/day over 3 weeks led to a difference in craving between the control and intervention groups at the post-intervention time point (t1).

2.3. Exploratory objectives

The influence of smartphone use, i.e. how the smartphone is used during the period of reduction and in which areas the most reduction takes place, as well as craving, loneliness, and physical activity on the primary outcome parameters of mental health (see 2.1) will be explored.

3. Investigational plan

3.1. Study design

The Digital Detox study is designed as a randomized controlled trial with two unblinded, parallel arms (intervention group and control group). Participants will be randomly assigned to two groups. Randomization will take place after an initial eligibility screening. The screening takes place when participants enter the study after they have given their informed consent to participate. After the randomization, the intervention group will start the intervention, a three-week digital detox in which smartphone use is to be reduced to ≤ 2 hours per day, while the control group continues to use their smartphone as before. The intervention phase starts on a Monday and ends on a Sunday three weeks later (see Schedule below). On the Sunday, before the start of the intervention, the mental health parameters (depressive symptoms (PHQ-9), sleep quality (ISI), stress (PSQ-20), well-being (WHO-5), loneliness (three-item loneliness scale), craving (CEQ-F), and physical activity) are measured (baseline survey, t0). At the end of the intervention (Sunday three weeks later), these are measured again (post-intervention survey, t1). After the end of the intervention, the intervention group also returns to their normal, unrestricted smartphone use. Three weeks after the end of the intervention (again on a Sunday), a follow-up survey of the mental health parameters (same as for t0 and t1) takes place (follow-up survey, t2). Baseline, post-intervention and follow-up surveys take place in parallel for both groups. Both groups will also complete items on loneliness and physical activity twice during the intervention (after the first and second week of the intervention) to monitor changes in these variables during the intervention. From the beginning of the intervention (t0) until the follow-up time point (t2), the smartphone screen time of the past week, the smartphone activations, and the most frequently used apps are recorded in the study app via self-report and uploading a screenshot every Monday. Monday was chosen to have a complete picture of the past week's smartphone usage behavior. The study will be performed entirely via a smartphone app (ESMira), which is designed especially to run longitudinal studies.

Schedule

			week 1		week 2		week 3		week 4		week 5		week 6		
upon entering		**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**
	CG	no intervention	no intervention		no intervention		no intervention		no intervention		no intervention		no intervention		
	IG	no intervention	Detox (≤2h)		Detox (≤2h)		Detox (≤2h)		no intervention		no intervention		no intervention		
Elibility screening: Sociodemographic variables Smartphone screen time ≥ 3h/day Psychological, psychotherapeutic, or psychopharmacological treatment PHQ-9 WHO-5 ISI PSQ-20 Loneliness Physical activity	Randomization	**Baseline (t0):** PHQ-9 WHO-5 ISI PSQ-20 CEQ-F Loneliness Physical activity	ST W0 (B)	Weekly (1): Loneliness Physical activity	ST W1	Weekly (2): Loneliness Physical activity	ST W2	**Post-Intervention (t1):** PHQ-9 WHO-5 ISI PSQ-20 CEQ-F Loneliness Physical activity	ST W3		ST W4		ST W5	**Follow-up (t2):** PHQ-9 WHO-5 ISI PSQ-20 CEQ-F Loneliness Physical activity	ST W6

Note. CG = control group; IG = intervention group; ST = screen time; Detox (≤2h) = smartphone screen time restriction to a maximum of 2 hours per day; Sun = Sunday; Mon = Monday; W = week, PHQ-9 = Patient Health Questionnaire; WHO-5 = World Health Organization Well-Being Index; ISI = Insomnia Severity Index; PSQ-20 = short form of the Perceived Stress Questionnaire; CEQ-F = Craving Experience Questionnaire.

The following variables are collected in the study:
Assessed only in the screening:

- Sociodemographic variables: Age (in years), gender, country of residence, highest completed education, current educational/employment status, urban/rural classification of residence.
- Mental health (self-report):
    - Do you have a mental health condition for which you are currently receiving treatment? (yes/no)
    - Are you currently taking medication for a mental health condition? (yes/no)
    - Smartphone usage: Do you use your smartphone for an average of ≥3 hours per day? (yes/no)

Assessed in screening and at all subsequent time points (t0, t1, t2):

- Depressive Symptoms (PHQ-9): The Patient Health Questionnaire (PHQ-9) is used to assess depressive symptoms in its validated German version, consisting of 9 items (Kroenke et al., 2001; Löwe et al., 2004).
- Well-being (WHO-5): The validated German version of the World Health Organization Well-Being Index (WHO-5) is used to assess participants' well-being and consists of 5 items (Brähler et al., 2007; Topp et al., 2015).
- Sleep Quality (ISI): The Insomnia Severity Index (ISI) is used in its validated German version to assess the quality of sleep and consists of 7 items (Bastien et al., 2001; Gerber et al., 2016; Morin et al., 2001).
- Stress (PSQ-20): Stress is assessed using the German version of the short form of the Perceived Stress Questionnaire (PSQ-20), which consists of 20 items (Fliege et al., 2009; Fliege et al.; 2005; Levenstein et al., 1993).
- Loneliness (3-Item Loneliness Questionnaire): Loneliness is assessed using the German version of the Three Items Loneliness Scale, consisting of 3 items (Klein et al., 2021; Reinwarth et al., 2024).
- Physical activity: "On how many of the last 7 days were you physically active for at least 60 minutes?" and "How many minutes did you spend doing sport in the last 7 days?"
- Craving (CEQ-F) *[not in screening]*: Craving is measured using the Craving Experience Questionnaire (CEQ-F) in the German version, for behavioral addictions and smartphone use in particular, and consists of 9 items (Brandtner & Wegmann, 2023; Cornil et al., 2019; Fritz, n.d.).
- Smartphone use (self-report and upload of screenshots of screen time over the last week, activations, and the most frequently used apps).

3.2. Rationale of study design

It is an unblinded two-armed study because the participants are informed about their group allocation before the start of the intervention. This is necessary so that they can reduce their smartphone screen time if they are in the intervention group.

3.3. Rationale of dose/regimen, route of administration, and duration of treatment

Rationale of dose/regimen, route of administration: not applicable.
The intervention period is based on the previous study (Pieh et al., 2025).

3.4. Rationale for choice of comparator

The control group with its unchanged usage behavior is used as a comparator to allow insights into "normal" smartphone usage behavior.

3.5. Purpose and timing of interim analyses/design adaptations

Not applicable.

3.6. Risks and benefits

The preceding study clearly indicates an improvement in well-being, depression, sleep quality, and stress due to the three-week screen time reduction (Pieh et al., 2025). In addition, a higher awareness of one's own media use is to be expected. It can be assumed that participants will gain a better understanding of their habits by examining their smartphone use. This awareness can help them to develop a healthier balance between online and offline activities in the long term. Continuous monitoring during the course of the study gives participants a regular overview of their mental health and well-being. The opportunity to observe changes in these parameters can have a motivating effect and promote commitment to sustainable improvement.

Even if preliminary studies indicate a positive effect of the intervention on mental health (Pieh et al., 2025), it cannot be ruled out that in individual cases mental health may also deteriorate during the intervention. In this case, study participants have the opportunity to contact psychologists from the study team directly via ESMira, without jeopardizing their anonymity. In this case, the contact persons provide information on low-threshold psychological and psychotherapeutic resources in the respective country. The study team maintains a central document, stored on the UWK server, in which adverse effects and their handling are systematically documented.

To prevent foreseeable undesirable effects, transparent communication about the content and objectives of the study takes place in advance. In addition, the study refrains from complete smartphone abstinence, since this may increase the risk of stress, loneliness, or other psychological stress. Furthermore, the study team does not intervene in the smartphone settings of the participants. The guidelines for maximum daily screentime are to be adhered to independently by the participants. Non-compliance is not subject to sanctions.

To ensure the safety and well-being of the participants, a written explanation of the objectives and the course of the study will be provided. The consent of the participants to participate in the study will be obtained. During the study, participants will have the opportunity to contact the study team via a message in ESMira and to report any unwanted effects (e.g. deterioration in mental health). Psychologists from the research team have been defined as the primary contact persons. Participants may withdraw from the study at any time and without having to expect negative consequences. Participants will be informed of this right before they take part in the study. The study team will also be available as a point of contact even after they have withdrawn or left the study.

Measures in the event of foreseeable adverse effects include the provision of resources for low-threshold psychological and psychotherapeutic services. Furthermore, participants can withdraw from the study at any time without negative consequences. Participants are informed of this right before participating in the

study. The responsibility for discontinuing lies with the study participants themselves, while the study team provides the framework for discontinuing without consequences.

4. Population

German-speaking adults of any gender can participate in the study. The inclusion and exclusion criteria are presented below:

4.1. Inclusion criteria

Participants must fulfill the following criteria for study participation:

- At least 18 years old
- Sufficient skills in German
- Daily smartphone use of ≥ 3 hours
- No ongoing psychotherapeutic, psychological or psychopharmacological treatment

4.2. Exclusion criteria

The following persons are not allowed to participate:

- Under 18 years old
- Insufficient skills in German
- Daily smartphone use < 3 hours
- In ongoing psychotherapeutic, psychological, or psychopharmacological treatment

4.3. Recruitment

Participants will be recruited via the university's and the department's social media channels (Instagram: istokay.at and unikrems, and X (formerly Twitter): @PsychUniKrems). These will be used to post and upload stories to provide information about the study. Furthermore, e-mails with information will be sent to universities, colleges, and other educational institutions and associations. The main channel for recruitment will be social media channels.

4.4. Sampling

Convenience sampling is used to recruit participants. The recruitment channels are described above (4.3). Via a link or associated QR code, interested persons can access the study page on ESMira, where they electronically give informed consent to participate in the study and subsequently access the eligibility screening questionnaire, which also asks about the inclusion and exclusion criteria of the study (see 4.1 and 4.2).

5. Treatment (intervention)

The intervention consists of reducing one's daily smartphone screen time to a maximum of two hours for three consecutive weeks.

5.1. Protocol requested treatment

5.1.1. Investigational treatment

The study assessed the variables described under 3.1.

5.1.2. Additional study treatment

No additional study treatments beyond the investigational treatment are requested for this trial.

5.2. Arms

The study has two parallel unblinded arms (control group and intervention group):

1. The intervention group reduces their daily smartphone screen time to a maximum of 2 hours during the three-week intervention.
2. The control group continues to use their smartphone as usual during the intervention phase.

5.3. Randomization and arm assignment

The method of simple randomization is used to assign participants to the two arms purely at random. Randomization takes place after screening. Participants will be informed of the allocation to the arm before the start of the intervention by a message in the ESMira app. All instructions for the intervention period (i.e. reduction of screentime for the intervention group and unrestricted use for the control group) will also be provided in this message.

5.4. Treating the participants

5.4.1. Participant numbering

The anonymity of the participants is ensured in ESMira by a randomly generated user ID (12 numbers/letters, e.g. 4mZm-F8vN-5Vyk).Dispensing the investigational treatment

5.4.2. Handling of study treatment

Not applicable. Handling of investigational treatment

5.4.3. Instructions on study treatment

Participants will receive instructions on what to do during the intervention period via a message in ESMira before the start of the intervention.

5.4.4. Permitted dose adjustments and interruptions of study treatment

Not applicable.

5.4.5. Rescue medication

Not applicable.

5.4.6. Concomitant treatment

Not applicable.

5.4.7. Prohibited treatment

Not applicable.

5.4. Premature participant withdrawal

Participants can withdraw from the study at any time without giving reasons and without negative consequences. To do so, they only have to leave the study in the ESMira app.

5.5. Study completion and post-study treatment

For both groups, participation in the study is completed after they have provided information on their smartphone use at the follow-up point in time (t2). After the study, the study team will be available to answer questions via the email addresses provided. The control group has the option of participating in the intervention after t2 in order to also benefit from the expected positive effects on mental health.

6. Schedule and assessments

The table below lists all assessments from eligibility screening to follow-up (t2). The respective questions and questionnaires are described under 3.1.

Schedule

			week 1		week 2		week 3		week 4		week 5		week 6		
upon entering		**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**	**Sun**	**Mon**
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	IG	no intervention	Detox (≤2h)		Detox (≤2h)		Detox (≤2h)		no intervention		no intervention		no intervention		
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Note. CG = control group; IG = intervention group; ST = screen time; Detox (≤2h) = smartphone screen time restriction to a maximum of 2 hours per day; Sun = Sunday; Mon = Monday; W = week, PHQ-9 = Patient Health Questionnaire; WHO-5 = World Health Organization Well-Being Index; ISI = Insomnia Severity Index; PSQ-20 = short form of the Perceived Stress Questionnaire; CEQ-F = Craving Experience Questionnaire.

6.1. Information to be collected on screening failures

All patients who give informed consent to participate in the study but discontinue at baseline (t0) are considered screening failures. Information on the reasons for discontinuation will not be collected.

6.2. Participant demographics/other baseline characteristics

Participants' sociodemographic characteristics (described under 3.1) will be assessed at the eligibility screening. Baseline data will be collected at t0, right before the start of the intervention.

6.3. Treatment exposure and compliance

The intervention in the form of screen-time reduction is regarded as treatment in this study. The intervention group exposes itself to this intervention. Compliance with the maximum screen time can be checked using the weekly screen-time data (screenshots).

6.4. Efficacy

Not applicable.

6.5. Safety

Not appliable.

7. Safety monitoring

7.1. Adverse events

An adverse event (AE) is any unfavorable medical occurrence (i.e., any unfavorable and unintended sign in a clinical trial participant after written informed consent for participation in the study. Therefore, an AE may or may not be temporally or causally associated with the intervention. One possible AE could be a deterioration in mental health. Measures have been referred to under 3.6.

7.2. Serious adverse events

No serious AE adverse events to be expected.

8. Data review and database management

8.1. Site monitoring

Not applicable.

8.2. Data collection

This is a purely web-based study. The data will be collected using the ESMira application. Questionnaires are scheduled to appear directly in the app at pre-set times and participants receive a notification that they must be completed. Screenshots of smartphone usage are also uploaded in the app.

Data collection and communication with the participants takes place exclusively via the research application ESMira. ESMira can be installed on all smartphones and was developed specifically for scientific studies (especially with longitudinal design). The app not only allows questionnaires to be sent at pre-set times, but also enables completely anonymous communication with the participants. No permanent internet connection is required to use the ESMira app. Completed questionnaires are stored locally in the app and automatically uploaded as soon as an internet connection is available. The research data is stored in encrypted form on a server at the University for Continuing Education Krems. The anonymity of the participants is ensured in ESMira by a randomly generated user-id (12 numbers/letters, e.g. 4mZm-F8vN-5Vyk). Further information about ESMira can be found under: https://github.com/KL-Psychological-Methodology/

8.3. Database management and quality control

Data is stored directly on the university server. In agreement with the data protection officers, the personal data will only be stored for the duration of the study. After that, the data will be stored in a completely anonymized form (deletion of all personal data) without any time limit. Access to the raw research data is restricted to the scientific team at the Center for Mental Health Research at the University for Continuing Education Krems. App developers are not able to access the study data.

Participants can contact the study team anonymously via ESMira and register that they would like to have access to their study-relevant personal data. In this case, the data protection officers will be contacted to ensure a legally correct process.

In accordance with Art. 32 DSGVO, appropriate technical and organizational measures are taken to protect personal data. All scientific staff involved in the research project are bound to data secrecy and regularly take part in data protection awareness training. Only the scientific staff of the Center for Mental Health Research will have access to the raw research data. The data is stored on a local server at the university with access protection. Unauthorized reading, copying, modifying, or deleting is thus not possible. Furthermore, the data is only collected and stored in pseudonymized form. The personal data will only be stored for the duration of the study. After that, it will only be stored in a completely anonymized form.

8.4. Data monitoring committee

Not applicable.

8.5. Adjudication committee

Not applicable.

9. Data analysis

The data analysis will be performed by the researcher at the Center of Mental Health Research at the University for Continuing Education Krems. Unless otherwise specified, all statistical tests will be conducted against a two-sided alternative hypothesis with a significance level of $\alpha = 5\%$. Participants who discontinued the study at the baseline time point (t0) will be excluded from the analysis. Following the intention-to-treat principle, participants will be primarily analyzed according to their arm allocation. Exploratory analyses per-protocol are also possible.

9.1. Analysis sets

There will be only one analysis set containing all collected data.

9.2. Participant demographics and other baseline characteristics

The following variables are collected in the study:
Assessed only in the screening:

- Sociodemographic variables: Age (in years), gender, country of residence, highest completed education, current educational/employment status, urban/rural classification of residence.
- Mental health (self-report):

- Do you have a mental health condition for which you are currently receiving treatment? (yes/no)
- Are you currently taking medication for a mental health condition? (yes/no)
- Smartphone usage: Do you use your smartphone for an average of ≥3 hours per day? (yes/no)

Assessed in screening and at all subsequent time points (t0, t1, t2):

- Depressive Symptoms (PHQ-9): The Patient Health Questionnaire (PHQ-9) is used to assess depressive symptoms in its validated German version, consisting of 9 items (Kroenke et al., 2001; Löwe et al., 2004).
- Well-being (WHO-5): The validated German version of the World Health Organization Well-Being Index (WHO-5) is used to assess participants' well-being and consists of 5 items (Brähler et al., 2007; Topp et al., 2015).
- Sleep Quality (ISI): The Insomnia Severity Index (ISI) is used in its validated German version to assess the quality of sleep and consists of 7 items (Bastien et al., 2001; Gerber et al., 2016; Morin et al., 2001).
- Stress (PSQ-20): Stress is assessed using the German version of the short form of the Perceived Stress Questionnaire (PSQ-20), which consists of 20 items (Fliege et al., 2009; Fliege et al.; 2005; Levenstein et al., 1993).
- Loneliness (3-Item Loneliness Questionnaire): Loneliness is assessed using the German version of the Three Items Loneliness Scale, consisting of 3 items (Klein et al., 2021; Reinwarth et al., 2024).
- Physical activity: "On how many of the last 7 days were you physically active for at least 60 minutes?" and "How many minutes did you spend doing sport in the last 7 days?"
- Craving (CEQ-F) *[not in screening]*: Craving is measured using the Craving Experience Questionnaire (CEQ-F) in the German version, for behavioral addictions and smartphone use in particular, and consists of 9 items (Brandtner & Wegmann, 2023; Cornil et al., 2019; Fritz, n.d.).
- Smartphone use (self-report and upload of screenshots of screen time over the last week, activations, and the most frequently used apps).

9.3. Treatments

The intervention acts as a treatment. During the intervention, the smartphone screen time of the intervention group is reduced to a maximum of 2 hours per day for three weeks.

9.4. Analysis of primary variables

9.4.1. Statistical model, hypotheses, and method analysis

χ^2-Test and independent samples t-tests will be used to examine differences regarding sociodemographic variables and mental health indicators (see 9.2) between the control and intervention group.

In order to examine the effect of smartphone screen time reduction on the participants' mental health (see 2.1), repeated measures ANOVAs (rm-ANOVAs) will be performed. The primary hypotheses focus on the difference between the baseline and the post-intervention time points (t0 – t1) in the intervention group as well as on the difference between the control and the intervention group at t1. An intention-to-treat analysis will be carried out. Arm allocation (control group or intervention group) will be the between-group factor.

Time (t0, t1) will be the within-group factor. Effect sizes will be presented as partial eta squared (η^2 = time × group) or group mean differences.

In a secondary analysis, the difference between the baseline (t0), the post-intervention (t1), and the follow-up time points (t2) in the intervention group as well as the difference between the control and the intervention group at t2 will be additionally examined using the same statistical approach.

In case of baseline group differences, the respective variables will be added as covariates in the rm-ANOVAs. If the sphericity assumptions are violated, corrections will be applied. Corrections for multiple comparisons will be applied in the post-hoc pairwise comparisons.

Percentage changes in the mental health outcomes between the time points will be calculated (Hurst & Bolton, 2004).

Furthermore, subgroup analyses are planned, especially of the subgroup from the intervention group that strictly adhered to the screentime limit (per-protocol), but also with regard to sociodemographic variables (e.g., gender or age) or pre-intervention (t0) mental health parameter scores. The analysis is performed as described above. Due to the planned subgroup analyses, a larger sample is also aimed for than is intended in the sample size calculation for the main analysis.

9.4.2. Handling of missing values/censoring/discontinuations

Assuming that the respective assumptions are met, missing values will be dealt with using maximum likelihood estimation.

9.4.3. Supportive analyses

Not applicable.

9.5. Analysis of secondary variables

The same statistical analysis methods as for the primary variables will be applied (see 9.4).

9.5.1. Efficacy variables

Not applicable.

9.5.2. Safety variables

Not applicable.

9.6. Interim analysis

No interim analysis is planned.

9.7. Sample size calculation

The calculation for the required sample size to detect potential effects was carried out using G*Power. The following parameters were set for an rm-ANOVA with within-between interaction: error probability α = 5%,

power = 90%, effect size partial $\eta^2 = 0.05$, number of groups = 2, number of measurements = 2, correlation among repeated measures = 0.5, and nonsphericity correction $\varepsilon = 1$ (based on the preliminary study from Pieh et al., 2025). The sample size calculation resulted in a total sample of at least 52 participants. A drop-out rate of 40% is expected, hence at least 87 participants must be recruited. The aim is to recruit a sample that is as large and diverse as possible (minimum target: approx. 200 participants). In order to have a sufficiently large sample for planned subgroup analyses, the target is approximately 500 participants.

10. Ethical considerations

10.1. Regulatory and ethical compliance

The study will be conducted in accordance with the guidelines of the Declaration of Helsinki and CONSORT guidelines for non-pharmacological trials. The ethics committee of the University for Continuing Education Krems approved the study's ethics application on December 12, 2024 (EK_GZ_15_2024-2027).

10.2. Informed consent procedures

Informed consent will be obtained from all participants upon entering the study in the ESMira app, before filling in any questionnaires. Participants will give their consent to participate electronically in ESMira. Information on informed consent (information about the study and data protection declaration) will be presented in German. An English translation of it will be provided with the study registration.

10.3. Responsibilities of the investigators and IRB/IEC

The IEC (ethics committee of the University for Continuing Education Krems) received the study protocol, the written informed consent form, information about the recruitment, information about the compensation for subjects (none), all questionnaires intended to be used, a study timeline as well as information about the research app (ESMira). The IEC has reviewed the documents to determine whether the study complies with the ethical guidelines and has assessed it positively.

The ethics committee will be informed about the progress and results of the study.

10.4. Publication of study protocol and results

Key elements of this study protocol will be published in a publicly accessible database for study registrations (clinicaltrials.gov). Upon study completion and finalization of the study report, the results of this study will be submitted to scientific journals for publication.

11. Protocol adherence

The study objectives, the study procedure (schedule), and the data to be collected are defined in this study protocol. Investigators will ensure that they use due diligence to avoid protocol deviations. If an investigator believes that a protocol deviation would improve the conduct of the study, these will be considered protocol amendments. Such a modification will only be made after IEC approval.

11.1. Protocol amendments

Any changes to the protocol will only be made in written form after the approval of the IEC.

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