Self-guided digital mental health promotion targeting young people: Study protocol for a randomized controlled trial of Mindhelper.dk

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Abstract

Background: The high and increasing rates of poor mental health in young people are a global concern. Experiencing poor mental health during this formative stage of life can adversely impact interpersonal relationships, academic and professional performance, and future health and well-being if not addressed early. Yet only a minority of those in need seek help. Research indicates that young people perceive digital mental health support as having many benefits compared to traditional face-to-face services. However, the effectiveness of self-guided digital mental health services is not well documented, and research on their cost-effectiveness is missing.
Mindhelper is Denmark's largest open-access, digital, self-guided mental health service for young people. While it does not provide direct psychological or therapeutic care, it offers practical strategies and tools to promote well-being and address a broad spectrum of mental health challenges, from everyday stress to more complex issues. Despite its widespread use, the effectiveness of Mindhelper has not been evaluated.

Objective: This trial aims to evaluate the effectiveness of building on the results of our feasibility study. We will assess Mindhelper's impact on mental health and well-being, psychological functioning, intentions of help-seeking, and body appreciation among 15-25-year-olds, and provide insights into the service's cost-effectiveness.

Methods: 4,910 15-25-year-olds will be recruited via social media and randomized and allocated to an intervention group (receiving information about Mindhelper.dk) or a control group (no information about Mindhelper.dk). Outcomes are self-assessed and collected at baseline and 2-, 6-, and 12-weeks post-randomization though online surveys, and analyzed using the intention-to-treat approach. Qualitative interviews with intervention group participants will provide complementary insights, and a cost-effectiveness analysis will also be conducted.

Results: Data are not collected.

Conclusions: This study will deliver crucial evidence on the effectiveness of self-guided digital mental health promotion targeting young people. If effective, this highly scalable service may contribute to combating the trend of rising mental health issues among young people and address key challenges in primary care by delivering timely, coordinated, and effective services to young individuals, potentially at a low cost. Clinical Trial: ClinicalTrials.gov NCT06385457; https://clinicaltrials.gov/ct2/show/NCT06385457

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promotion targeting young people. If effective, this highly scalable service may contribute to combating the trend of rising mental health issues among young people and address key challenges in primary care by delivering timely, coordinated, and effective services to young individuals, potentially at a low cost.

Trial Registration: ClinicalTrials.gov NCT06385457; https://clinicaltrials.gov/ct2/show/NCT06385457

Keywords: *Provide 3 to 10 author-selected keywords or short phrases separated with semicolons (;) that will assist indexers in cross-indexing the article and that may be published with the abstract.*

1. Unsupervised
2. Self-management
3. Digital health
4. Well-being
5. Mental health
6. Adolescents
7. Young people
8. Evaluation
9. Effectiveness
10. Psychological functioning

Introduction

The high and increasing rates of poor mental health in young people are a global concern [1]. In Denmark, the proportion of 16–24-year-olds reporting poor mental health rose from 12% in 2010 to 26% in 2023 [2, 3]. If left unaddressed, poor mental health—even below the diagnostic threshold—during this formative stage of life can negatively affect interpersonal relationships, academic and professional performance, and long-term health and well-being[1, 4].

Young people are the age group most affected by mental health problems, yet only a minority of those in need seek help. Barriers to seeking help include concerns about stigma, confidentiality, difficulties navigating mental health services, and a preference for informal help [5-7].

Digital services, such as apps and websites, offer significant potential to enhance the scalability of mental health services. Research indicates that young people perceive digital mental health support as having many benefits compared to traditional face-to-face services, including greater accessibility, interactivity, anonymity, and reduced stigma associated with help-seeking [5, 8-13].

Most digital mental health services focus on addressing symptoms after their onset, primarily targeting depression and anxiety. Digital services designed to reduce these conditions have shown small but promising effects [13-16]. However, evidence for symptoms beyond depression, and anxiety remains limited, making the results more inconclusive [13].

Digital services incorporating an in-person element (e.g. therapist or other health professional) are associated with greater effectiveness, better adherence, and lower dropout rates compared to fully self-guided services [13, 15]. Nevertheless, self-guided services are highly scalable, as they can be delivered to a higher number of users with low additional costs. Although the effects remain mixed, self-guided smartphone apps have shown potential for improving symptoms across various domains, particularly for depression [17].

Most studies assess the effects of an experimental service designed by researchers for testing in a controlled research setting, aimed to reduce one issue, with little research on multicomponent services applied in real-world settings. Samples are often drawn from narrowly defined populations, such as students from single universities or individuals with specific symptomatology, reducing generalizability. Few large-scale randomized controlled trials (RCTs) have been conducted, as most involve fewer than 250 participants [14, 17]. Further, despite being widely considered low-cost, there is a lack of evidence on the cost-effectiveness of digital mental health services targeting young people [13].

Mindhelper is Denmark's largest open-access, digital, self-guided mental health service for young people. While it does not provide direct psychological or therapeutic care, it offers practical strategies and tools to promote well-being and address a broad spectrum of mental health challenges, from everyday stress to more complex issues. Despite its widespread use, the effectiveness of Mindhelper has not been evaluated.

Building on the results of our feasibility study [18], our current research will evaluate Mindhelper's impact on mental health and well-being, psychological functioning, intentions of help-seeking, and body appreciation among 15-25-year-olds. Additionally, it will provide insights into the service's cost-effectiveness. We aim to recruit 4,910 participants making this the largest RCT to assess the effects of a self-guided digital mental health promotion service targeting young people.

Methods

The study protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [19]. It is legally approved by the University of Southern Denmark (11.882) and ethically approved by the Research Ethics Committee of the University of Southern Denmark (24-2933). Furthermore, the study was registered at ClinicalTrials.org before its initiation (NCT06385457).

Intervention: Mindhelper

Mindhelper is a service hosted at Centre for Digital Psychiatry in Denmark and is free to use for everyone. Mindhelpers main service is a website [20] launched in 2016, which provides information, self-help tools, and evidence-based guidance on various mental health challenges young people face today. This includes dealing with anxiety, loneliness, family difficulties, depression, romantic relations, eating disorders and self-harm. Tools and information are derived mainly from the cognitive field, including mindfulness exercises, Acceptance and Commitment Therapy-inspired self-instructions around beliefs, values, and general strategies for good mental health and well-being. The website further serves as a national directory to local youth mental health services for further support and help.

The Mindhelper website also offers a supportive outreach service, where psychology students respond to digital letters sent by young people, supported by experienced psychologists when needed. The letters exchanged are published in an anonymized form, so that other young people with similar concerns or worries may benefit from the supportive advice.

Mindhelper was co-developed between 2014 and 2016 by the Centre for Digital Psychiatry in partnership with young people and four Danish municipalities (Svend-borg, Odense, Faaborg-Midtfyn, and Varde). The primary inspiration for Mindhelper is the Australian platform ReachOut [21].

Throughout its development and dissemination phase, Mindhelper has adopted a participatory approach, co-

designing its resources with young people, parents, teachers, school counsellors, youth workers, psychologists in community care, general practitioners, and youth mental health experts. More than 300 young people have participated in workshops, user panels, and content production teams. Iterative co-production methods, based on the core principles of Design Thinking (Understanding, Defining, Ideating, Prototyping, and Refining), have been crucial in ensuring that service remains relevant and useful to young people [22-24].

Since January 2019, Mindhelper has received permanent funding through a joint agreement between the five Danish Regions and has been freely available and disseminated to young people and youth mental health professionals across the country.

Mindhelper receives approximately 1 million visits a year [25]. Mindhelper's primary target group is 13-20-year-olds, users however also include adults, parents, and youth mental health professionals [25].

In 2024, Mindhelper launched their first mobile application named *Ro* (Ro is Danish for calm), aiming to reduce stress and increase everyday calmness. The app is free to use and may be downloaded for android and iPhone. In the following, the Mindhelper website and the app Ro will be referred to commonly as "Mindhelper".

The research team was not involved in developing Mindhelper or its maintenance or promotion. Partnering with the Centre for Digital Psychiatry meant that the service tested builds on evidence-based information and is built by an expert team. Further, the service is sustainable—independent of research funds—in opposition to most services tested, as Mindhelper was constructed, and is funded and used independently of this study.

Study design

The effects of Mindhelper will be evaluated in a two-armed 1:1 RCT and complemented by qualitative insights from interviews with participants assigned to the intervention group. Figure 1 provides an overview of the study design.

Participants are randomized upon responding to the baseline survey, and based on their group assignment, they will receive information about Mindhelper at the end of the survey (intervention group) or be informed that they have been placed in the control group. All data is collected online (in SurveyXact). Randomization is conducted automatically in the survey setup and is done independently of the participants' baseline responses.

There is no care provider or outcome assessor as all measures are self-reported and collected through online questionnaires. Randomization, invitations for follow-ups, reminders to non-responders, and distribution of information to the intervention group were all done automatically and independently of the research team.

By the end of the baseline survey participants are asked to provide their mobile numbers and invitations to follow-up surveys are sent by SMS. Therefore, it is solely participants completing the baseline survey that can be invited to the following surveys. In our feasibility study participants preferred contact via SMS as compared to email, which is consistent with studies exploring how to engage young people in digital mental health interventions [18, 26].

All participants aged 15 to 25 who complete the baseline survey will be invited to respond to follow-up surveys two weeks after randomization (T2), six weeks after randomization (T3), and 12 weeks after randomization (T4). By the end of the survey at T4, the control group will be informed about Mindhelper and directed to the site.

Our feasibility study revealed very low engagement when participants were merely provided with a link to Mindhelper at the end of the baseline survey [18]. To increase usage in the intervention group, we developed an SMS campaign. Participants will receive 29 messages throughout the study, each offering tips and guidance on using Mindhelper. Each SMS links to a closed section of the website, where participants are introduced to a specific theme or feature through brief texts and videos before being guided to the open site. See Appendix 1 for a detailed overview of the campaign themes.

The recruitment material informs participants that the study evaluates a mental health promotion website for young people, but Mindhelper is not mentioned to prevent promoting its use in the control group. Mindhelper remains publicly accessible during the study, and there is no way to ban participants from the control group's access. However, our feasibility study found that very few control group participants accessed the site, suggesting this is not a significant concern [18].

The intervention group may use the service as much as they like. Participants in the intervention group control group may continue any usual care they receive in addition to the trial.

Non-response is minimized by sending up to two reminders. Additionally, participants who complete all follow-up surveys will be included in a lottery for cinema gift cards (299 DKK ≈ €40 [US $43]), with 200 gift cards being distributed.

At T3, participants in the intervention group will be invited to participate in two interviews (when responding to the survey): one close to T3 and a follow-up interview approximately 12 weeks later. Further details of the qualitative part of the study are presented in a later paragraph of the paper.

At the end of each survey, it is emphasized that the research team does not provide counseling or treatment and will not contact anyone based on their survey responses. Participants (in the intervention and control group) are strongly encouraged to seek help and support if they experience distress or require assistance, and are directed to counseling services, including *Børnetelefonen* and *HØRT* (Danish consulting services for young people). Further, in cases of acute suicidal crises, they are encouraged to contact *Livslinien* (A Danish

service for people with suicidal thoughts) or emergency services.

----------INSET FIGURE 1 HERE ----------

Figure 1: Overview of the study design.

Recruitment

We aim to recruit approximately 4,910 participants via Facebook, Instagram, and Reddit (the final number of participants depends on attrition at 1. follow-up as described under “Sample size calculation”).
The only inclusion criterion is age, with participants required to be between 15 and 25 years old at baseline (T1).
We aim to recruit participants in need of mental health promotion, targeting a study population with below-average mental health and well-being rather than a representative sample. However, as Mindhelper is a universal public health service, we have decided that all participants are eligible regardless of baseline mental health, allowing us to assess the service's effectiveness in the broader target population.

Our feasibility study demonstrated that Facebook and Instagram were effective platforms for recruiting young people and that the self-selection based on the framing of ads resulted in a study population with below-average mental health and well-being: 50% of the sample had experienced a mental illness, and of those, 49% reported daily impairment in the past 12 months [18]. Additionally, 64% of respondents were identified as being at risk for depression or stress based on the World Health Organization-5 Well-being Index (WHO-5) [18].

Before initiating data collection, we defined an optimal study population composition based on the parameters available for targeted ads: gender and age (from user profiles) and geographical location (from IP addresses). We aimed for a sample of 70% women, as young women generally report lower mental health and well-being than young men [3]. To ensure balanced representation, we aimed for an equal distribution across ages, as unpublished data from “Danes’ Health - the National Health Profile 2011” indicated no substantial age-related differences in mental health and well-being among 16–25-year-olds. Similarly, since no significant regional variation was observed in the same data for this age group, we sought to match the regional distribution of the general population in this age group.
The recruitment strategy will be monitored weekly throughout the study period and adjusted to target individuals underrepresented in the sample based on these characteristics.

The ability to create multiple ads targeting different populations, closely monitor their real-time performance, and continuously adjust them makes online advertising a powerful tool for recruiting according to specific demographic requirements. However, as of November 6, 2023, Meta has prohibited direct advertisement to individuals under the age of 18 due to EU legislation. This regulatory change may challenge our goal of

achieving equal representation across age groups, yet it remains our target.

In the feasibility study, we neither defined an optimal study population composition nor adjusted the recruitment strategy, resulting in a sample with 87% women [18]. To increase male participation, we will include Reddit as a recruitment platform in this study. As of 2024, 70% of Reddit's global users were male [27], compared to 52% on Instagram [28] and 57% on Facebook[29]. In Denmark, 41% of Instagram users and 46% of Facebook users are male [30], while Danish user demographics for Reddit are unavailable, we assume they align with global trends.

Figure 2 illustrates the recruitment process, from viewing an ad on one of the platforms to becoming a study participant. From the ads, young people will be directed to a landing page containing information about the study design, data protection, and other details, presented with graphics and a short explainer video[31]. If they choose to participate, they will be guided to the baseline survey and provided with additional information before consenting to participate. The participants are informed that the study is conducted in collaboration between Region of Southern Denmark and the National Institute of Public Health, University of Southern Denmark.

At the end of the baseline survey, the intervention group will be automatically directed to Mindhelper[20], while the control group will receive instructions about the next steps in the study.

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Figure 2: Recruitment flow from advertisement to participant

Measures and outcomes

The data are self-reported and include demographic characteristics, use of Mindhelper, and validated scales for mental health and well-being (see Table 1). Though we include some measures capturing negative aspects of mental health and well-being, the primary focus in the surveys is on positive aspects rather than symptomatology.

The primary outcome is mental well-being, measured using the World Health Organization-5 Well-being Index (WHO-5), while the secondary outcome is well-being and psychological functioning assessed with the Short Warwick–Edinburgh Mental Well-being Scale (SWEMWBS). Additionally, the intention and barriers of help-seeking are explorative outcomes. The impact of Mindhelper will also be evaluated on body appreciation, and an economic effectiveness analysis will be conducted.

Where no suitable scale existed for specific measures, such as intentions to seek help, we developed our own. To maximize the response proportion, we aimed to balance comprehensiveness with brevity, ensuring that surveys are clear, easy to interpret, and completable within 5 to 15 minutes.

Objective data on usage metrics from Mindhelper will not be collected at an individual level, as this is not

possible without violating the core principle of anonymity of Mindhelper users. However, data on the intervention group's interactions with the SMS campaign will be collected at an aggregate level, and self-reported measures of usage of Mindhelper will be collected in the surveys.

Table 1: Overview of measures and outcomes	**Surveys**			
Measures and outcomes	**T1***	**T2***	**T3***	**T4***
Participant characteristics Age (years), gender, primary occupation, educational level, parental educational level, region of residence	X			
Use of Mindhelper				
Digital behaviour when feeling down	X	X	X	X
Use of Mindhelper (in the intervention group)		X	X	X
Thoughts on the SMS campaign (in the intervention group)		X	X	X
Familiarity with/use of Mindhelper and Ro (at T1 for all participants, at T4 for control group)	X			X
Primary Outcome				
WHO-Five Well-Being Index (WHO-5)	X	X	X	X
Secondary outcome				
The Short Warwick–Edinburgh Mental Well-Being Scale (SWEMWBS)	X	X	X	X
Explorative outcome				
Intentions of help-seeking	X		X	X
Barriers of help-seeking	X		X	X
Other measures of mental health and well-being				
Patient Health Questionnaire-4 (PHQ-4)	X	X	X	X
The Short Form Perceived Stress Scale (PSS-4)	X		X	X
2-item Body Appreciation Scale-2 short form (2-item BAS-2SF)	X	X	X	X
Diagnoses with mental health issue	X		X	X
Affected be diagnosis within the last month	X		X	X
Treated for diagnosis within the last month	X		X	X
Use of health care system				
Absence from work/school	X	X	X	X
Contact to the healthcare system	X	X	X	X

**T1: Baseline, T2: 2 weeks after baseline, T3:6 weeks after baseline, T4: 12 weeks after baseline*

Primary outcome: the World Health Organization-5 Well-being Index (WHO-5)

The WHO-5 captures positive aspects of mental health and well-being, aligning well with the promotion-focused objectives of Mindhelper. Further, the measure is brief (five items) and has demonstrated high sensitivity to changes in mental well-being, which is crucial when applied to an evaluation [32].

It consists of five positively framed items asking respondents to rate how often they felt cheerful, calm, active, rested, and interested in life over the past two weeks, using a 6-point Likert scale from 0 (not at all) to 5 (all the time). Scores range from 0 to 25, to standardize, the raw score is multiplied by 4, producing a final score from 0 to 100, where higher scores indicate greater well-being.

The WHO-5 Well-Being Index is a widely recognized measure of mental well-being with extensive validation across diverse populations, including young people, and has been translated into more than 30 languages,

including Danish [32, 33]. Given its widespread use in mental health research using the WHO-5 allows for comparability with other studies,

Secondary outcome: The short Warwick–Edinburgh mental well-being scale (SWEMWBS)

SWEMWBS, like WHO-5, is used to assess mental health and well-being by focusing on positive mental health aspects. It is a seven-item questionnaire, focusing on the past two weeks, covering aspects of both feeling good and functioning well, including optimism, relaxation, problem-solving, and interpersonal closeness. Each item is rated on a 5-point Likert scale from 1 ("none of the time") to 5 ("all of the time"), with total scores indicating overall well-being; higher scores reflect greater well-being. Where the WHO-5 is an affective measure focusing on emotions and energy, the SWEMWBS is a hybrid measure that in addition to measuring positive emotions also includes aspects of functioning [34].

SWEMWBS is derived from the original 14-item version and is validated for screening mental well-being in both general and clinical populations, including young people, and has proven sensitive to changes [35].

Explorative outcome: Intentions of help-seeking

There is no standard approach for measuring intentions and barriers of help-seeking, and existing studies have employed a wide range of measures and definitions [5].

To retrieve a comprehensive measure of young people's intentions of help-seeking we developed our own questions:

Imagine that you have been feeling very down over the past couple of months. Everything feels overwhelming, and you have started to feel that life is meaningless.
How likely is it that you would seek help or support from the following if you found yourself in this situation?

(1) Family, (2) Friends, (3) Partner, (4) A healthcare provider (e.g., doctor or psychologist), (5) Teacher, study counselor, manager, or HR., (6) Internet search (e.g. Google search or ChatGPT), (7) Social media (e.g., Instagram, TikTok and Reddit), (8) Telephone/chat counseling (e.g., Børnetelefonen or Headspace). Response categories included: "Very likely", "Likely", "Unlikely", "Very unlikely", and "Don't know/don't have".

The intention was to present the responders with a scenario that we consider to be of severity demanding support and help. Further, a scenario related to symptoms of depression was chosen as this is one of the most common issues among young people.

If participants indicate that they are unlikely or very unlikely to seek help from the listed sources of support, they are prompted to select their reasons from the following categories: (1) "I don't think they can help me", (2)"I prefer to handle it by myself", (3)"I am afraid of burdening them", (4)"I find it embarrassing/shameful to feel this way", (5)"I have sought help but did not receive it", (6)"I don't believe I can get better", or (7)

"Other, please describe."

Additionally, all participants are asked what factors might encourage them to seek help for mental health issues through an app or website and what barriers prevent them from doing so, explored through four different phrasings in open-text questions.

Other effect measure: 2-item Body Appreciation Scale-2 short form (2-item BAS-2SF)

The body appreciation scale focuses on positive body image and not just body appearance. Since its release in 2015, the BAS-2 has been translated into over 20 languages and is well-validated. BAS-2 consists of 10 items, however, Tylka et al.'s work demonstrated that two items explain over 95% of the variance captured by the full 10-item questionnaire, named 2-item BAS-2SF [36]. To shorten the survey, we decided to just include these two items ("I feel love for my body" and "I am comfortable in my body"). We are using a Danish translation of the BAS-2, previously tested among 12–19-year-olds [37]. The 2-item BAS-2 has not yet been validated in a Danish context, nor among 15-25-year-olds, however, we are currently conducting this validation and will consider these results when interpreting our findings.

Tests of surveys and set-up

The initial survey was pilot tested through cognitive interviews with five informants aged 15-25. This process aimed to assess how the questions were interpreted and to identify potential challenges in responding to the surveys [50]. Special attention was given to questions we had developed ourselves. Based on the informants' feedback, the wording was adjusted for clarity, categories were refined to better capture expected answers, and some questions were omitted due to misinterpretations. Additionally, as the preexisting scales for intentions of help-seeking were found to be unfeasible, the researchers constructed a new scale for the study, inspired by preexisting scales and the informants' comments. The constructed scale was tested among four new informants aged 15-25, and two from the initial test, and adjusted accordingly.

Due to technical difficulties, an unplanned test phase of the survey setup was conducted. During this phase, 323 respondents, recruited via Facebook and Instagram, completed the baseline survey and were invited to participate in the follow-up surveys. The intervention group also received the SMS campaign. However, technical errors led to some participants being invited to follow-up surveys at incorrect times, and most participants did not receive reminders for non-response. Additionally, some participants in the intervention group received the SMS campaign late or not at all.

This phase allowed us to thoroughly assess the surveys. We reviewed all participants' comments and corrected or omitted questions that did not work as intended.

Sample size calculation

We performed a sample size calculation, considering an average effect size of 0.1 in mental well-being (on the WHO5 scale) at T2, to be of public health relevance (equal to an improved WHO-5 score of 1.94 points on average in the intervention group compared to the control group). Even small effects on individual mental health outcomes can lead to a major impact at a population level, particularly when the service can be scaled widely and reach a large target audience.

We applied the conventional levels of statistical power (0.8) and level of significance (0.05) and assumed a standard deviation of 19.4 at baseline among the intervention- and control groups combined (based on data from the feasibility study) [18]. Based on these assumptions at least 3,142 participants were required (1,571 in each group). In the test phase, we retrieved a response proportion of 64% at T2 (primary endpoint), 53% at T3, and 48% at T4. Assuming a similar retention proportion we aim to include 4,910 participants. The proportion of participants responding to the follow-up surveys will be regularly reviewed to evaluate if the assumption on retention in the sample size calculation is correct or if the number of participants included should be increased or decreased.

Planned statistical analysis

We will evaluate the effect of Mindhelper on multiple outcomes, as illustrated in Figure 3.

Firstly, we will conduct a randomization check and a dropout analysis.
The primary analyses will follow the intention-to-treat principle, including all participants according to their randomized allocation, regardless of intervention usage, and will be based on imputed data in cases of missingness. Missing data will be handled by multiple imputations using information from all time points [38]. To test the robustness of the findings, sensitivity analyses will be conducted among complete cases. Additionally, we will assess the complier average causal effect using the “contamination-adjusted intention-to-treat” method, an instrumental variable approach that accounts for adherence while preserving the benefits of randomization [39]. In this analysis, self-reported Mindhelper usage at T4 in both the intervention and control groups will serve as the measure of adherence.

Analyses of data and interpretation of results will be done masked to the allocation of participants. No interim analysis will be conducted during the trial.

The following section outlines the planned statistical analysis of each outcome and the cost-effectiveness analysis. A detailed statistical analysis plan will be made publicly available before initiating any outcome analyses and unblinding the data.

----------INSET FIGURE 3 HERE ----------

Figure 3: Overview of the planned analysis.

The effects of Mindhelper on mental well-being and psychological functioning

The primary analysis will compare mean mental well-being, measured by WHO-5, between the intervention and control groups at T2, adjusted for baseline WHO-5 scores. If model assumptions are met, we will use a linear regression model. Psychological functioning, the secondary outcome measured by SWEMWBS, will be analyzed similarly as a continuous outcome, also adjusted for baseline values.

T2 was chosen for the primary assessment of effect because Mindhelper aims to provide immediate support and advice when problems arise. Most users visit the site for a shorter period rather than regularly over multiple weeks.

If the model assumptions are met, long-term effects will be evaluated at T3 and T4 using a repeated measures linear regression model.

To assess variation in effect by participants' gender (male, female, other) and socioeconomic background (parents' highest educational attainment), analyses will be stratified accordingly. Additionally, we will stratify by baseline mental well-being, expecting Mindhelper to be most effective for participants with moderate mental well-being (WHO-5 scores between 36 and 50), compared to those at high risk of depression or long-term stress (WHO-5 scores between 0 and 35) and those with mental well-being scores within the average range of the general population (WHO-5 scores above 50). Further, this stratified analysis will enable us to assess potential negative side effects of the intervention, assessing if the intervention group with WHO-5 scores above 50 at baseline has decreasing mental well-being compared to the control group.

The effects of Mindhelper on intentions of help-seeking

To evaluate the impact of Mindhelper on help-seeking intentions, we will compare scores on the constructed scale between the intervention and control group at T3, adjusted for baseline values. Potential long-term effects will be assessed at T4 using a model accounting for repeated measures. We selected T3 for this evaluation because we hypothesize that changes in help-seeking intentions take longer to manifest compared to the primary and secondary outcomes.

The eight categories of support will be assessed separately. Further, we will categorize the sources into three groups: informal sources (categories 1, 2, and 3), formal sources (categories 4, 5, and 8), and self-guided sources (categories 6, and 7). Special attention will be given to category 6, which is the most common way to access Mindhelper.

The severity of mental health issues at baseline, along with prior help-seeking behaviours, may influence both use of Mindhelper and its effect on help-seeking intentions. To account for this, analyses will be stratified by symptoms of depression and anxiety (PHQ-4), and intentions of help-seeking at baseline. Among those with a

mental health diagnosis, we will further stratify by baseline levels of impairment by mental health diagnosis within the last month (daily, weekly, more seldom than weekly, not affected, don't know), and whether any treatment was received within the past month for the diagnosis (treatment received, on waitlist for treatment, no treatment received).

The effect of Mindhelper on body appreciation

The effect of Mindhelper on body appreciation will be assessed by comparing body appreciation scores, measured using the 2-item BAS-2SF [36], between the intervention and control groups at T2, using a linear regression model, if model assumptions are met, and adjusted for baseline scores. If model assumptions are met, potential long-term effects will be evaluated at T3 and T4 using a repeated measures linear regression model.

Additionally, we will explore the mediating role of mental well-being and psychological function (WHO-5 and SWEMWBS) in the relationship between Mindhelper and body appreciation. The mediation analysis will estimate the natural direct and indirect effects [40], providing insight into how mental well-being and psychological function may explain any influence of Mindhelper on body appreciation.

Cost-effectiveness analysis

The cost-effectiveness analysis will be performed by constructing a standard incremental cost-effectiveness ratio (ICER) expressing the additional cost per mean mental well-being score, measured by WHO-5, gained from the randomization to Mindhelper compared with standard care [41]. The analysis will apply standard techniques from economic evaluation aimed at estimating costs per quality-adjusted life years gain. The results from this analysis will contribute to the evidence-based economic evaluation of interventions aimed at increasing mental health and well-being.

Incremental estimates of costs and mental well-being score gained will be assessed in a regression model. To examine the second-order uncertainty of the estimated ICERs a probabilistic sensitivity analysis utilizing a 5,000 bootstrap re-sample with a 95% confidence interval will be conducted. Cost-effectiveness planes illustrating the re-sampled ICERs and cost-effectiveness acceptability curves (CEACs) at T2-T4 will be constructed to show the probability that the intervention is cost-effective given varying threshold values for an additional change in the mean mental well-being score gained. No standardized fixed threshold for the value of an additional mean mental well-being score gained from a new health intervention exists. Therefore, the probability of cost-effectiveness will be investigated for several thresholds e.g. values ranging from 0 to 500,000 DKK.

The information includes self-reported all-cause demand for acute health care services, GP visits, usage, and absence from employment in the project period. The average unit cost of acute health care usage and average

hourly wage earnings depending on gender and age will be used in the economic evaluation. For the intervention group operating costs related to Mindhelper will also be included based on the overall cost per user. These costs cover development, maintenance, and costs for technical support for the service. Cost estimates will be calculated based on list prices from providers and scenarios of changes in the number of users will be explored.

Transportability of results

To assess how many young Danes may benefit from Mindhelper, if it shows to be effective, we will compare the characteristics of our sample to a nationally representative sample of 31,420 young Danes aged 15-25. The national sample, drawn from the study 'Young in 2023 – Room for Everybody?' includes self-reported data on demographics, WHO-5, and PHQ-4 [42]. Further, we will use the national sample to retrieve information on how our study population varies from a representative sample.

Qualitative contributions

To gain a deeper understanding of how young people use and integrate self-help tools from Mindhelper in their everyday lives to promote mental health, a qualitative interview study will be conducted. 20 young people will be interviewed twice, approximately three months apart. Participants for the interviews are recruited from the intervention group at T3. From the pool of participants consenting to be contacted to participate in interviews, 20 participants will be selected considering gender, age, region of residence, and medical history of mental disorders to ensure a diverse group. This information will be based on responses to the baseline survey and solely used for selection purposes, without influencing the themes of the interviews.

Selected respondents will be contacted via SMS to arrange a time for the first interview. After the first interview, respondents will again be contacted via SMS to schedule the second interview. Upon completing both interviews, participants will receive a cinema gift card via SMS. Each interview will last up to one hour and follow a semi-structured interview guide. The interviews will be conducted by AOK via phone or Teams/ Zoom, based on the participant's preference. They will be audio-recorded and transcribed verbatim. Conducting the second interview after T4 will also allow for insights into how respondents use Mindhelper following the SMS campaign’s end. Themes for the first and second interviews are shown in Table 2. The qualitative data analysis program NVivo will be used to process all data, with interviews analyzed according to the research questions, systematic text condensation, and template analysis [43, 44].

Table 2: Themes for the first and second interview

Theme	1. interview	2. Interview
Background Gender, age, region of residence, primary occupation	x	

Knowledge of Mindhelper How did they become aware of Mindhelper?	x	
Use of Mindhelper Have they used Mindhelper – before or during the SMS campaign?	x	
How have they used Mindhelper? What (topics/features) have they used on Mindhelper?	x	x
Use of Mindhelper after SMS campaign ended? Future use of Mindhelper?		x
Impact of Mindhelper What has the impact been? Are there any areas for improvement on Mindhelper?	x	x
Handling mental health struggles What challenges does the young person face? Behavior in response to mental health struggles	x	
Any changes since last time?		x
Digital Behavior How is the internet used in relation to mental health topics? Where do they get their information?	x	
Help-Seeking – Online vs. Network When do they use the internet, and when do they turn to friends/family or professionals?	x	

Discussion

This is the first large-scale RCT to evaluate the effects of a digital, multi-component, self-guided mental health promotion service among young people. The large sample size enhances statistical power, enabling the detection of even small effect sizes that, while modest at the individual level, could generate substantial impact at the population level if the service is widely scalable and accessible, as is the case with Mindhelper. Additionally, this study includes a more diverse participant sample than previous research, encompassing a broader population beyond specific university settings or clinical symptom profiles. This diversity may more accurately reflect the potential user base for the intervention.
This is the first study to assess the cost-effectiveness of a digital, self-guided mental health promotion service targeting young people.

Mindhelper is publicly accessible and will continue to be so during the trial, raising the risk of exposure misclassification, which could dilute any observed differences between intervention and control groups. This misclassification would likely bias results toward the null, underestimating the intervention's effect. However, in the feasibility study, very few control group participants accessed the site[18], and thus we do not consider this to be a major risk.

Individuals most commonly access Mindhelper via diagnostic and research-related search queries through search engines (e.g., Google), where users are organically drawn to the content. In contrast, the Mindhelper

study actively directs content to the intervention group. As a result, our study deviates from the natural usage patterns and evaluates the combined effects of the SMS campaign and Mindhelper. Conducting the study in Mindhelper's natural usage context would preclude the establishment of a control group, thereby making it impossible to evaluate its effects within the framework of an RCT.

A key challenge is expected to be adherence in the intervention group, meaning the extent to which participants in the intervention group engage with Mindhelper. Our feasibility study indicated (very) low engagement when participants were solely provided a link to Mindhelper by the end of the baseline survey [18]. Therefore, the SMS campaign was developed aiming to boost adherence, however, we do not know yet whether this was sufficient.

Low adherence could lead to misclassification of exposure within the intervention group, potentially biasing results. If non-adherence is unrelated to mental health outcomes (non-differential misclassification), this misclassification could reduce observed intervention effects. However, if non-adherence is related to mental health outcomes (differential misclassification) this could either inflate or attenuate the observed effect, depending on adherence patterns. We will conduct sensitivity analyses based on the as-treated principle (Complier Average Causal Effect) to assess potential effects under full adherence. Adherence data will be collected in binary format (use yes/no) at T2-T4 for the intervention group. For the control group adherence will be assessed at T1 and T4. In the feasibility study, participants' self-reports on specific Mindhelper features used did not align with their actual web history [18]. Therefore, we have revised our approach, asking the intervention group to describe how they have used Mindhelper and/or Ro appen in open-text questions, which will be coded with natural language processing models. Further, qualitative information will provide insights into participant engagement and reasons for non-use, and aggregated data on participants' interaction with the SMS campaign will provide information of adherence.

It must be noted that the self-guided nature of Mindhelper and the diversity of topics covered, means that adherent participants in the intervention group may engage with different content and receive varying "doses" of the intervention, which aligns with the real-world application but makes the evaluation more complex.

Low retention rates are a major challenge in digital mental health trials [45]. Particularly self-guided ones, as an example, the average level of dropout of treatment for depression was found to be 26% in self-guided services and 72% in guided services [46]. Retention proportion will be regularly reviewed to evaluate if the assumption on retention in the sample size calculation is correct or if the number of participants included should be revised, to secure the statistical power of the primary analysis. Missing data will further be addressed through multiple imputations). If we retain a response proportion of 64% at T2 (primary endpoint), as was the case in the test phase of this study, this may not be as critical as in other studies of self-guided digital services. However, non-random dropout could still bias the findings, potentially skewing the results

and overestimating or underestimating the true impact of Mindhelper, depending on the characteristics of those who drop out compared to those who remain in the study.

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SHH, APF, LCT, and AOK conceptualized the study and its design. SHH is the main responsible for the management of the study, coordination of recruitment, and conduction of the RCT with support and supervision from LCT and APF. AOK is primarily responsible for the qualitative contributions, and IPM is primarily responsible for the cost-effectiveness analysis. SHH drafted the initial manuscript, and all authors critically reviewed and approved the final version.

During the preparation of this manuscript, SHH used ChatGPT to improve the readability and language of the manuscript. After using this tool/service, SHH reviewed and edited the content as needed and the authors take full responsibility for the content of the published article.

Conflicts of Interest

The authors declare no competing interests. The evaluation will be conducted independently, although the authors collaborated with the team that developed and maintain Mindhelper. Further, the team of Mindhelper has developed the SMS campaign, the landing page, and has been vital for the practical setup of the evaluation. This collaboration did not influence the study's design or the planned data analysis.

Abbreviations

PHQ-4: Patient Health Questionnaire-4

PSS-4: The Short Form Perceived Stress Scale

RCT: randomized controlled trial

SWEMWBS: The Short Warwick–Edinburgh Mental Well-Being Scale

WHO-5: World Health Organization-5 Well-being Index

2-item BAS-2SF: 2-item Body Appreciation Scale-2 short form

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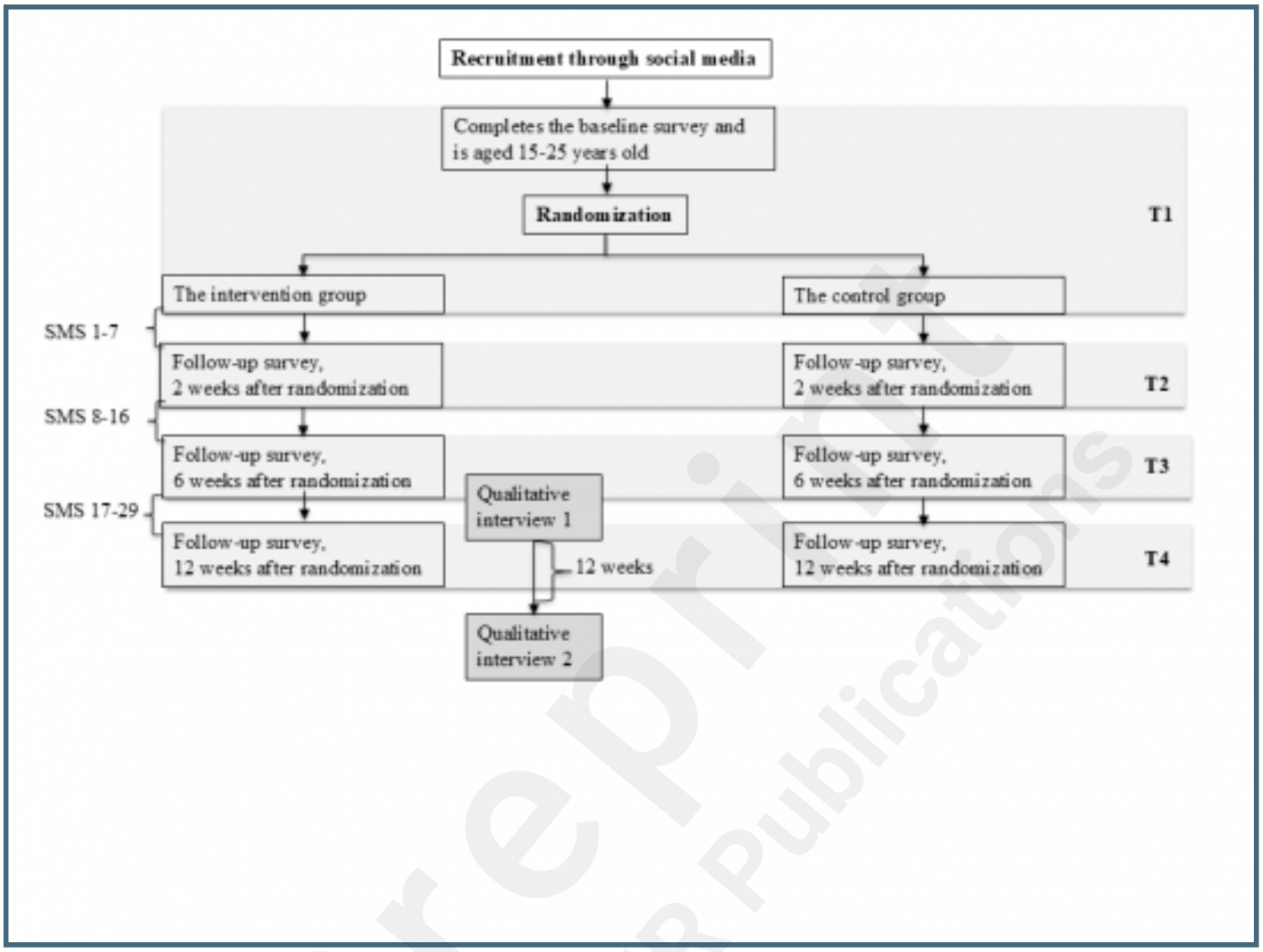
Appendix 1: Themes and timing of the SMS campaign.

No	Theme	Distribution time
	Start of study	Day 0: Be assigned to the intervention group after completing the baseline survey.
1	Welcome	Day 1
2	The alternate breath	Day 3
3	Gratitude list	Day 5
4	Online course on anxiety	Day 7
5	Self-care	Day 9
6	Meet Amalie and Victor from the letterbox	Day 11
7	Ro: an app for stress	Day 13
	2. survey distributed	Day 14
	Reminder to respond to 2. survey	Day 15
	Second reminder to respond to 2. survey	Day 16
8	Falling a sleep	Day 17
9	Worries	Day 20
10	End the day by focusing on the good things in your life	Day 23
11	Box Breathing	Day 26
12	You are not alone if you are having a hard time	Day 29
13	Mindfulness course	Day 32
14	Share your problems with others	Day 35
15	Halfway there, a high-five from Linn	Day 38
16	Write a letter of gratitude to someone you appreciate	Day 41
	3. survey distributed	Day 42
	Reminder to respond to 3. survey	Day 43
	Second reminder to respond to 3. survey	Day 44
17	Conversation cards about friendship	Day 45
18	Get to know new people	Day 48
19	Nervousness	Day 51
20	Pomodoro (Difficulty concentrating)	Day 54
21	Honey depots	Day 57
22	Course on prioritization and planning	Day 60
23	Discontent - gratitude	Day 63
24	Online course on anxiety (also presented on day 7)	Day 66
25	Three mini-meditations	Day 70
26	Stress	Day 74
27	Be kind to yourself when life is hard	Day 78
28	Shake tension out of the body	Day 81
29	Thank you for now	Day 83
	4. survey distributed	Day 84
	Reminder to respond to 4. survey	Day 85
	Second reminder to respond to 4. survey	Day 86
	End of study	

Supplementary Files

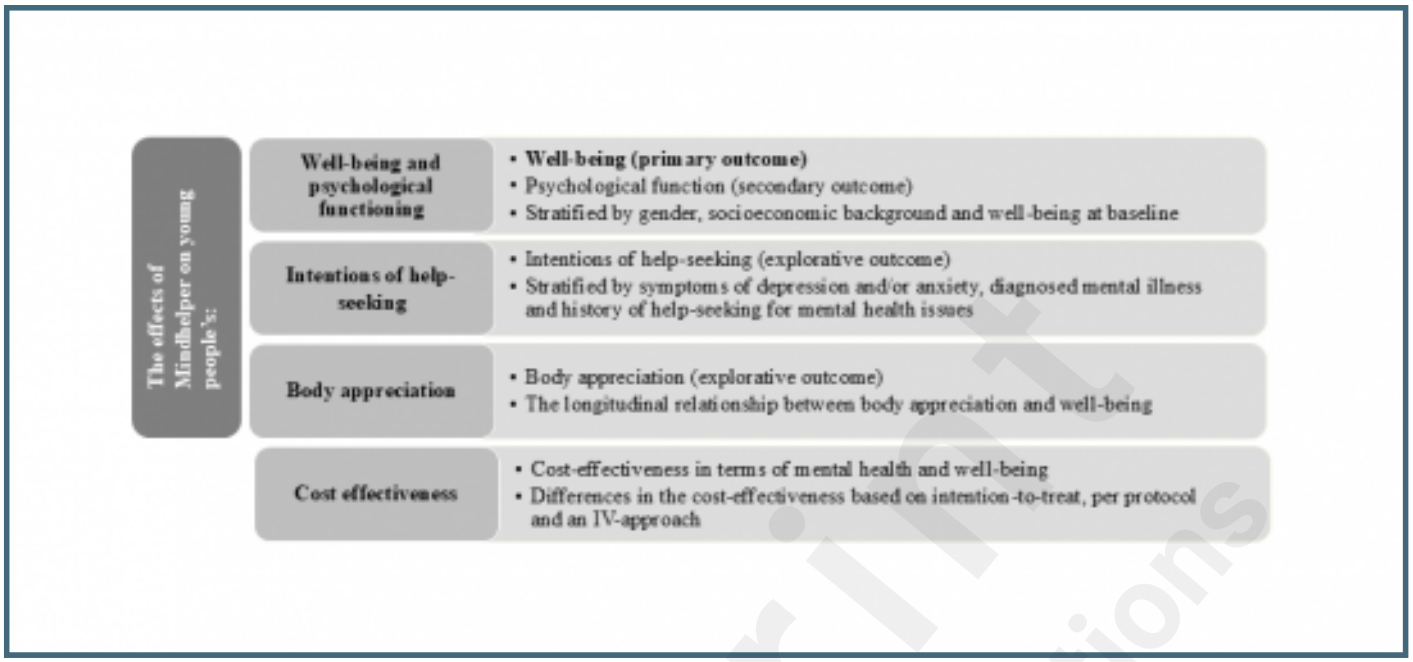
Figures

Overview of the study design.



Recruitment flow from advertisement to participant.

Overview of the planned analysis.



CONSORT (or other) checklists

CONSORT-EHEALTH (V 1.6.1) - Submission Publication Form.
URL: http://asset.jmir.pub/assets/fa0bf790659dbfcb94b047d254bd38da.pdf