

Building an AI Predictive Analytics Dataset to Optimize Engagement in a Self-Guided Resiliency Course for Ukrainian Refugees: A Randomized Controlled Trial Protocol Using Behavioral Economics

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Abstract

Background: Digital interventions for mental health are pivotal for addressing barriers such as stigma, cost, and accessibility, particularly for underserved populations. While the effectiveness of digital interventions has been established, poor adherence and lack of engagement remain critical factors that undermine efficacy. Millions of individuals will never have access to a trained mental health practitioner, so there is substantial need for highly tailored and engaging self-guided resources. This study builds on a prior study that successfully leveraged behavioral economics (nudges and prompts) to enhance engagement. Building on that study, this research will focus on building a predictive analytics data set for a specific, geographically diverse population.

Objective: Using the EvolutionHealth.care platform, this 6-arm randomized controlled trial (RCT) aims to analyze user engagement with randomized tips and to-do lists within a resiliency course tailored for Ukrainian refugees affected by the ongoing humanitarian crisis (?????? ????). Insights will inform the development of an AI-based personalization system to optimize engagement and address behavioral health challenges. Secondary objectives include identifying demographic and behavioral predictors of engagement and creating a scalable, culturally sensitive intervention model.

Methods: Participants will be recruited through digital outreach, enrolled anonymously, and randomized into six groups to compare combinations of tips, nudges, and to-do lists. Engagement metrics (e.g., clicks, completion rates, session duration) and demographic data (e.g., age, gender) will be collected. Statistical analyses will include comparison between arms and interaction testing to evaluate the effectiveness of each intervention component. Ethical safeguards include IRB approval, informed consent, and strict data privacy standards.

Results: The primary outcome is user engagement with randomized prompts. Secondary outcomes include correlations between engagement and demographic or behavioral characteristics. Findings will establish a robust dataset to train an AI-driven personalization engine for digital mental health interventions.

Conclusions: This trial represents a novel approach to behavioral health research by integrating AI-ready datasets and randomized experiments to enhance engagement. By targeting a culturally sensitive and underserved population, the study contributes valuable insights into scalable, personalized digital health solutions. Clinical Trial: <https://doi.org/10.17605/OSF.IO/34RMG>

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Original Manuscript



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Abstract

Background: Digital interventions for mental health are pivotal for addressing barriers such as stigma, cost, and accessibility, particularly for underserved populations. While the effectiveness of digital interventions has been established, poor adherence and lack of engagement remain critical factors that undermine efficacy. Millions of individuals will never have access to a trained mental health practitioner, so there is substantial need for highly tailored and engaging self-guided resources. This study builds on a prior study that successfully leveraged behavioral economics (nudges and prompts) to enhance engagement. Building on that study, this research will focus on building a predictive analytics data set for a specific, geographically diverse population.

Objective: Using the EvolutionHealth.care platform, this 6-arm randomized controlled trial (RCT) aims to analyze user engagement with randomized tips and to-do lists within a resiliency course tailored for Ukrainian refugees affected by the ongoing humanitarian crisis (Спільна Сила). Insights will inform the development of an AI-based personalization system to optimize engagement and address behavioral health challenges. Secondary objectives include identifying demographic and behavioral predictors of engagement and creating a scalable, culturally sensitive intervention model.

Methods: Participants will be recruited through digital outreach, enrolled anonymously, and randomized into six groups to compare combinations of tips, nudges, and to-do lists. Engagement metrics (e.g., clicks, completion rates, session duration) and demographic data (e.g., age, gender) will be collected. Statistical analyses will include comparison between arms and interaction testing to evaluate the effectiveness of each intervention component. Ethical safeguards include IRB approval, informed consent, and strict data privacy standards.

Results: The primary outcome is user engagement with randomized prompts. Secondary outcomes include correlations between engagement and demographic or behavioral characteristics. Findings will establish a robust dataset to train an AI-driven personalization engine for digital mental health interventions.

Conclusions: This trial represents a novel approach to behavioral health research by integrating AI-ready datasets and randomized experiments to enhance engagement. By targeting a culturally sensitive and underserved population, the study contributes valuable insights into scalable, personalized digital health solutions.

Trial Registration: <https://doi.org/10.17605/OSF.IO/34RMG>

Keywords: Digital mental health, Behavioral economics, Engagement, Attrition, AI-driven personalization, Machine learning, Self-guided therapy

Introduction

Background

Self-guided digital mental health interventions play a crucial role in overcoming barriers such as stigma, cost, and accessibility, particularly for underserved populations [1-3]. While their efficacy is well documented in meta studies [4-7], low adherence and lack of engagement limit their potential impact in publicly available interventions [8-14].

Optimizing engagement is crucial as research suggests dose-response relationships; higher engagement is associated with better outcomes such as improvements in mental health [15-17]. This mirrors the commercial world, where higher user engagement results in increased revenue [18, 19], and research investigating ways to increase participation is common.

For example, a 2015 study revealed that LinkedIn conducted over 400 controlled engagement experiments per day [20]. The language app Duolingo regularly conducts controlled experiments to assess the impact of features to make learning more engaging [21]. Meta (Facebook and Instagram) teaches, and technically enables, business customers to conduct randomized A/B experiments to optimize ad messaging and conversion [22].

Leveraging similar strategies that commercial platforms use to increase engagement holds the potential to both enhance the user experience in digital mental health and increase overall effectiveness. To that aim, this study builds on prior research on the EvolutionHealth.care platform, which leveraged behavioral economics to tailor user experiences with the goal of increasing platform engagement [23, 24].

For reasons described below, self-guided digital health has not been adequately funded [25-27] and falls far behind other large-scale commercial platforms that rely on increasing engagement.

Telehealth: a digital health distraction

Intensified by the COVID-19 pandemic, digital health interventions have become increasingly common. Investment in mental health treatment, mainly telehealth, has seen significant growth [28, 29].

In 2021, US-based mental and behavioral health companies attracted approximately \$6.9 billion in funding, nearly tripling the amount raised in 2019 [30]. Overall, from 2020 to 2022 global investments in digital health, including online psychological counseling, exceeded \$100 billion [31, 32]. However, the telehealth sector, particularly companies offering online counseling, are facing significant challenges related to market saturation, intense competition, profitability, and workforce shortages [33].

Other factors contributing to economic instability include high costs related to

patient acquisition and retention, and regulatory demands [34]. While demand for telehealth services increases, there is a projected shortage of trained professionals [35, 36]. Exacerbated by low compensation, high caseloads, burnout, complex credentialing processes, these issues are estimated to extend into the next decade [37].

This counselling crisis extends beyond America. Globally, the WHO estimates a deficit of 1.2 million mental health professionals, including 55,000 nurses, 628,000 nurses in mental health settings, and 493,000 psychosocial care providers across 144 low- and middle-income countries [38]. This will result in a significant gap that requires comprehensive resource allocation, increased investment in mental health education, policy reforms, and innovative approaches to treatment [39, 40].

Other barriers

Those who require access to mental health support often face significant barriers. According to the National Institute of Mental Health (NIMH), in 2022, 50.6% of adults with any mental illness received treatment [41]. The National Alliance on Mental Illness (NAMI) reported that in 2021, 65.4% of adults with serious mental health illness received treatment, suggesting that those with more severe conditions received help, while a significant portion remains untreated [42].

Disparities in mental health treatment are observed across various populations. Racial and ethnic minorities frequently encounter difficulties caused by cultural stigma and a shortage of culturally competent care. There are also significant geographic differences, with rural areas often having fewer resources and mental health practitioners versus urban locations.

In Ukraine, healthcare shortages are common. For example, there are almost 13 thousand vacancies in the healthcare sector [43]. Although 30% of Ukrainians live in rural areas, only 5.3% of medical doctors and 11.5% of middle and junior medical staff work outside of urban centers [44]. A recent study indicated the need for the digitization of health care to ensure equal access to healthcare services [45]. Although the interactive resiliency course will be primarily built for refugees, core course elements will also be adapted to consider the needs to Ukrainians living in rural areas.

Course content will

These gaps are made worse by socioeconomic factors such high co-payments, high treatment expenses, and lack of insurance. These treatment disparities are evident across gender, age, and geographic location [46, 47]. Socioeconomic issues like, lack of insurance, high treatment costs, and high co-pay costs exacerbate the issue [48, 49].

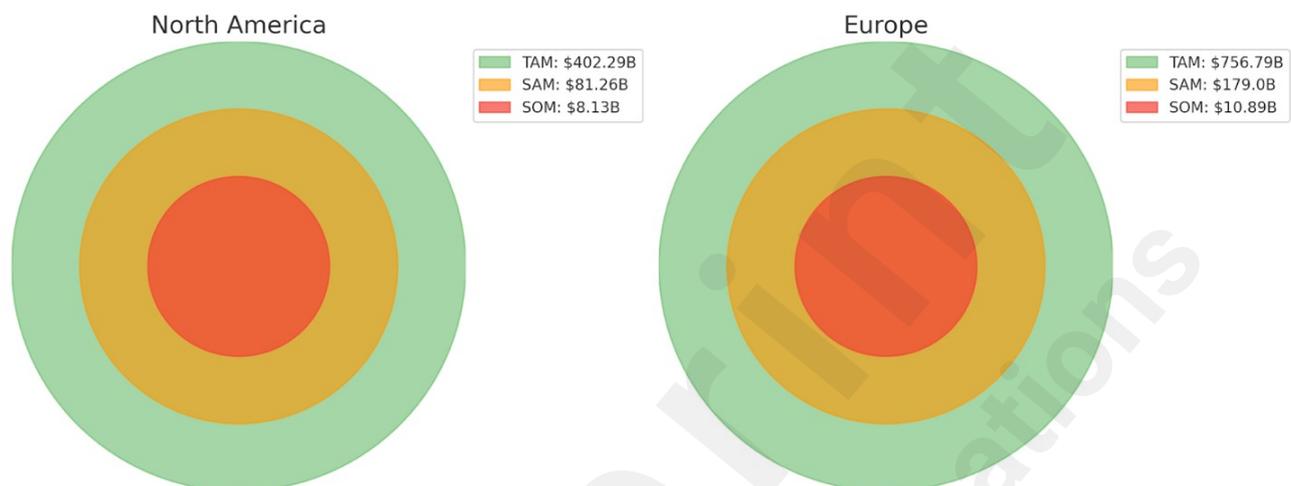
North American and European market size

Despite the barriers preventing trained professionals from reaching individuals, with the market for mental health and substance use treatment is immense.

To understand the scale of self-guided digital mental health and addiction treatments, we turn to standard frameworks widely used by investors to help evaluate market potential: Total Addressable Market (TAM), Service Available Market (SAM), and Serviceable Obtainable Market (SOM) (Figure 1).

Figure 1: TAM, SAM, and SOM for North America and Europe: Mental Health and Substance Use

TAM, SAM, and SOM for North America and Europe: Mental Health and Substance Use



The TAM for United States and Canada is estimated to be \$402.3 billion. This is calculated by estimating the number of individuals affected by common mental health and substance use disorders and multiplying that by estimated average treatment costs. Using this same process for Europe results in an annual TAM of \$756.8 billion. In Australasia, the TAM, SAM, and SOM can be estimated at \$60, \$15, and \$3 billion, respectively.

The SOM is the portion of the SAM that can be realistically captured, based on traditional business models, market penetration rates, and adoption feasibility. The estimated SOM for North America is \$8.1 billion, and \$10.9 billion for Europe, for a combined \$19 billion.

A lack of comprehensive epidemiological data prohibits the TAM, SAM, and SOM from being calculated for Asia, but growth opportunities remain enormous. In Central and South America, diverse economies, government-led healthcare systems, and cultural perceptions of mental health further complicate precise estimations. Mexico was intentionally left out of our North American calculations due to low healthcare spending per capita, fewer national-level economic valuation studies for behavioral health, and insufficient data to fit our North American model. However, based on available data the TAM, SAM, and SOM for Mexico are estimated at \$18.6 billion, 4.7 billion, and \$465 million, respectively.

Traditionally, the digital health market has focused on the SOM as it aligns with insurance and government-run healthcare systems. However, from a user engagement perspective, the TAM represents a massive untapped opportunity. Unlike widely adopted consumer applications (e.g., Google Maps, which benefits

from advertising potential and user data), behavioral health solutions face different monetization challenges.

While millions struggle with mental health concerns, consumer-driven behavioral health models targeting the TAM - such as subscription-based meditation apps - have failed to generate sustainable revenue, with platforms like Headspace and Calm reliant on continuous fundraising to operate [50-53]. Digital health companies that have attempted to replicate traditional pharmaceutical drug reimbursement models to target the SAM, such as prescription digital therapies (PDTs), have also faced significant challenges. A notable example is Pear Therapeutics, which filed for Chapter 11 bankruptcy in April 2023 after raising over \$400 million in venture capital [54].

Analyzing business models is beyond the scope of this paper. However, the key issue remains engagement. Millions worldwide could benefit from scalable, evidence-based digital behavioral health interventions, but current digital solutions struggle to retain users and secure payer adoption.

How do we develop interventions to target the untapped market? Can AI be leveraged to solve the engagement challenge, integrate with evidence-based models, decrease delivery costs, and scale behavioral health solutions beyond segmented user groups into broader populations?

AI models: large language models versus predictive analytics

In digital health, AI has primarily focused on large language models (LLMs). Predictive analytics have fallen behind the use of LLMs as they require large amounts of AI training data.

LLMs

LLMs are advanced AI systems trained on vast amounts of text data to understand and generate human-like language. In digital health, LLMs power chatbots and virtual assistants that provide patient support, answer health-related queries, and assist healthcare professionals with information retrieval. These models can engage in natural language conversations, making them valuable tools for enhancing patient education.

Predictive Analytics

Predictive analytics involves analyzing current and historical healthcare data (including behavioral phenotypes) to forecast future outcomes. By leveraging statistical models and machine learning algorithms, healthcare providers can predict disease progression, patient admissions, and treatment responses. This proactive approach can enable personalized care and tailor user experiences, ultimately improving patient outcomes and operational efficiency.

Russia's Invasion of Ukraine and resulting displacement

In February 2022, Russia initiated a full-scale invasion of Ukraine, leading to widespread destruction and a significant humanitarian crisis. As a result, millions of Ukrainians have been displaced both internally and internationally, seeking refuge in various countries worldwide.

While exact figures are challenging to determine, Los Angeles has a significant Ukrainian community. The city has seen an influx of Ukrainian refugees since the onset of the war, with many individuals and families seeking to rebuild their lives in the area [55]. Prior to the 2022 invasion, approximately 60,000 Ukrainian immigrants resided in the state. Following the invasion, an estimated 20,000 or more Ukrainians have arrived, bringing the total to around 80,000 [56]. Major cities such as Los Angeles, San Francisco, and Sacramento have been primary destinations for these new arrivals.

Nationally, the Ukrainian diaspora includes more than 1.1 million individuals, encompassing both immigrants and those of Ukrainian ancestry. As of 2019, there were approximately 355,000 Ukrainian immigrants in the U.S. In response to the 2022 invasion, the U.S. government announced plans to accept up to 100,000 Ukrainian refugees. By late 2022, approximately 85,000 Ukrainians had utilized the "Uniting for Ukraine" program, which allows refugees with an American sponsor to remain in the country for two years [57]. By December 2022, President Joe Biden announced that the U.S. had accepted roughly 221,000 Ukrainian refugees through various programs [58].

Globally, the conflict in Ukraine has led to the displacement of approximately 6.8 million refugees, with nearly 4 million people internally displaced within the country as of November 2024 [59]. European nations have accepted the greatest number of refugees, hosting around 6 million Ukrainians, with Germany now hosting the largest number [60]. Canada has also received a significant number of Ukrainian refugees, with major cities such as Toronto, Montreal, and Winnipeg welcoming thousands of newcomers and implementing resettlement programs to support housing, employment, and cultural integration [61, 62]. This mass displacement represents the largest population movement in Europe since World War II [63].

Behavioral Economics

Overview

Behavioral economics leverages psychological experimentation to develop theories about human decision-making. The field has identified a range of biases around how people think and feel. In this study, we will examine the engagement of users with nudges and behavioral prompts in an ad libitum self-guided digital behavior change course.

Digital interventions can be customized using behavioral economics to correspond with the needs and behaviors associated with specific user types. Since interventions become more appealing and relevant to each user's unique

needs and goals, this personalized approach may improve user engagement. Digital platforms can dynamically adjust their content and engagement techniques to better match specific goals and motivations by using data on user interactions and behavior trends. Through making digital interventions accessible [64] and culturally acceptable, personalization based on behavioral economics techniques can assist in fulfilling the various demands of different types of population.

Nudge Theory

Nudge theory, popularized in the 2008 book *Nudge: Improving Decisions About Health, Wealth, and Happiness* [65], leverages indirect, positive suggestions to influence decision-making and behavior, through designs or changes of the decision environments.

There is a lack of quality research analyzing the use of nudges in digital health. A 2019 scoping review examined the use of nudges in both web-based and real-world settings in physical activity interventions [66]. Of the 35 publications reviewed, 8 were web-based studies. The authors concluded that although nudging may be an effective approach to promote physical activity, there are large gaps in research, and further studies that are explicitly based on nudge insights are needed.

A 2020 editorial in *Personalized Medicine* addressed the meaningful adoption of nudges in digital health [67]. The authors acknowledged that using nudges in digital health interventions is rare and advocated for the use of nudges to promote positive behavior change.

It is critical for nudges to be culturally sensitive and adaptable to different cultural backgrounds [68]. This ensures that interventions work and are accepted in many kinds of cultural contexts. Addressing ethical issues including consent, privacy, and potential biases in nudge design is essential as nudges become more common in digital health. Reliability in digital health platforms can be strengthened by ensuring transparency and user control over the use of nudges, which we will employ in this study [69].

Behavioral Prompts

Behavioral prompts are cues specifically designed to encourage a specific task [70]. In this study, we will use 2 types of behavioral prompts anchored in nudge theory: daily tips and a to-do checklist (**Table 1**).

Table 1: Example nudges and prompts

Delivery format	Content Type	Example from our study
Tip	Directive Content	Express yourself by uploading your own image!
Tip	Social Proof	Many members have similar goals as yours. Reviewing other members' goals can help you reach your own.
Tip	Present Bias	Feel better sooner by learning from others. Read what others have posted on the community.
Prompt	To-Do	Watch the Getting Started Video

	Checklist	
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An effective approach for boosting user involvement in digital health interventions may be offered by analyzing users' engagement with different combinations of nudges.

An effective approach for boosting user involvement in digital health interventions may be offered by analyzing combinations of behavioral prompts that users engage with. Through machine learning techniques, the dataset emerging from this study may provide insight on which and prompts work best with specific demographics and usage patterns [71]. By customizing interventions to meet the unique needs of every user, this integrated approach might increase the possibility of long-term behavior change and better health outcomes.

Our Prior Work

In our previous 3-arm RCT [24], Arm 1 featured a member home page without nudges or prompts. Arm 2 featured a home page with a tip-of-the-day section. Arm 3 featured a home page with a tip-of-the-day section and a to-do checklist.

Control arm members (1788/13,224, 13.52%) completed an average of 1.5 course components. Arm 2 members (865/13,224, 6.54%) clicked on 5% of tips and completed an average of 1.8 course components. Arm 3 members (1914/13,224, 14.47%) clicked on 5% of tips, completed 2.7 of 8 to-do checklist items, and completed an average of 2.11 course components. Completion rates in Arm 2 were greater than those in Arm 1 (z score=3.37; $P<.001$), and completion rates in Arm 3 were greater than those in Arm 1 (z score=12.23; $P<.001$). Engagement in all 8 components in Arm 3 was higher than that in Arm 2 (z score=1.31; $P<.001$).

Further analysis confirmed that behavioral economics techniques, such as nudges and prompts, significantly enhance engagement in digital health interventions. Specifically, users in the Nudge + Prompt condition (Arm 3) were 93% more likely to engage compared to those in the control group (Arm 1), as indicated by an odds ratio (OR) of 1.93 (95% CI: 1.71–2.17, $p < .001$). This increase in engagement was reflected across multiple platform activities, including self-assessments, goal setting, and content interaction.

However, while these findings validate the effectiveness of nudges and prompts, the study did not explore how individual-level factors shaped these outcomes. Specifically, we did not examine how the intersection of demographic characteristics and cognitive or behavioral phenotypes influenced engagement, if individual engagement followed properties of power laws [72], or if we could leverage economic tools like the Gini coefficient to plot participation inequality [73].

Understanding these nuanced engagement drivers is critical for optimizing future interventions, tailoring engagement strategies to specific user segments, and maximizing the effectiveness of digital health tools.

Objective

The primary objective is to analyze user engagement with randomized tips and

to-do lists within a resiliency course tailored for Ukrainian refugees affected by the ongoing humanitarian crisis. Insights will inform the development of an AI-based personalization system to optimize engagement and address behavioral health challenges.

Secondary objectives include identifying demographic and behavioral predictors of engagement and creating a scalable, culturally sensitive nudging [74, 75] and intervention models.

Since there is a paucity of published research in this area [76-78], our unique dataset holds the potential to customize user experiences and transform digital engagement by leveraging behavioral phenotypes and machine learning.

Methods

Digital health platform

The digital health platform used in this study is managed by Evolution Health. EvolutionHealth.Care is an evidence-based, digital health content provider that features courses based on behavior change techniques including cognitive behavioral therapy, stages of change, structured relapse prevention, harm reduction; and quizzes based on brief intervention.

The platform offers interactive courses and quizzes for mental health issues, addiction issues, and obesity. It also contains a moderated community based on social cognitive theory.

Limited memberships are available to individuals who register through the organization's free-to-consumer program. Full memberships are available through white-label instances licensed to employers, insurance companies, Employee Assistance Programs, educational institutions, non-profit organizations, for-profit healthcare organizations, and individual therapists.

The intervention

Shared Strength (Спільна Сила) is a self-guided interactive behavior change treatment course based on traditional, evidence-based treatments (**Table 2**).

Table 2: Theoretical constructs and evidence-base

Theoretical construct	Shared Strength (Спільна Сила)
Brief Intervention	X
Cognitive behavioral therapy	X
Gamification	X
Health belief model	X
Motivational interviewing	X
Social cognitive	X

theory	
Targeting and tailoring	X

Other interactive courses in the Evolution Health platform have been extensively examined in the literature [10, 23, 24, 72, 73, 79-101]. As an interactive course, Shared Strength mirrors their structure and design (**Table 3**).

Table 3: Main course components

Course component	Shared Strength (Спільна Сила)
Avatar upload	X
Course completion certificate	X
Course Worksheets	X
Gamified CBT course	X
Getting started video	X
Goals exercise	X
Moderated community	X
Private messaging	X
Statistics extranet (for corporate clients)	X
Tailored depression & anxiety test	X
Therapist extranet	X

Recruitment and Participants

Participants will be recruited through partnerships with NGOs, digital outreach campaigns, and community organizations. Enrollment will occur via the EvolutionHealth.care platform, where participants will be randomized automatically upon sign-up using a computer-generated sequence, ensuring unbiased allocation.

Ethical considerations and consent

All data collection policies and procedures adhere to international privacy guidelines, including the General Data Protection Regulation (GDPR), U.S. Health Insurance Portability and Accountability Act (HIPAA) where applicable, and the Declaration of Helsinki [102-105]. At registration, all members endorse a check box confirming that they consent to have their data used for research purposes and approve the platform's privacy policy.

The platform does not collect personally identifiable information except a user's email address, which is required for registration confirmation, the retrieval of lost passwords, and two-factor authentication. Email addresses are encrypted using AES-256 encryption and are stored in a separate database.

This study is conducted on a self-guided resiliency course for displaced

Ukrainian refugees, but it does not measure clinical outcomes. While participants are randomized into six intervention arms, the study is classified as a randomized controlled trial (RCT), but it is not a randomized clinical trial under medical research standards [106]. To clarify, this study adheres to principles of an RCT, where participants are randomly assigned to conditions, but does not fall under medical trial classification as it does not measure health outcomes. The CONSORT- SPI guidelines for social and psychological intervention trials will be followed [107].

The primary outcome variable being tested is course engagement, not wellness or symptom reduction. The study does not evaluate whether participant engagement with course tools improves mental health or reduces emotional stress related to forced displacement. Any potential clinical effects of engagement strategies tested in this study will require investigation in future research.

Since this study does not measure clinical outcomes, it does not fall under ClinicalTrials.gov or WHO International Clinical Trials Registry Platform (ICTRP) requirements. However, to ensure transparency, the trial was registered with Open Science Framework, a widely recognized registry for social science and behavioral health research.

As the study was based on de-identified user data and does not collect medical or conical measures, it was deemed exempt from further review by Evolution Health's Institutional Review Board. This exemption is in accordance with regulatory standards for minimal-risk research involving non-identifiable behavioral data.

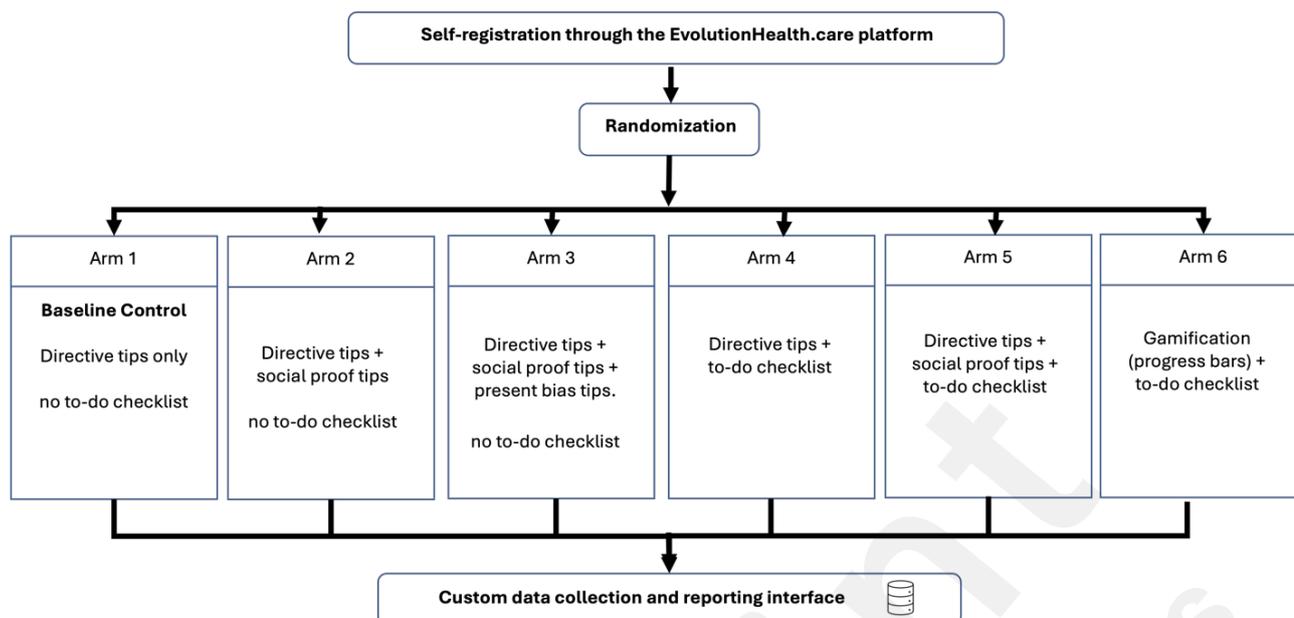
Randomization

Participants will be randomly assigned to one of the following six arms (**Figure 2**):

1. **Arm 1 (Baseline Control)**: Directive tips only, no to-do checklist.
2. **Arm 2**: Directive tips + social proof tips, no to-do checklist.
3. **Arm 3**: Directive tips + social proof tips + present bias tips, no to-do checklist.
4. **Arm 4**: Directive tips + to-do checklist.
5. **Arm 5**: Directive tips + social proof tips + to-do checklist.
6. **Arm 6**: Gamification (progress bars) + to-do checklist.

Participants will be randomly assigned to one of the six experimental arms using computer-generated randomization in a 1:1:1:1:1:1 ratio, and will be conducted at the point of user registration, ensuring equal probability of assignment to any condition. No stratification or blocking will be used, as randomization is expected to produce comparable groups given the planned sample size.

Figure 2: Study flow.



Power and sample size

The primary outcome of interest is engagement, measured through click-through rates, session duration, and to-do checklist completion rates across six experimental arms.

The study is designed to detect small-to-moderate effect sizes in engagement differences between intervention groups. Expected effect sizes range from Cohen's $f = 0.1$ (small) to $f = 0.25$ (moderate). Our goal is to obtain a power of 80% ($\beta = 0.20$) and a significance level of 0.05 (α) to ensure adequate sensitivity in detecting meaningful differences between groups.

Sample size calculation for ANOVA

Given that engagement metrics will be compared across six arms, a one-way ANOVA test was used to estimate the required sample size. The following estimates were derived:

- For a small effect size ($f = 0.1$), approximately 86 participants per arm (total 516 participants) are required.
- For a moderate effect size ($f = 0.25$), approximately 28 participants per arm (total 168 participants) are required.

These calculations assume normality of residuals and homogeneity of variance for ANOVA-based analysis. Chosen effect sizes are based on prior research in digital health engagement studies [108-110]. In our prior RCT [23, 24] engagement data was analyzed using mixed-effect logistic regression, which does not rely on these assumptions.

Sample size calculation for regression analysis

Regression analysis will be applied to assess the relationship between

engagement and demographic factors (age, gender). This will assist in the identification of predictors of engagement and potential subgroup effects [111].

- For linear regression, a common rule of thumb suggests 15-20 participants per predictor variable [112, 113].
- For logistic regression, a minimum of 10 outcome events per predictor variable is required [114].

A total of 600 participants will provide sufficient sample size power for multiple predictors while ensuring a balanced distribution across intervention arms.

Sample size for repeated measures (GEE)

Since engagement data will be collected across multiple time points, Generalized Estimating Equations (GEE) will be used to account for within-subject correlations.

- A within-group correlation of $\rho = 0.3$ was assumed, based on prior studies of engagement in digital health. This estimate aligns with findings from longitudinal analysis in behavioral health studies that report moderate within-person correlation of repeated engagement measures [115, 116].
- A 15% attrition rate was factored into the final sample size, suggesting an adjusted recruitment target of 100 participants per arm to maintain statistical power.

Sample size justification

To ensure the predictive model has sufficient training data, the study aims to recruit a minimum of 600 participants (100 per arm). This sample size balances feasibility with analytic rigor, ensuring adequate power to detect differences in engagement and train AI-driven predictive models. See multimedia appendix 1 for the studies CONSORT-SPI checklist [107] [See Multimedia Appendix 1].

Data collection

The Evolution Health platform is equipped with a custom data collection interface and reporting mechanism. Data will be collected for each member who is randomized into the experiment. All data is self-report. Data on age and identified gender will be collected at registration or at secure sign-on in various white-label versions.

The following behaviors are tracked in the custom database for each tip and to-do items that is randomly presented to a user: whether a tip was shown, whether a tip was clicked on, and whether a user completed the course component described in the tip or to-do item

Results

This protocol was designed in January 2025. Alpha and beta testing of the

intervention is scheduled to be in March 2025. We expect the experiment to be soft launched in May of 2025. The experiment will be run until sample size requirements are met.

Discussion

Hypothesis

From our previous study, we anticipate higher engagement in arms that include the to-do checklist, particularly when combined with gamification (Arm 6) or social proof tips (Arm 5) (H1, H2).

The study will also contribute to the development of AI models capable of predicting and optimizing user engagement, allowing for the customized delivery of to-do items and tips based on behavioral phenotypes (H2). Findings will support future scalability to other indications and populations.

In our previous research on user engagement within the platform's social network, we observed that engagement patterns followed power law distributions [99]. A follow-up study found that demographic and condition-specific characteristics did not predict social network engagement [100]. However, this study will help determine whether course engagement follows similar power law properties or if age and gender are predictive of engagement outcomes, particularly given the inclusion of session duration and behavioral phenotypes as new analytical factors (H3).

Expected Results

This study builds on prior RCT findings, extending the use of behavioral economics to underserved, culturally sensitive populations. Unlike existing studies by platforms, our focus on mental health and refugees offers unique contributions to both research and practice. Findings may also advance AI-driven personalization in digital health.

Strengths & Limitations

A strength to this experiment is that it will be conducted in an *ad libitum* environment. Unlike most digital health studies, it will not be conducted with a small population in a controlled environment. Further, members will not be aware of the experiment, which will limit participant bias and the Hawthorne Effect.

Based on stratified randomization, which will balance demographic factors, the dataset generated will enable predictive analytics for adaptive engagement strategies. Other indication specific data, like results and qualifying criteria from the mental health screener [92], has the potential to enrich tailoring.

A limitation to this experiment is that, especially due to the anonymity of members, we have no way of knowing who members are. Registrants may be displaced Ukrainians, individuals reviewing the program based on general

interest, researchers or practitioners reviewing the platform for professional use, Evolution Health competitors, industry analysts, or any other number of other possible users who are not engaging with the platform to help achieve wellness. Sensitivity analysis will be conducted to filter and exclude anomalous user engagement data.

Although engagement correlates with improved intervention outcomes, this study does not measure wellness improvements. Follow-up research will be required to establish clinical efficacy.

Future Directions

By leveraging randomized experiments and AI, this study provides a blueprint for scalable, culturally sensitive digital health interventions based on demographic characteristics, indication-specific variables, and behavioral phenotypes. The integration of behavioral economics with machine learning represents a critical step toward addressing global mental health disparities.

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Data Availability

Allowing the dataset in this study to be publicly available would violate the platform's data privacy policy, terms of use, and user agreement.

Furthermore, the data emerging from this experiment will be leveraged to train AI models to better understand how to increase and encourage healthy behavior change. Making this data publicly available may have the opposite effect and enable the development of models that can detect and target vulnerable populations.

However, the rich dataset from this study, ongoing engagement data that is continually collected, or other platform datasets can be made available to researchers interested in conducting studies for non-commercial purposes. Interested researchers are encouraged to contact Evolution Health.

Conflicts of Interest

Trevor van Mierlo is the founder of Evolution Health, the owner of the EvolutionHealth.care digital health platform. Rachel Fournier is an Evolution Health Board Member.

Abbreviations

CGT: Cognitive Behavioral Therapy
NAMI: National Alliance on Mental Illness

NIMH: National Institute of Mental Health

RCT: Randomized Controlled Trial

TAM: Total Accessible Market

SAM: Service Available Market

SOM: Serviceable Obtainable Market

WHO: World Health Organization

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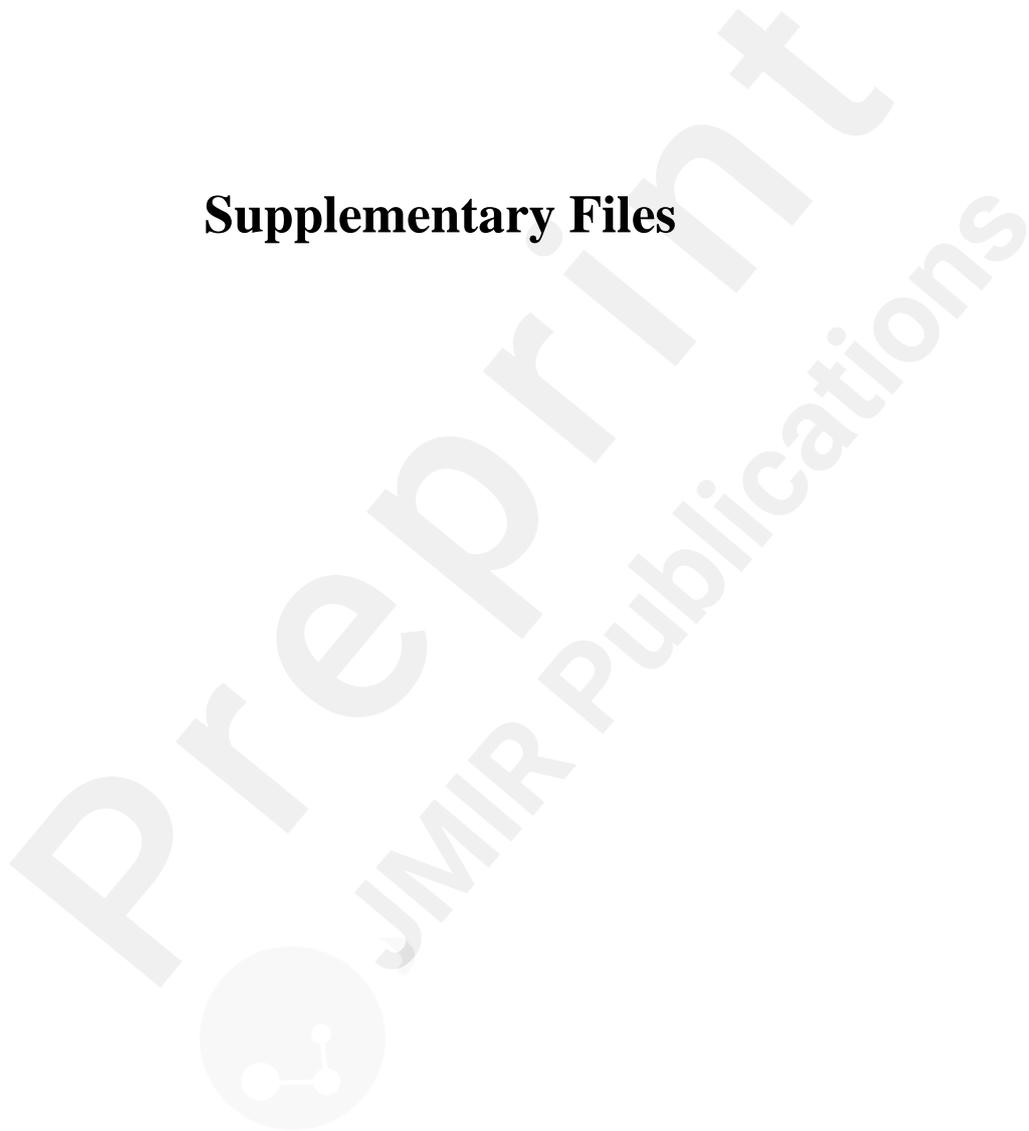
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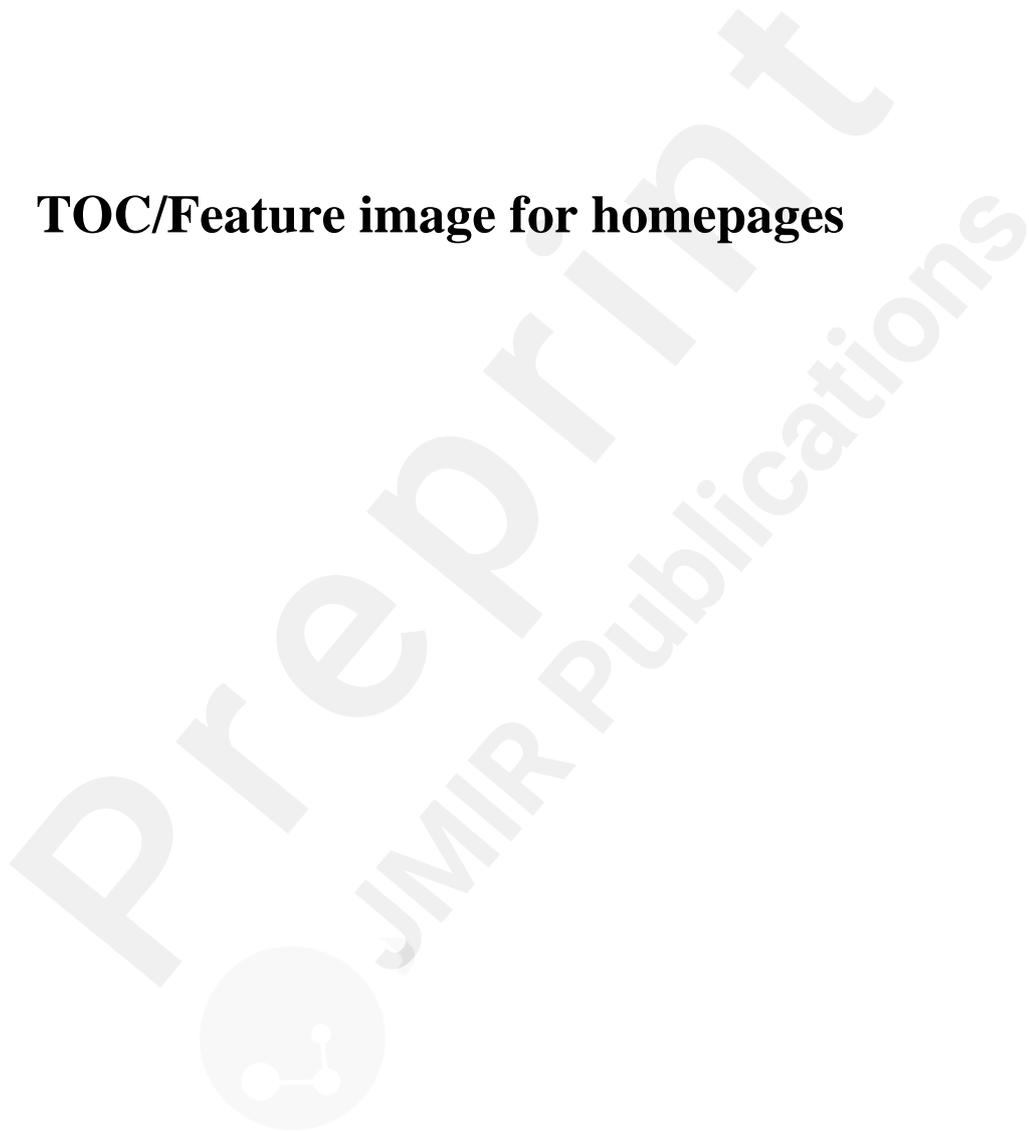
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Supplementary Files



TOC/Feature image for homepages



AI-generated image of a robot mother elephant nudging its baby robot elephant.

