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Testing an AI emotional support companion for university students' psychological wellbeing and mental health

Submission date
07/05/2025

Recruitment status
No longer recruiting

Registration date
12/05/2025

Overall study status
Completed

Last Edited
12/05/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
University students often experience emotional distress but may not have access to or seek traditional mental health support. This study tests whether an AI-based emotional support companion called Kai can help improve psychological wellbeing, including anxiety, depression, PTSD symptoms, and substance use. Through two related experiments, we will compare this digital approach with traditional face-to-face group therapy, individual university counseling services, and a waitlist control group to understand its effectiveness and identify who benefits most from each intervention approach.

Who can participate?
For the first experiment: University students aged 18-35 experiencing mild-to-moderate emotional distress, fluent in Hebrew, with access to digital devices, and not currently receiving mental health treatment.
For the second experiment: Similar criteria, but participants must also be eligible for university counseling services and not have previously used these services within the past year.

What does the study involve?
The study involves two related experiments. In Experiment 1, participants will be randomly assigned to one of three groups: (1) using the Kai AI companion for emotional support for 12 weeks, (2) attending 12 weekly 90-minute group therapy sessions over 12 weeks, or (3) joining a waitlist control group that receives no intervention during the study period but is offered access after completion.
Experiment 2 will include three groups: (1) using the Kai AI companion, (2) receiving traditional face-to-face therapy through the university's Student Counseling Services, and (3) a waitlist control group. We will measure psychological outcomes including anxiety, depression, well-being, PTSD symptoms, and substance use at the beginning and end of the study.

What are the possible benefits and risks of participating?
Potential benefits include improved psychological wellbeing, reduced symptoms of anxiety and depression, and access to support that might otherwise be unavailable. Risks are minimal but

may include some emotional discomfort when discussing personal issues, and there's a possibility that the interventions may not be effective for everyone.

Where is the study run from?
The study will be conducted at Reichman University in Israel.

When is the study starting and how long is it expected to run for?
October 2024 to August 2025.

Who is funding the study?
This study is investigator initiated and self-funded without external financial support. Participants will receive academic credits for their participation as part of university coursework requirements.

Who is the main contact?
Prof. Anat Shoshani, Reichman University, ashoshani@runi.ac.il

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
p_2024178

Study information

Scientific Title

Effectiveness of Kai AI Companion compared to traditional therapeutic approaches for improving psychological wellbeing among university students experiencing mild-to-moderate emotional distress: A comprehensive two-experiment randomized controlled trial

Acronym
KAI-SUPPORT

Study objectives
1. Primary Hypotheses:
1.1. University students using the Kai AI companion will show significantly greater improvements in anxiety, depression, and wellbeing compared to waitlist controls.
1.2. The effectiveness of the Kai AI companion for improving psychological outcomes will be comparable to or exceed face-to-face group (Exp 1) or individual (Exp 2) therapy across multiple mental health domains.
1.3. Kai AI intervention will significantly reduce substance use behaviors compared to both face-to-face group therapy and waitlist control conditions (Exp 1).
1.4. Users of the Kai AI companion will report decreased intention to seek traditional therapy compared to participants in the face-to-face therapy and waitlist control groups.

2. Moderation Hypotheses:
2.1. The effectiveness of the Kai AI intervention will be moderated by relational factors, with participants reporting higher loneliness, lower social support, and higher attachment insecurity (both anxious and avoidant) showing stronger intervention benefits, particularly for anxiety outcomes.
2.2. Life events exposure will moderate intervention effectiveness, with participants reporting higher exposure to negative life events and political stressors showing more substantial benefits from Kai AI intervention, especially for anxiety and depression outcomes.

3. Mediation and Engagement Hypotheses:
3.1. Higher engagement with Kai (measured by message frequency) will be associated with greater improvements in mental health outcomes.
3.2. Therapeutic alliance (perceptions of Kai's professional competence and empathy) will predict user engagement, which will in turn mediate mental health improvements.
3.3. Mental health improvements through Kai usage will mediate reductions in perceived need for traditional therapy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/10/2024, Institutional review board , the Baruch Ivcher School of Psychology, Reichman University (Ha-Universita Street 8, Herzliya, 4610101, Israel; +972 9 952-7223; psylab-manager@runi.ac.il), ref: P_2024178

Study design
A three-arm parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)

Prevention, Treatment

Health condition(s) or problem(s) studied
Anxiety, Depression, Psychological Distress, PTSD Symptoms, Substance Use

Interventions
Experiment 1:
The study comprises three arms:
1. Kai AI Companion (Experimental): Participants will use Kai, a digital AI companion, daily for three months. Kai offers empathetic, affirming, and non-judgmental dialogue based on evidence-based psychological principles including CBT, ACT, and positive psychology. Users will engage with features including daily check-ins, mood tracking, mindfulness and positive psychology exercises, and progress monitoring, with the system continuously adapting to user engagement patterns to maintain effectiveness. Recommended use is ≥3 times/week for 10–15 minutes /session.
2. Face-to-Face Group Intervention (Active Comparator): Participants will attend 12 weekly 90-minute group sessions over 3 months with a psychologist (20 participants per group). Sessions incorporate CBT, ACT, mindfulness, and positive psychology approaches.
3. Waitlist Control: Participants receive no intervention during the 3-month study period but are offered access to an intervention after study completion.
Randomization will be conducted using a computer-generated sequence with allocation concealed in sealed envelopes. Only the outcomes assessor will be blinded to treatment allocation.

Experiment 2:
A second experiment will be conducted with three groups:
Kai AI Companion (Experimental): Same intervention as in Experiment 1.
University Student Counseling Services (Active Comparator): Participants will receive traditional face-to-face therapy through the university's Student Counseling Services.This will involve standard individual counseling sessions following the established protocols of the university counseling services (3 month, once a week)
Waitlist Control: Same as in Experiment 1.

Intervention Type
Behavioural

Primary outcome(s)
1. Life Satisfaction measured using the Brief Multidimensional Students' Life Satisfaction Scale (BMSLSS) at baseline and 3 months
2. Anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7) at baseline and 3 months
3. Depression measured using the Patient Health Questionnaire (PHQ-9) at baseline and 3 months
4. Well-Being measured using the WHO-5 Well-Being Index at baseline and 3 months
5. PTSD Symptoms measured using the PCL-5 (4-item version) at baseline and 3 months
6. Substance Use measured using the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) at baseline and 3 months

Key secondary outcome(s))
1. Help-Seeking Intention measured using the General Help Seeking Questionnaire at baseline and 3 months
2. Engagement with Kai measured by number of messages sent throughout intervention period

3. Perceptions of Kai's Supportive Qualities measured using an adapted version of Cash's Perceptions of Counselor Behavior scale at 3 months

Completion date
02/08/2025

Eligibility

Key inclusion criteria
Experiment 1 - Participant inclusion criteria:
1. University students aged 18-35 years
2. Self-reported mild-to-moderate emotional distress (anxiety, sadness, stress)
3. Fluent in Hebrew
4. Access to smartphone or computer with internet
5. Willing to provide informed consent
6. Available to participate in weekly group sessions (for those assigned to group intervention)

Experiment 2 - Participant inclusion criteria:
1. University students aged 18-35 years
2. Self-reported mild-to-moderate emotional distress (anxiety, sadness, stress)
3. Fluent in Hebrew
4. Access to smartphone or computer with internet
5. Willing to provide informed consent
6. Eligible for university counseling services
7. Not previously enrolled in university counseling services

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Key exclusion criteria
Experiment 1 - Participant exclusion criteria:
1. Active suicidal ideation or psychiatric crisis
2. Currently receiving psychotherapy or psychiatric medication

3. Diagnosed with severe mental disorder (psychosis, bipolar disorder)
4. Unable to commit to 12-week intervention period
5. Previous participation in similar group intervention programs

Experiment 2 - Participant exclusion criteria:
1. Active suicidal ideation or psychiatric crisis
2. Currently receiving psychotherapy or psychiatric medication
3. Diagnosed with severe mental disorder (psychosis, bipolar disorder)
4. Previous participation in university counseling services within the past year
5. Current enrollment in other intervention studies

Date of first enrolment
10/05/2025

Date of final enrolment
02/08/2025

Locations

Countries of recruitment
Israel

Study participating centre
Reichman University
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Sponsor information

Organisation
Reichman University

ROR
https://ror.org/01px5cv07

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Prof. Anat Shoshani, ashoshani@runi.ac.il

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet		12/05/2025	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file			12/05/2025	No	No