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Assessment of feasibility and accessibility of digitalized aftercare for drug addicts who completed residential drug rehabilitation in Sri Lanka

Submission date
28/05/2023

Recruitment status
No longer recruiting

Registration date
31/05/2023

Overall study status
Completed

Last Edited
31/05/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
"Aftercare" refers to the interventions that assist individuals with substance use disorder (drug addiction) who have completed the treatment or rehabilitation for reintegration into society. Aftercare will facilitate a favorable and safe environment for sustaining the substance-free state and also it provides interactive platforms to overcome the issues and problems associated with abstinence and recovery. However, the aftercare treatment provided in Sri Lanka has certain limitations, and individuals who have undergone residential rehabilitation require an evidence-based aftercare intervention that addresses these limitations. The study aims to assess the feasibility and acceptability of the digitalized aftercare (SECOND WIND Mobile Application) for drug addicts who completed residential drug rehabilitation in Sri Lanka.

Who can participate?
Volunteer adults with substance use disorder who have completed the residential rehabilitation treatment program can participate in the study

What does the study involve? (for participants)
Participants will be randomly allocated into an intervention group or control group. The intervention group will receive the digitalized aftercare via the SECOND WIND mobile application while the control group will receive the existing aftercare services facilitated by physical visits and contacts over the telephone. This mobile application offers a comprehensive suite of features aimed at supporting recovery, including client-counselor communication, a platform for educational information on relapse prevention via lectures, videos, and testimonials, an SOS emergency contact feature, engaging family members for treatment continuum and setting up short term and long-term goals. The digitalized aftercare treatment will span a three-month period.

What are the possible benefits and risks of participating?
By participating in this study, individuals allocated to the intervention group will receive

aftercare via a digitalized and safe platform. Individuals allocated to the control group will receive the usual aftercare and if they are willing to experience the digitalized aftercare via the SECOND WIND mobile application they also will be provided the opportunity to participate after the study period. There is a potential risk of exposing confidential information in the event of hacking or unauthorized access for the SECOND WIND mobile application.
Since this is a digital intervention, the likelihood of any serious adverse events (SAEs) in this intervention is very minimal as it is a digitized mobile application-based intervention. Provisions for modifications or termination of the trial will be provided if safety concerns arise for the participants. Any such modifications or termination of the trial will be informed to the ethics review committee, director of the rehabilitation center, funding body and the participants. Participants will be provided with the provisions for re-consenting after any change of the approved proposal.

Where is the study run from?
The study participants will be enrolled from 3 selected rehabilitation centers namely Talangama Prevention, Treatment & Rehabilitation Centre located in Colombo, Nawadiganthaya Youth Prevention, Treatment & Rehabilitation Centre in Urapola, Nittambuwa, and Galle Youth Prevention, Treatment & Rehabilitation Centre in Unawatuna, Galle which is governed by the National Dangerous Drugs Control Board, of Sri Lanka.

When is the study starting and how long is it expected to run for?
January 2022 to December 2023

Who is funding the study?
This study is funded by the Accelerating Higher Education Expansion and Development (AHEAD) Operation of the Ministry of Higher Education, Technology, and Innovation (Grant number HEI DOR (R2) No. 06).

Who is the main contact?
Akila R. Jayamaha (Principal Investigator), akila@kiu.ac.lk

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
AHEAD DOR (R2) No. 06

Study information

Scientific Title
Feasibility and acceptability of digitalized aftercare (SECOND WIND mobile application) for individuals with substance use disorder who completed residential drug rehabilitation in Sri Lanka: A randomized control feasibility trial

Acronym
SECOND WIND

Study objectives
SECOND WIND mobile application is a feasible and acceptable digitalized aftercare for individuals with substance use disorder (SUD) who completed residential drug rehabilitation in Sri Lanka

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/01/2023, Ethics Review Committee of KIU, (No 249/1 Malabe Rd, Battaramulla, Sri Lanka; +94 11 2 741 878; erc@kiu.ac.lk), ref: KIU/ERC/22/102

Primary study design
Interventional

Study design
Multicenter single-blind randomized controlled feasibility trial

Study type(s)
Other, Prevention, Quality of life, Safety

Health condition(s) or problem(s) studied
Prevention of relapse into substance use behavior in individuals who have undergone residential rehabilitation treatment

Interventions
Individuals with substance use disorder who completed the residential rehabilitation will be 1:1 randomized into an intervention group or control group using Sealed Envelope software [https://www.sealedenvelope.com/]. The intervention group will receive the digitalized aftercare via SECOND WIND mobile application (https://play.google.com/store/apps/details?id=com.fishifox.secondwindlk&pli=1) while control group will receive the existing aftercare services facilitated by physical visits and contacts over the telephone.
SECOND WIND is a mobile application created to provide digitalized aftercare for individuals with substance use disorder who have successfully completed residential rehabilitation. This mobile application offers a comprehensive suite of features aimed at supporting recovery, including client-counselor communication, a platform for educational information on relapse prevention via lectures, videos, and testimonials, an SOS emergency contact feature, engaging family members for treatment continuum and setting up short term and long-term goals. The digitalized aftercare treatment will span a three-month period. Individuals belonging to both groups were assessed monthly for lapses and relapses of substance use behavior during the three-month period.
Focus groups and in-depth interviews will be conducted to assess the acceptability and feasibility of SECOND WIND mobile application among the stakeholders at the end of the three-month period.

Intervention Type
Other

Primary outcome(s)
The primary outcome of the trial will be assessing the feasibility and acceptability of digitalized aftercare (SECOND WIND mobile application) for individuals with substance use disorder (clients) who completed residential drug rehabilitation in Sri Lanka. The feasibility of enrolling clients, counselors, and outreach officers into the SECOND WIND mobile application will be assessed using a screening log, at the initial stage of the study. The feasibility of the digitalized follow-up will be assessed using the System Usability Scale (SUS) and the metadata log files of the SECOND WIND mobile application during the follow-up period.
The acceptability of the stakeholders (clients, counselors, and outreach officers) will be assessed via in-depth interviews at the end of the follow-up period.

Key secondary outcome(s)
1. Lapse and relapses of substance use behavior will be measured using interviews at the end of the follow-up period
2. Quality of life, will be measured using EuroQol 5 Dimensions 5 Levels (EQ-5D-5L) at baseline and end of the follow-up period
3. Addiction wellness will be measured using the Recovery Capital Index (RCI) at baseline and end of the follow-up period
4. Severity of consequences related drug abuse will be measured using the Drug Abuse Screening Test (DAST-10) at baseline and end of the follow-up period.

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Volunteer adults with substance use disorder who have completed the residential rehabilitation treatment will be included in the study.

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Participants will be excluded from the study if they exhibit severe cognitive impairment or have acute psychiatric conditions, or if they plan to travel overseas after completing their residential rehabilitation treatment program/ not have access to a smartphone device.

Date of first enrolment
01/06/2023

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
Sri Lanka

Study participating centre
“Nawadiganthaya” Youth Prevention, Treatment & Rehabilitation Centre
Urapola
Nittambuwa
Sri Lanka
11880

Study participating centre
“Galle” Youth Prevention,Treatment & Rehabilitation Centre
Unawatuna
Galle
Sri Lanka
80000

Study participating centre
“Talangama” Prevention,Treatment & Rehabilitation Centre
172, Shanthi Mawatha
Thalangama
Sri Lanka
10120

Sponsor information

Organisation
KAATSU International (Private) University (KIU) Sri Lanka

Funder(s)

Funder type
Government

Funder Name
Accelerating Higher Education Expansion and Development (AHEAD) Operation of the Ministry of Higher Education, Technology, and innovation

Results and Publications

Individual participant data (IPD) sharing plan
The data sets generated during and/ or analysed during the current study are not expected to be made available due to ethical agreement of maintaining confidentiality of individual participant data.

IPD sharing plan summary
Not expected to be made available