ISRCTN17143198 https://doi.org/10.1186/ISRCTN17143198

An evaluation of the feasibility, acceptability, and effectiveness of Kica, a mobile application based on the WHO Caregiver Skills Training

Submission date
09/11/2024

Recruitment status
No longer recruiting

Registration date
12/11/2024

Overall study status
Completed

Last Edited
12/11/2024

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
The use of mobile technology to support clinical practice (mHealth) has the potential to support access to care for autistic children, improving accessibility, scalability, and cost-effectiveness of interventions. However, there is limited evidence of the usability, acceptability and effectiveness of mobile applications that deliver evidence-informed caregiver-mediated interventions.
In collaboration with the World Health Organization (WHO) the researchers have developed Kica, a user-centered mobile application based on the WHO Caregiver Skills Training (CST) intervention and informed by a comprehensive stakeholder consultation.
This mHealth intervention aims to transform the traditional in-person training into a self-paced digital format, equipping caregivers of children with neurodevelopmental disorders and disabilities, including autism, with evidence-based strategies for daily interactions.
After successfully testing the usability of the prototype, this study aims to assess the effectiveness, acceptability and feasibility of the Kica-CST intervention.

Who can participate?
Children between the ages of 18 and 72 months with a clinical diagnosis of Autism Spectrum Disorder and their parents and legal guardians ("caregivers"). Specifically, since the researchers are interested in knowing if the Kica-CST intervention is acceptable and effective regardless of previous exposure to the CST in-person intervention, they aim to recruit participants from two pools: a pool of caregivers who have previously received in-person CST (referred to as “experienced caregivers”) and a pool of caregivers who have not participated in any in-person CST (referred to as “naïve caregivers”).

What does the study involve?
Participants will be asked to sign an informed consent form before the study begins.
The research phases (from 1 to 5) are described below. Caregivers will be free to leave the studio at any time for any reason.

Phase 1: Baseline assessments
Caregivers from each of the two pools (experienced vs naïve) will be asked to complete some

questionnaires online and to video record an interaction with their child lasting about 10-15 minutes.

Phase 2: Random assignment for the trial
After initial evaluations, through a code generated automatically by a computer at the Department of Psychology of the University of Milan-Bicocca, each participant in each of the recruitment pools will be randomly assigned to one of the following two groups:
1. Kica group (i.e., experimental group)
2. Waitlist group (i.e., control group)

Phase 3: Trial
During the experimentation phase, which will last about 2 months, the activities will be defined as follows:
1. The experimental group will receive the Kica-CST intervention, in addition to the usual care
2. The control group will continue to receive their regular care.

Phase 4: End-point assessment
Following the experimentation phase, all the research participants will be invited to the final evaluation activities. At this stage, caregivers in each of the groups (experienced vs. naïve) will be asked to complete some questionnaire and to video record an interaction with their child lasting about 10-15 minutes.

Phase 5: Follow-up assessment
About 3 months after the final evaluations, there will be a final invite to a research visit. During this phase, caregivers in each of the groups (experienced vs. naïve) will be asked to complete some questionnaire and to video record an interaction with their child lasting about 10-15 minutes.

What are the possible benefits and risks of participating?
While there are no direct benefits to participating in the research, the data gathered will enhance our understanding of effective interventions for parents of children with autism spectrum disorder. The Kica-CST intervention may improve caregiver well-being and child development, which the researchers aim to validate through this effectiveness study.
Participants will be informed from the outset that there are no proven direct benefits of taking part in this study, except for receiving an intervention that is based on the WHO CST contents, for which evidence indicates excellent acceptability and positive clinical effects on caregiver and dyad outcomes.
The study is safe for participants and does not use any dangerous or stressful methods. The activities (i.e., interactions) involved are common in educational contexts and do not disrupt the child's daily routine. The questionnaires are also frequently used in international research and are generally welcomed by parents. However, like in many psychological or educational programs, some problems could occur during or right after the intervention. For example, parents might find it hard to interact with their child, which could cause some temporary discomfort or there might be a moment of mild, temporary child distress. Therefore, if at any time the caregiver or child does not like the activities, or does not want to answer some questions, it will be possible to suspend the participation temporarily or permanently.

Where is the study run from?
University of Milano-Bicocca (Italy)

When is the study starting and how long is it expected to run for?
September 2023 to December 2025

Who is funding the study?
Research is conducted within the MUSA – Multilayered Urban Sustainability Action – project, funded by the European Union – NextGenerationEU, under the National Recovery and Resilience Plan (NRRP) Mission 4 Component 2 Investment Line 1.5: Strengthening of research structures and creation of R&D “innovation ecosystems”, set up of “territorial leaders in R&D”.

Who is the main contact?
Prof. Erica Salomone, erica.salomone@unimib.it

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Erica Salomone

ORCID ID
https://orcid.org/0000-0002-8083-5942

Contact details
Piazza dell'Ateneo Nuovo 1
Milano
Italy
20126
+39 (0)2 6448 3816
erica.salomone@unimib.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocol 859

Study information

Scientific Title
Randomised controlled trial of Kica, a mobile application based on the WHO Caregiver Skills Training

Acronym
KICA-CST

Study objectives

The addition of Kica to treatment as usual (TAU) in children with autism spectrum disorder (ASD) improves child and caregiver outcomes more than TAU.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/07/2024, Ethics Committee of the University of Milano-Bicocca (Piazza dell'Ateneo Nuovo, 1 20126, Milan, 10126, Italy; +39 (0)2 6448 6581; comitatoetico@unimib.it), ref: Prot. n. 0305475 (11/07/2024) - UOR: 003406

Study design
Two-arm single-(assessor)-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism spectrum disorder

Interventions
The researchers are inviting participation from two pools of participants: caregivers who have previously received in-person CST (referred to as "experienced caregivers") and caregivers who have not participated in any in-person CST (referred to as "naïve caregivers").
Following baseline ascertainment, participants in each pool (experienced vs naïve), identified by sequentially assigned identification numbers, will be randomly assigned by an independent statistician to either Kica-CST (experienced parents n=30, naïve parents n=30) or TAU (experienced parents, n = 30; naïve parents, n = 30) on a 1:1 allocation ratio using stratified randomization by age (below 60 months and 60 months and above) and autism severity (ADOS-2 Comparative Severity Score: minimal/low and moderate/high algorithm categorizations). These characteristics were selected as factors that may influence the treatment response. Allocation will be conveyed by email to the site coordinator who will relay it to the intervention team. The research and intervention teams will use separate office facilities. Research assistants, who were masked to treatment allocation, will rate baseline, immediate post-intervention and 3-month post-intervention measures from anonymized video recordings without indication of arm or timepoint.

Kica-CST:
Kica-CST is a self-paced mobile application based on the WHO Caregiver Skills Training, an open-access caregiver-mediated intervention (CST; Salomone et al., 2019). Kica-CST aims to support caregivers of children with Autism Spectrum Disorder in acquiring knowledge and strategies to promote caregiver-child interactions. It consists of six lessons, structured as follows:
Lessons 1 and 2 focus on child's engagement
Lessons 3 and 4 focus on play and home routines
Lessons 5 and 6 focus on communication
Each lesson includes a Learning mode for psychoeducation, a Practice mode for guidance on using strategies for interaction with children, and a Well-being mode to support caregiver's self-care. The intervention is fully self-paced, with an expected duration of 6 to 8 weeks.

Treatment as usual (TAU):
In line with standard practice for clinical trials in autism, access to normally provided services (TAU) will not be restricted in either group during the study. The researchers will examine the amount and type of intervention services that the Experimental group children will receive during treatment and the Control group children will receive during the waitlist period in relation to the primary outcome measures at post-treatment and 3-month follow-up (controlling for pre-treatment scores).
In Italy, TAU for children with autism in this age range predominantly consists of publicly provided occupational and speech and language therapy and generic psycho-education.; additionally, families may choose to privately access autism-specific behavioural interventions.

Intervention Type
Behavioural

Primary outcome(s)
1. Parent skills supportive of interaction measured using the Caregiver items (three items: scaffolding, following in, caregiver's affect) of the JERI at baseline and post-intervention
2. The amount of child communication acts that are initiations of communication during free-play caregiver/child interaction measured using the Child Initiations item of the Dyadic Communication Measure for Autism (DCMA) at baseline and post-intervention
3. Flow of the interaction measured using the Interaction Items (i.e., fluency and connectedness, shared routines and rituals) of the Joint Engagement Rating Inventory (JERI) at baseline and post-intervention

Key secondary outcome(s))
1. The use of parental strategies during free-play caregiver/child interaction measured using the WHO CST Adult-Child Interaction Fidelity Rating at baseline and post-intervention
2. The use of parental strategies during free-play caregiver/child interaction measured using the Naturalistic Developmental Behavioral Interventions-Fidelity (NDBI-Fi) at baseline and post-intervention
3. Parental interpretation of communicative signals measured using the Perceived Maternal Parenting Self-Efficacy (PMP S-E) at baseline and post-intervention
4. Parental self-efficacy measured using the Brief Parental Self-Efficacy Scale (BPSES) at baseline and post-intervention
5. Parental self-efficacy measured using the Me as a Parent Scale Short Form (MaaPs-SF) at baseline and post-intervention
6. Parental mental well-being measured using the Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS) at baseline and post-intervention
7. Parental depression, anxiety and stress measured using the Depression Anxiety Stress Scales (DASS-21) at baseline and post-intervention
8. Parental knowledge of intervention strategies and skills to apply them in a naturalistic context measured using the Participant Knowledge and Skills Test at baseline and post-intervention
9. Child joint engagement measured using the Child's Joint Engagement item of the Joint Engagement Rating Inventory (JERI) at baseline and post-intervention
10. Child availability to interact measured using the Child Availability to Interaction items (unengaged; object engagement; stereotyped, restricted, repetitive behavior; attention to caregiver; initiation of communication; expressive language level and use) of the JERI at baseline and post-intervention
11. Child gestures measured using the Total Gestures raw counts on the Italian version of the MacArthur-Bates Communicative Development Inventories (CDI) at baseline and post-intervention

12. Child expressive vocabulary measured using the Total Expressive Words raw counts on the Italian version of the MacArthur-Bates Communicative Development Inventories (CDI) at baseline and post-intervention
13. Child sentence complexity measured using the Total Complexity raw counts on the Italian version of the MacArthur-Bates Communicative Development Inventories (CDI) at baseline and post-intervention
14. Child adaptive behaviour measured using the Adaptive Behaviour Assessment System-Second Edition (ABAS II) at baseline and post-intervention

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Children aged between 18 and 72 months old and their parent(s)/guardian(s) or other caregivers
2. Recruited from Child Neuropsychiatry Services of the Italian National Health System
3. Child local Clinical diagnosis of autism meeting the diagnostic cutoff on the ADOS-2

Participant type(s)
Patient, Carer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
18 months

Upper age limit
72 months

Sex
All

Key exclusion criteria
1. Severe sensory disabilities (blindness, deafness) of the child, for whom intervention strategies are not adequate
2. Level of fluency in Italian language in parents insufficient to understand short written texts and audiovisual material

Date of first enrolment
20/11/2024

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Italy

Study participating centre
University of Milano-Bicocca
Department of Psychology
Piazza dell'Ateneo Nuovo 1
U6Building
Milan
Italy
20126

Sponsor information

Organisation
University of Milano-Bicocca

ROR
https://ror.org/01ynf4891

Funder(s)

Funder type
Government

Funder Name
European Union

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Erica Salomone (erica.salomone@unimib.it)

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	11/11/2025	11/11/2025	No	Yes