

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/11/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

<http://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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Community, Internet/virtual

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2023

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

Age group

Child

Lower age limit

18 Months

Upper age limit

72 Months

Sex

Both

Target number of participants

120

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

Sponsor details

Piazza dell'Ateneo Nuovo 1

Milano

Italy

20126

+39 (0)2 6448 3816

comitatoetico@unimib.it

Sponsor type

University/education

Website

<https://www.unimib.it>

ROR

<https://ror.org/01ynf4891>

Funder(s)

Funder type

Government

Funder Name

European Union

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2026

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