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The feasibility, acceptability and clinical impact of a guided self-help mobile intervention (INTERconNEcT-EDs) for individuals with eating disorders: protocol for two multicenter randomized controlled trials

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Abstract

Background Treatments for eating disorders (EDs) are marked by high rates of relapses and can be ineffective for almost one in two people. It has been suggested that digital self-help might enhance treatment engagement, retention and efficacy in this patient group. A novel guided self-help mobile intervention (i.e. INTERconNEcT-EDs) to target psychological distress and eating psychopathology in young adults with ED symptoms has been developed. INTERconNEct-EDs is an online, eight-week, guided self-help (GSH) program based on an integrated approach which combines elements of psychoeducation, behaviour change and interpersonal therapy tailored to individual's interpersonal difficulties.

Methods Two randomized controlled trials (RCTs) will be conducted to examine the acceptability, feasibility and impact of INTERconNEcT-EDs on a range of psychological outcomes of outpatients with eating disorders or people in the community with symptoms of disordered eating, in Italy. In the first RCT, 172 adult outpatients with EDs from two public clinical services will be recruited and randomised to treatment as usual (TAU) alone or TAU plus INTERconNEcT-EDs. The primary outcome will be patient psychological distress. Secondary outcomes will include eating disorder psychopathology, interpersonal distress, quality of life, motivation to adhere to standard treatment and INTERconNEcT-EDs, emotion dysregulation, and patient satisfaction, at end of the eight-week treatment and 3-month follow-up. In the second RCT, 70 adult individuals from the community with symptoms of disordered eating (measured by a self-report) will be randomised to receiving INTERconNEcT-EDs or a waiting list condition. The primary and secondary outcomes are identical to those of the first RCT. Moreover, participant's service use will be recorded at the end of the eight-week protocol. INTERconNEcT-EDs consists of psychoeducational workbooks, video-clips, weekly themed, and synchronous forum groups facilitated by individuals recovered from an ED. Participants randomised to

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TAU + INTERconNEcT-EDs in the first trial will also receive weekly online interpersonal group sessions. Group sessions will be tailored to target individual's interpersonal difficulties, as measured by the Inventory of Interpersonal Problems at baseline.

Discussion The results of this study will determine the feasibility and clinical impact of a novel eating disorder transdiagnostic self-help intervention with the potential of broad reach and scalability.

Trial registration ClinicalTrials.gov Identifier NCT06551974.

Keywords Eating disorders, Disordered eating, Guided self-help, Task-sharing, Online intervention, Peer mentoring, Personalization, Interpersonal therapy, Group treatment

Background

Eating disorders (EDs) are psychiatric illnesses characterised by dangerous eating behaviours, ranging from protracted undereating to recurrent episodes of loss of control overeating [1]. These unhealthy behaviours cause both physical problems and psychological distress. It has been estimated that 13% of young women experience a diagnosable eating disorder in their lifetime, possibly in association with functional impairment, emotional distress and suicidality risk [2, 3]. Moreover, individuals with an eating disorder are likely to report interpersonal difficulties, such as fear of negative social evaluation, which can lead to low self-esteem and negative affect [4, 5].

Despite the disabling nature of eating disorders, many individuals fail to access mental health care [3] due to feelings of shame and fear, ED-related beliefs such as defectiveness or failure-to-achieve, and lack of access to or availability of treatment sites [4]. In addition, high relapse rates and low rates of full recovery are common in EDs [6], and there is a call for the development of personalized interventions [7].

The use of eHealth technology has been proposed as a potentially effective alternative or addition to traditional, in person treatment for those with EDs. eHealth treatments can facilitate access to care by overcoming barriers such as geographical distance, stigma, and feelings of shame [8]. Self-help often includes the use of materials, such as books, workbooks and videoclips, to empower patients through information and skills to cope with the illness. Guided self-help (GSH) adds the element of guidance to the use of these materials. Guidance is usually provided by health professionals or expert-by-experience individuals (e.g., those recovered from an eating disorder) through websites or mobile applications. Online GSH has been used in EDs [9–11] to augment or replace standard care, and guidelines from the National Institute for Health and Care Excellence in the UK recommended it as first-line intervention for these conditions [12]. There is promising support for the effectiveness of online GSH in improving motivation to change and eating disorder symptoms in patients with EDs [8, 13]. Furthermore, the online format and the involvement of low trained individuals (i.e. individuals without formal clinical training, such as lay counselors, peer mentors with past lived experience, or psychology students) in providing guidance seem to reach more consensus among participants; for instance, previous research has showed that patients find ED management apps convenient and easy to use [14, 15]. Patients also found in-app social support from peers and professionals to be helpful in recovery [16]. A substantial body of evidence from meta-analyses indicates that the administration of digital GSH can result in substantial improvements in both eating disorders and general psychological well-being, across a range of eating disorders [9, 17, 18]. GSH interventions are also especially relevant for individuals who may be reluctant to seek conventional, in-person treatment [19]. Common barriers include shame, fear of judgment, and perceived stigma, all of which are frequently reported by individuals with eating disorders [20]. A number of studies have demonstrated that digital interventions, incorporating guided self-help, are regarded as more private, accessible, and acceptable [21] emphasizing the capacity of online GSH to engage individuals who might otherwise remain untreated [22, 23].

However, building a working alliance in digital interventions can be challenging, particularly in the context of EDs, where trust and engagement with clinicians are often hindered by feelings of shame and mistrust [24]. A recent study indicated that the therapeutic alliance with peer mentors who recovered from EDs was predictive of patient clinical outcomes in an online self-help intervention [25]. The relationship between the working alliance and treatment outcome in the GSH intervention is an important area of research to pursue.

As noted above, prior research has suggested that eating disorder psychopathology is maintained by interpersonal difficulties and that these difficulties can lead to poorer treatment outcomes [4, 5, 26–28]. For example, the interpersonal psychotherapy model of EDs [5] posits that difficulties in reciprocal interactions between the individual and the social world can trigger and maintain eating disorder symptoms [29]. According to this model, eating disorder symptoms can be viewed as a response to negative social evaluation [4]. It was hypothesised that negative interpersonal feedback about an individual's

social worth could trigger eating symptoms by negatively affecting self-esteem and emotional regulation [5–26]. Furthermore, evidence has been presented which indicates that interpersonal difficulties may contribute to the maintenance of an eating disorder through mechanisms such as social isolation [4]. Moreover, it has been demonstrated that dietary restraint and binge eating can occur in the context of adverse interpersonal events, such as conflicts or grief [29]. Given that individual heterogeneity in eating disorders is significant and that this variability can lead to different treatment needs and outcomes [30], individual interpersonal patterns of behavior, cognition and emotion can be identified and used for developing personalized guidance.

Aims

The overall aim of this project is to exploit the use of digital technologies (i.e., online GSH delivered through a smartphone application) to target psychological distress and eating disorder psychopathology in young adults with ED symptoms. Psychological distress has been identified as a key transdiagnostic factor implicated in the onset and maintenance of disordered eating behaviours [31, 32]. Moreover, it is an essential component in interpersonal interventions, which seek to enhance mental health and relational functioning in general [33], as well as in online guidance interventions that promote greater awareness [34]. A considerable corpus of research has demonstrated the efficacy of digital self-help interventions in alleviating psychological distress in individuals diagnosed with various eating disorders [17]. A novel GSH mobile intervention (INTERconNEcT-EDs) has been developed based on RecoveryMANTRA and ECHOMANTRA, two guided self-help interventions for eating disorders tested in the UK [34, 35]. INTERconNEcT-EDs will be tested in two different settings: (1) the outpatient setting for those with a diagnosis of ED; and (2) the community setting for those reporting disordered eating behaviors. Two randomized controlled trials (RCT) will be conducted to examine the acceptability, feasibility and impact of INTERconNEcT-EDs on psychological variables.

A secondary aim is to determine the extent to which working alliance with the INTERconNEcT-EDs therapists delivering the weekly online group guidance is associated with patients' clinical changes on a session-by-session basis during the eight-week intervention. Consistently with prior evidence supporting the association between working alliance and treatment outcomes in EDs [25, 36], it was hypothesized that higher alliance with the clinician and other group members in a group session would predict lower psychological distress in the following session.

Methods

Study design

Two parallel RCTs will be conducted to examine the efficacy of online GSH delivered through a mobile app for people with a diagnosis of EDs or disordered eating behaviors. This study was prepared in accordance with the SPIRIT and CONSORT guidelines [37].

Participant enrolment and setting of study 1

The first study is a multicentric RCT where people with a diagnosis of eating disorders attending outpatient eating disorder treatment at the University Hospital of Catanzaro or Padova (in Italy) will be recruited. The aim of this RCT is to answer the question: "Does INTERconNEcT-EDs provided in addition to treatment as usual (TAU) improve overall psychological distress, eating disorder psychopathology, interpersonal distress, quality of life, motivation for treatment, emotion dysregulation and client satisfaction compared to treatment as usual alone among people with an eating disorder attending outpatient treatment?". The inclusion criteria are: (1) ≥ 18 years, (2) a clinician-formulated diagnosis of eating disorder (i.e., anorexia nervosa, bulimia nervosa, binge eating disorder) or Other Specified Feeding or Eating Disorder based on the criteria of the DSM-5-TR, (3) having started TAU within one year (4), access to Internet connection through a mobile device, (5) Italian speaking. The exclusion criteria are: acute psychosis, pregnancy, use of medication that might influence eating behavior, neurological and visual impairment and intellectual disability, as established through clinical records.

Clinicians will schedule an enrolment session with eligible participants. If eligibility is confirmed, a brief introductory template explaining the aims of the study and intervention will be presented. Patients who agree to participate will be asked to provide their informed consent and to complete the baseline questionnaires through a link emailed to them by a research assistant. Participants will be randomized to one of two groups: (1) online guided self-help + treatment as usual (i.e. EDs multicomponent outpatient therapy provided by the treatment site, including CBT standard, individual psychotherapy, nutritional support and medical monitoring) or (2) treatment as usual alone. Participants will be randomized using a Web-based randomization tool, once they filled in the informed consent and baseline questionnaires. The research team at the University of Palermo will develop the randomization scheme and will provide the recruitment sites with opaque envelopes containing treatment assignments. Randomization after patient inclusion prevents the possibility of selection bias and will take place at the end of each enrolment session after the baseline survey will have been completed. Randomization will take place in blocks, in size of 16 participants, with a 1:1

allocation ratio to ensure a random allocation of 8 participants in each group per time. All outcomes will be collected by a research assistant who is blind to the participant's treatment allocation.

Participant enrolment and setting of study 2

The second study is a RCT involving individuals with disordered eating behaviors. Participants will be recruited from the community through advertisements posted in the psychoeducation Instagram profile "Dicci Come Aiutarti - #DCA" [38]. The main aim of this RCT is to answer to the question: "Does INTERconNEcT-EDs improve overall psychological distress as well as eating disorder psychopathology, interpersonal distress, quality of life, motivation for treatment, emotion dysregulation and patient satisfaction compared to a waiting list condition (only general practitioner consultation) in people with disordered eating in the community?". Moreover, the RCT will examine whether participants will access standard care by the end of the intervention (eight weeks) or 3 months follow-up. The inclusion criteria are: (1) ≥ 18 years, (2) a score > 2.77 on the Eating Disorders Examination Questionnaire, (3) regular monitoring of health status with own primary care physician (GP), 4) access to Internet connection through a mobile device, (4) Italian speaking. The exclusion criteria are: (1) self-reported acute psychosis, pregnancy, use of medication that might influence eating behavior, neurological and visual impairment and intellectual disability and (2) receiving specialised eating disorder treatment.

A research assistant will contact individuals interested in taking part to schedule a telephone session. If eligibility is confirmed, a brief introductory template explaining the aims of the study and intervention will be presented. Individuals who agree to participate will be asked to provide their informed consent and to complete the baseline questionnaires. Participants will be randomized to one of two groups: (1) guided self-help mobile intervention or (2) waiting list (only GP consultation). Participants, in accordance with the inclusion criteria and their score on the EDE-Q, will be randomly assigned to the intervention or control group with a 1:1 allocation ratio, using a Web-based randomization tool, once they filled in the informed consent and baseline survey. The Clinical Psychology Research Lab Unit at the University of Palermo will create the randomization scheme and provide the principal investigator with opaque envelopes containing treatment assignments. All outcomes will be collected by a research assistant who is blind to the participant's treatment allocation. A flowchart of the study is shown in Fig. 1.

Treatment arm: INTERconNEcT-EDs

In the first RCT, participants allocated to the intervention arm will have access to self-help materials (workbook and videoclips), weekly forum groups, and weekly online interpersonal group sessions for eight weeks, through a mobile app (see below for a detailed description of the intervention components).

In the second RCT, participants recruited from the community will have access to self-help resources and weekly forum groups for eight weeks. In order to improve the potential scalability of the intervention for participants in the community, they will not attend the weekly group interpersonal sessions. For this group of participants, a further workbook containing the list of available public EDs centres across the Italy regions will be provided to facilitate a first contact with public clinical services.

Self-help materials

INTERconNEcT-EDs will include self-help materials, i.e. a written workbook and a library of 74 brief video-clips with the goal of providing psychoeducation about eating disorders and interpersonal difficulties and describing and modelling the use of helpful strategies to reverse abnormal eating behaviours. Participants are permitted to utilize the self-help materials at a pace that is convenient to them. The workbooks have been meticulously designed to facilitate an exploration of the characteristics of anorexia nervosa, bulimia nervosa, and binge eating disorder. An additional workbook focuses on the transdiagnostic factor of interpersonal problems and how these can contribute to the development and maintenance of eating disorders. The video-clips are organised into seven main thematic areas: the maintenance of eating disorder symptoms, emotions, the importance of motivation, cognitive aspects and disorder-related thoughts, interpersonal relationships, life after an eating disorder, and the importance of seeking help.

Participants will use self-help materials through a mobile app and online platform, developed and managed by Tech Digit Easy s.r.l., a company leader in the design and development of E-health services and devices which has been cooperating with the Research Unit of the University of Palermo for 2 years. The online platform "aChiral" is an Electronic Data Capture system used in Clinical Research; it consists of mobile application and a web app. The system allows building the questionnaires in an easy way by giving the possibility to customize the app for the operator and for the patients (content, forum groups, notification). The system is validated according to GMP Annex 11 and FDA CFR 21 Part 11 and compliant with GDPR. Patient's sensitive data will be pseudonymized only after the Informed Consent and privacy form will have been signed by the patients. Data will be stored into

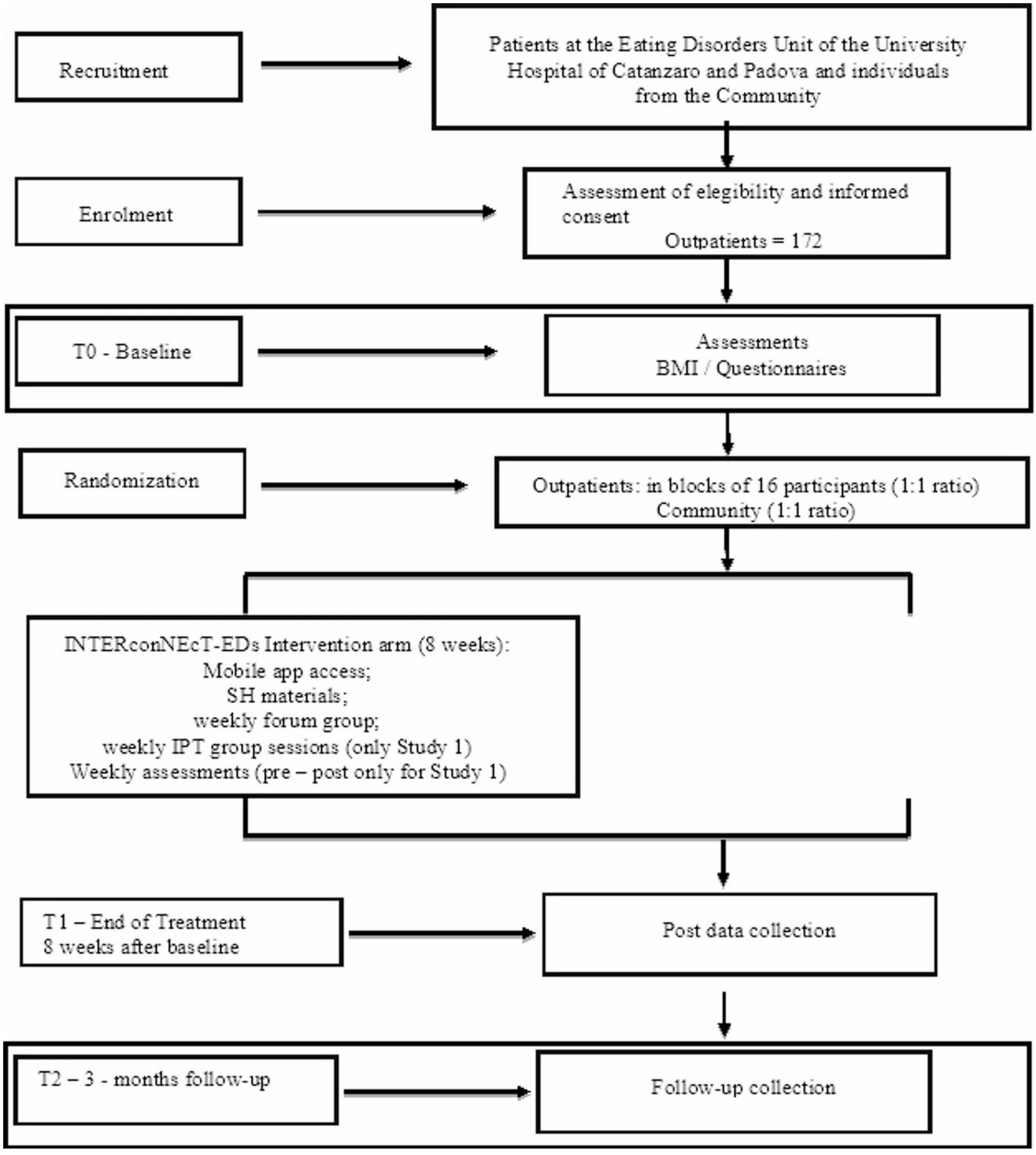

Fig. 1 Study design diagram flow

a private cloud server with a secure encryption based on exchange protocol https. Each patient will be pseudonymized with an identification code made up of 3 digit for the "site" identification, 3 digit for the Investigator that has enrolled the patient, 4 digit for the progressive number of the patient. The self-help resources will be available on the online platform for those randomly allocated to the intervention arms. The self-help materials, which include written workbooks and video-clips are based on the principles of the cognitive interpersonal model of eating disorders, eating disorder-specific model of interpersonal psychotherapy, behaviour change and the recovery approach [5, 35, 39]. The aChiral mobile application is designed to record the extent to which participants

utilize self-help resources, thereby facilitating an evaluation of their engagement with self-help interventions.

Online forum groups

The mobile app will enable participants to access synchronous weekly online forum groups through a 1-hour mobile chat with a peer mentor (a content creator recovered from an ED) and a low experienced professional (graduated students in psychology). A focus on motivation to change and hope in recovery will be promoted through motivational interviewing techniques and the lived experience of content creators (collaborators of #DCA). The peer mentors ($n = 8$) will encourage discussion around the information and exercises proposed in the workbook. Graduate psychology students will moderate contents against a pre-specified set of rules (e.g., to avoid sharing personal details and triggering contents). Peer mentors and psychology graduate students will receive training in motivational interviewing and the use of self-help resources, and supervision by the study team. The chat transcripts will remain available on the platform for all trial participants, peer mentors and interpersonal therapy therapists. Trial participants will be able to join any forum group for the duration of their participation in the trial (eight weeks). The text of the forums will be recorded, saved and used for team supervision. Each session is themed following the structure of the patient video-clips materials (see supplementary Table 1).

Interpersonal group sessions

Interpersonal therapy (IPT) is an evidence-based intervention to address interpersonal difficulties [40]. It has been adapted to treatment of eating disorders and demonstrated to be effective, especially for BN and BED [5, 29, 41]. In this project, IPT involves eight compulsory 90-minute online sessions, scheduled on a weekly basis. Like IPT-ED [42], the group intervention has 3 phases, each with its own aims and strategies. In phase one (session 1–2), the INTERconNEcT-EDs therapist engages participants in the group and describes the rationale of the intervention. Participants are guided to agree upon the interpersonal problems associated to the maintenance of the eating disorder that they will want to focus on during the intervention. Participants' baseline scores on the IIP-32 will be used by the therapist to identify individual dysfunctional interpersonal patterns (e.g. being overly invasive/dominant or submissive in interpersonal interactions) and to tailor the group intervention to the patient's interpersonal needs by helping them to manage their sources of interpersonal stress more effectively. In phase one, the therapist will provide to each group member the IIP visual map of individual's interpersonal style and this interpersonal profile will be used in problem identification and group planning. The visual map will highlight the predominant interpersonal challenges identified through the IIP-32 subscales, allowing the therapist to adjust the guidance to address these specific difficulties more effectively during the group sessions. For example, participants scoring high on social inhibition or avoidant behaviours might benefit from targeted encouragement to engage with others during group discussions, while those with issues related to controlling behaviours may be gently encouraged to adopt more collaborative communication patterns.

Phase two (sessions 3–6) is aimed to address participants' interpersonal problems, by sequentially working on the four IPT problem areas of grief, interpersonal role disputes, role transitions and interpersonal deficits. During phase three (session 7–8) the changes made during treatment are discussed and the use of helpful interpersonal strategies is reviewed to minimize relapses. Participants are reminded of the need to continue to address their interpersonal difficulties to make further progress.

Brief group intervention is solution-focused and action oriented [43] and suggests that the problem should be outlined and clarified collaboratively between the patient and the therapist [44]. The problem is framed with acceptance and positive feedback. The member then decides what he/she wants to change and examines if those changes will create the desired effect.

Group sessions will be led by experienced clinicians trained in IPT-ED. Fidelity to the intervention will be established during regular supervision meetings with the research staff and based on the treatment manual developed [5, 45]. The sessions will be delivered through a Zoom link available in the mobile application. The number of participants within each group will range from seven to eight.

Control arm

In Study 1, treatment as usual will include interdisciplinary approach consisting of weight monitoring and physical risks, dietetic assessment and some form of individual outpatient therapy (commonly cognitive behavioural therapy).

Structured interviews with clinicians will be conducted by at each study site to identify the content of treatment and any differences will be established based on the answers to the interview. We will also use an adapted form of the Client Service Receipt Inventory (a well-established tool used in health economics) to track the type and duration of treatment received over the year by participants [46]. The inventory will be administered at eight weeks and 3-month follow-up.

In Study 2, the control condition consists in receiving regular monitoring by a primary care physician and it is mandatory that participants provide the contact details of this professional.

Table 1 INTERconNEcT-EDs assessment content and schedule for both intervention and control groups for study 1 and 2

	BASELINE		WEEKLY		END OF 8 WEEKS INTERVENTION		3 MONTH FOLLOW-UP	
	IG	CG	IG	CG	IG	CG	IG	CG
Demographic questionnaire	✓	✓						
BMI	✓	✓	✓	✓	✓	✓	✓	✓
EDE-Q (28 items)	✓	✓			✓	✓	✓	✓
EDE-Q Short version			✓	✓				
CORE-OM (34 items)	✓	✓			✓	✓	✓	✓
CORE-10 Short version			✓	✓				
IIP-32	✓	✓			✓	✓	✓	✓
MOTIVATIONAL RULER	✓	✓			✓	✓	✓	✓
ACMTQ	✓	✓			✓	✓	✓	✓
DERS	✓	✓			✓	✓	✓	✓
WAI-P			✓					
GQ			✓					
DFlex	✓	✓			✓	✓	✓	✓
CSQ					✓			
PSU (only for the Study 2)	✓	✓			✓	✓	✓	✓
EQ-5D-5 L	✓	✓			✓	✓	✓	✓

IG: intervention group; CG: control group

At the end of the study, participants randomized to the control condition will be offered the intervention self-help materials (that is, videoclips and workbook).

Primary and secondary outcomes

Overview

The outcome assessments will be conducted at different time points (i.e., baseline, weekly, eight weeks, and 3-month follow-up; see Table 1 for the assessment schedule). Participants will complete the self-report measures on the Achiral capture platform. The control group will follow the same assessment schedule.

Demographic information

Age, height and weight, sex assigned at birth and gender identity, marital status, years of education, occupation, prior ED diagnosis, duration of illness, and medication will be assessed using a survey created for this study.

Primary outcome

Psychological distress will be assessed using the Clinical Outcomes in Routine Evaluation (CORE-OM) [47], a 34-item self-report measure measuring global distress across 4 domains: Well-being; Functioning; Problems/symptoms; Risk (to self and to others) over the previous week. Participants rate items on a 5-point Likert Scale, from 0 (not at all) to 4 (very often or always), with eight reverse-scored items. Higher scores indicate greater level of distress.

Secondary outcomes

Secondary outcomes will include eating disorder psychopathology, cognitive flexibility, interpersonal distress, quality of life, motivation for treatment, client satisfaction, emotion dysregulation.

The **Eating Disorder Examination Questionnaire (EDE-Q)** [48] is a 28-item self-report measure of eating disorder symptomatology on a 7-point Likert scale ranging from 1 (never) to 6 (every day) and includes both a global score and the following subscales: restraint, eating concern, shape concern, and weight concern, with higher scores reflecting greater psychopathology [49]over the previous 28 days.

The **Detail and Flexibility Questionnaire (DFlex)** [50] is a 24-item, self-report measure assessing two cognitive styles frequently reported in patients with eating disorders (ED): cognitive inflexibility (cognitive rigidity or difficulty in set-shifting) and over-attention to detail (weak central coherence) on a 6-point Likert scale ranging from 1 (strongly disagree) to 6 (strongly agree). evaluates. Higher scores reflecting higher levels of psychopathology.

The **Inventory of Interpersonal Problems (IIP-32)** [51] is a self-report 32-item inventory of distressing interpersonal behaviours on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely). It provides an overall score and eight subscale scores: (Domineering/Controlling, Vindictive/Self-centered, Cold/distant, Socially inhibited, Nonassertive, Overly accommodating, Self-sacrificing, Intrusive needy). Higher scores in each scale indicate the presence of interpersonal difficulties.

The **Difficulties in Emotion Regulation Scale (DERS)** [52] is a self-report instrument measuring emotion regulation problems on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always), with 11 reverse-scored items. The 36 items ask respondents how they relate to their emotions to produce scores on

the following subscales: non acceptance of emotional responses, difficulty engaging in goal-directed behaviour, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, lack of emotional clarity. Higher scores suggest greater problems with emotion regulation.

The **Autonomous and Controlled Motivations for Treatment Questionnaire (ACMTQ)** [53] is a 12-item self-report questionnaire; it consists of two subscales assessing autonomous and controlled motivation to adhere to standard treatment (TAU, in this study) on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). Higher scores indicate a stronger endorsement of the motivation type. Moreover, visual analogue scales will assess importance and confidence to change related to INTERconNEcT-EDs. Participants will be asked to rate how important it is for them to change (from 0 for 'not at all important' to 10 for 'extremely important') and how confident they are in their ability to change (from 0 for 'not at all confident' to 10 'extremely confident').

The **EQ-5D-5 L** [54] is a five-level health status measure and it was developed by a European consortium for use in health economics. It offers a simple index of health-related quality of life and it investigates five dimensions: mobility (MO), self-care (SC), usual activities (UA), pain/discomfort (PD), and anxiety/depression (AD).

The **Client Satisfaction Questionnaire (CSQ)** [55] is an eight-item self-report measure designed to assess participant satisfaction with the INTERconNEcT-EDs on a Likert scale ranging from 0 to 6. Higher scores indicate greater level of satisfaction. In the present study, the researchers adapted the CSQ to include one additional question to measure satisfaction with online-based treatment [56].

Participant's Service Use (PSU). Participants in study 2 will indicate the type of care accessed in the last eight weeks and the number of days they have used a service in the last eight weeks.

In study 1, participants will also complete the following measures weekly, for eight weeks.

The **Clinical Outcomes in Routine Evaluation short version (CORE-10)** [57] is a brief 10-item self-report measure assessing psychological distress developed for routine use in practice settings and taps into three domains: problems, functioning, risk. Participants rate items on a 5-point Likert Scale, from 0 (not at all) to 4 (very often or always), with 2 reverse-scored items. Higher scores reflecting higher symptomatology.

The **EDE-Q short version** [58]. This 7-item version of the EDE-Q measures three dimensions: dieting restriction, overestimation of weight and body shape and body dissatisfaction over the previous 7 days.

The **Working Alliance Inventory (WAI - SF)** [59] is a 12 item self-report measure assessing therapeutic alliance with the INTERconNEcT-EDs therapist on a 7-point Likert Scale, from 1 (never) to 4 (always). It yields a global scores and three subscales: (a) agreement on the tasks of therapy, (b) agreements on the goals of therapy, and (c) affective bond. A therapist version of the WAI will be administrated to the therapist at the end of each online group session.

The **Group Questionnaire (GQ)** [60] is a 30 item self-report measure assessing the therapeutic relationship in group on a Likert Scale from 1 (very little) to 7 (very much). It provides scores on three quality factors: (i) Positive Bonding, (ii) Positive Working, (iii) Negative Relationship.

Usability and acceptability

A brief online semi-structured interview will be administered to all intervention participants at the EOT. The aim of the interview will be to collect qualitative data on participant experiences and feedback on the programme and the app usability. The questions will centre on the participants' overall experience of participation, the utilisation and acceptability of the app and the self-help materials, the relationship with content creators/therapists or other participants, the challenges encountered, and suggestions for improvement. A thematic analysis will be employed to analyse these qualitative data. An amendment to the reviewed protocol has been submitted to the IRB prior to the usability implementation.

Procedure of outcome assessment

Once participants are added to the Achiral digital platform, the system sends them a notification on the app with the link to the scheduled questionnaires to complete. Patients are asked, where possible, to record weight and height at baseline, and weight also weekly, for eight weeks.

To minimise drop-out rates from completion of the assessment measures several strategies will be used: (i) participants will be cued by automated emails (sent by the Achiral online platform) or by phone call to complete the computerised self-report measures; (ii) they will receive a visual representation of their scores over time, which will also serve the purpose of checking symptoms changes over time and alert the GP of clinical team in case of worsening.

Statistical analyses

For first aim: Univariate analyses of variance will be used to compare the treatment arms in terms of baseline characteristics. Missing data will be imputed using multiple imputation based upon the Markov chain Monte Carlo method and maximum likelihood imputation based

upon the Expectation-Maximization (EM) algorithm. Linear Mixed-effects Models applying an intent-to-treat approach will be used to compare the intervention arm to the control group in terms of both primary and secondary outcomes. Each outcome will be examined in a separate model; participants will be treated as a random effect, and the treatment assignment will be treated as a fixed effect. Baseline levels of the outcome will be included as a covariate. Effect sizes will be calculated using Cohen's d. Furthermore, the Reliable Change Index of participants will be calculated for primary and secondary outcomes following the formula provided by Jacobson & Truax [61, 62] as a secondary analysis. This will facilitate the examination of patient improvement or deterioration following the GSH intervention. Regarding the secondary aim, a random intercepts cross-lagged panel model will assess the bidirectional association between therapeutic alliance (i.e. WAI and GQ) and post-session weekly outcomes (i.e. EDE-Q short, CORE-10). The random intercept in the model removes between-person variance (i.e., Level 2) such that the lagged relationships in the cross-lagged model characterize within-person change over time. Three fit indices will be used to evaluate the fit of the model: the comparative fit index (CFI), root mean square error of approximation (RMSEA), and standardized root mean square residual (SRMR). Two models will be estimated, one with the auto-correlation and the cross-lagged paths freely estimated, and a second model with the auto-correlation and the cross-lagged paths constrained to be equal across time periods.

Power calculation

An a-priori sample size was estimated using G*Power, based on previous research findings [10, 27]. Considering a mixed design factorial ANOVA, a statistical power of $(1 - \beta) = 0.90$, alpha level of 0.05, a small effect size (Cohen's $f = 0.10$) in mean improvement for outcome variables, and medium to high stability of the outcomes across time points ($r = .60$), the power analysis suggested a sample to include 86 participants per group, with a total of 172 participants in the study 1. An a-priori sample size was estimated using G*Power, based on previous research findings [63]. Considering a mixed design factorial ANOVA, a statistical power of $(1 - \beta) = 0.80$, a two-tailed alpha level and a small effect size (Cohen's $f = 0.10$) in mean improvement for outcome variables, and medium to high stability of the outcomes across time points ($r = .60$), the power analysis suggested a sample to include 35 participants per group, with a total of 70 participants in the study 2.

Ethical considerations

In compliance with the ethical standards for research outlined in the Ethical Principles of Psychologists and Code of Conduct [64], approval by the Ethics' Committee have been required and obtained by the Ethical Committee of the Catanzaro Region (protocol number 221 27.06.2024). In order to participate to the study, written consent from both clinical services and adult individuals from the community will be obtained. The number and proportion of people with adverse events will be registered. If patients need to be admitted to inpatient program whilst they are participating in the trial because their physical health has deteriorated, they will continue with their participation in the study. The number of days that patients spend in hospital throughout the study will be also recorded.

Data will be collected to assure participant's privacy and confidentiality protection (e.g., pseudonymization during the data collection). The collected survey data is only accessible to the research team, and the Principal Investigator is responsible for storing the identified data.

Discussion

According to prior research supporting the use of digital interventions in the treatment of EDs, it is expected that patients attending outpatient treatment for an ED who receive the guided self-help intervention will experience a significant reduction in overall psychological distress by the end of the eight-week intervention and at 3-month follow-up. This expectation is supported by previous findings that online and digital GSH interventions can reduce emotional distress in individuals with EDs, as these interventions promote greater awareness [65, 66]. In addition to reducing psychological distress, it is expected that the intervention will lead to improvements in eating disorder psychopathology, interpersonal distress, quality of life, emotion regulation and motivation to treatment. These improvements are likely due to the structured nature of the GSH intervention, which offers cognitive and behavioural strategies aimed at reducing disordered eating behaviours and at addressing underlying emotional and interpersonal triggers [67]. Given that interpersonal distress and emotion dysregulation have been identified as key factors in the development and maintenance of EDs [67], the app features that provide real-time feedback and promote emotional awareness of interpersonal stress may be particularly effective. Furthermore, the intervention is expected to enhance patient satisfaction with the treatment process, given the flexibility and accessibility of the digital format. Prior studies have shown that digital health interventions, such as mobile applications, can improve treatment engagement and satisfaction due to their ability to provide continuous support and real-time monitoring, which may be lacking in traditional face-to-face therapy [68]. This is particularly relevant in the case of EDs, where patients often face barriers to accessing specialized care [69].

Secondly, it is expected that the GSH intervention will lead to a reduction in overall psychological distress in participants with symptoms of disordered eating in the community and their increased likelihood of a first contact with clinical services. By raising awareness of symptoms of disordered eating patterns and providing early access to resources, the GSH app may encourage individuals to seek specialised treatment for their eating disorder, thus reducing the time lag between symptom onset and clinical treatment [70]. The potential for digital tools to reduce barriers to care, particularly in underserved populations such as individuals with symptoms of disordered eating, is one of the most promising aspects of this research.

Similarly to the clinical population in study 1, it is also expected that individuals from the community sample will demonstrate improvement in the secondary outcomes. Previous studies have demonstrated that psychoeducation and self-monitoring are effective in reducing symptoms of disordered eating [71]. Moreover, the flexibility of the digital format is expected to enhance individuals' satisfaction, particularly among those who are not attending a specialised, face-to-face eating disorder intervention and who may prefer the convenience and anonymity of online interventions instead [72].

Finally, it is expected that the strength of the therapeutic alliance with therapists during the online interpersonal guidance sessions could be positively associated with clinical improvements. Building a therapeutic alliance in digital interventions can be challenging in the context of EDs [25]. However, previous research has demonstrated that even in online and digital formats, a strong therapeutic alliance can predict better treatment outcomes [38]. We hypothesize that a higher degree of alliance with the clinician and group members will predict lower psychological distress in subsequent sessions, as the sense of connection and support within the group may enhance the individual's willingness to engage in treatment and apply the strategies learned during the sessions outside the therapy setting [25].

These expected results would align with previous research suggesting that digital health interventions can effectively bridge the treatment gap for both clinical and subclinical populations with EDs [22, 65, 69].

Despite the potential scalability of mobile and online platforms, it is worth noting that individual engagement with digital interventions can be variable. Previous studies have noted that adherence to self-help programs, particularly those delivered online, can be lower compared to traditional face-to-face therapies [73]. Dropout rates may pose a significant challenge, particularly among individuals with greater symptom severity, who may require more intensive support. To mitigate this risk, the intervention incorporates weekly online group guidance. The extent to which guidance might enhance engagement remains to be seen.

In summary, the current study addresses one of the most pressing challenges in the treatment of EDs: accessibility of care. Many individuals with EDs do not seek help due to stigma, logistical barriers, or lack of awareness [18]. By offering a scalable and cost-effective intervention through a smartphone app, this study has the potential to bridge the treatment gap and provide support to individuals who might otherwise remain untreated. If successful, this approach could also inform broader mental health strategies that aim to provide early intervention for those with emerging symptoms, thereby preventing the progression to more severe disorders [74]. Finally, by personalizing the intervention, the study will support a clinical guidance tailored to the unique interpersonal challenges faced by each participant suffering from a ED.

Trial status

Recruitment commenced in November 2024 and will continue for approximately 8 months. All data are expected to be collected by November 2025.

Abbreviations

EDs	Eating Disorders
GSH	Guided Self-Help
RCT	Randomized Controlled Trials
TAU	Treatment As Usual
UK	United Kingdom
DSM-5-TR	Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition – Text Revision
GP	General Practitioner
#DCA	Dicci Come Aiutarti
IPT	Interpersonal group therapy
BMI	Body Mass Index
EM	Expectation Maximization
CFI	Comparative Fit Index
RMSEA	Root Mean Square Error of Approximation
SRMR	Standardized Root Mean Square Residual
IG	Intervention Group
CG	Control group

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40337-025-01320-z.

Supplementary Material 1

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Author contributions

GL, VC, SG, GA contributed to conceptualization and the design of the project. SG, CSG, GL received funding for the project. GA and GL wrote the first draft of the manuscript. All authors contributed to the writing the manuscript. VC, SG, CSG, and GL are contributing to study supervision.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
The Ethics' Committee of the Catanzaro Region has granted ethical approval to the study (protocol number 221 27.06.2024). Study psychiatrists will discuss informed consent in detail with potential participants, including a discussion of any questions/concerns regarding the study. Participants will commence study participation once written informed consent is obtained. Both prior to signing the consent form, and on the form itself, it will be made clear to potential participants that entry into the study is voluntary and if they opt not to participate this will in no way affect their relationship with the hospital or study investigators/clinicians.

Consent for publication
N/A.

Competing interests
The authors declare no competing interests.

Confidentiality
To ensure confidentiality, all data collected will be pseudonymized. The digital platform is validated according to GMP Annex 11 and FDA CFR 21 Part 11 and compliant with GDPR. Research data will only be accessible to staff involved in the study as needed. Where participant consent is provided for data to be re used and shared with other researchers for future research projects, data will only be provided in a de-identified format and with separate ethics approval.

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