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BMJ Open Designing an online intervention for adults with addictive eating: a qualitative integrated knowledge translation approach

Mark Leary , ¹ Kirrilly Pursey, ¹ Antonio Verdejo-García, ² Janelle Skinner, ¹ Megan C Whatnall, ¹ Phillipa Hay , ³ Clare Collins, ¹ Amanda L Baker, ¹

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¹College of Health Medicine and Wellbeing, The University of Newcastle and Hunter Medical Research Institute. Newcastle. New South Wales, Australia ²Monash University, Clayton, Victoria, Australia ³Western Sydney University, Penrith South, New South Wales, Australia

Correspondence to

Professor Tracy Burrows; Tracy.Burrows@newcastle. edu.au

ABSTRACT

Introduction Codesign is a meaningful end-user engagement in research design. The integrated knowledge translation (IKT) framework involves adopting a collaborative research approach to produce and apply knowledge to address real-world needs, resulting in useful and useable recommendations that will more likely be applied in policy and practice. In the field of food addiction (FA), there are limited treatment options that have been reported to show improvements in FA symptoms.

Objectives The primary aim of this paper is to describe the step-by-step codesign and refinement of a complex intervention delivered via telehealth for adults with FA using an IKT approach. The secondary aim is to describe our intervention in detail according to the TIDieR

Design This study applies the IKT process and describes the codesign and refinement of an intervention through a series of online meetings, workshops and interviews.

Participants This study included researchers, clinicians, consumers and health professionals.

Primary outcome measure The primary outcome was a refined intervention for use in adults with symptoms of FA for a research trial.

Results A total of six female health professionals and five consumers (n=4 female) with lived overeating experience participated in two interviews lasting 60 min each. This process resulted in the identification of eight barriers and three facilitators to providing and receiving treatment for FA, eight components needed or missing from current treatments, telehealth as a feasible delivery platform, and refinement of key elements to ensure the intervention met the needs of both health professionals and possible

Conclusion Using an IKT approach allowed for a range of viewpoints and enabled multiple professions and disciplines to engage in a semiformalised way to bring expertise to formulate a possible intervention for FA. Mapping the intervention plan to the TIDieR checklist for complex interventions, allowed for detailed description of the intervention and the identification of a number of areas that needed to be refined before development of the finalised intervention protocol.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Our study engages consumers, end-users and stakeholders in the codesign process to improve the translation into clinical practice.
- ⇒ Our study adopts the integrated knowledge translation approach as a framework which aims to produce and apply knowledge to address real-world needs, resulting in useful and useable recommendations that will more likely be applied in policy and
- ⇒ A limitation of our study was the underrepresentation of males as both consumers and health professionals.

INTRODUCTION

The interest of health research codesign, which typically includes collaboration across all stages of the research process, has been increasing globally over the past few decades.² Codesign is considered a meaningful enduser engagement in research design and is seen as a way of increasing the use of known effective healthcare innovations while decreasing overuse of ineffective ones. ^{1–3} Due to a reported lack of translation into clinical practice and the significant time delay, 45 the codesign process aims to help move research into clinical practice with greater ease and pace.² This approach involves working with stakeholders (business or customers) within the design development phase to ensure the results meet their needs.

In the field of food addiction (FA) which is considered a transdiagnostic dimension, research currently estimates that FA as assessed by self-reported tools affects 15%–20% of the adult population. ⁶⁷ Previous studies report consumers seeking help, as well as health professionals being asked by patients for treatment options.8 Reviews indicate that self-help groups are highly prevalent for the management of FA, vet often lack involvement of health professionals, and the efficacy on FA outcomes has not been explored. Other reviews show a number of treatments being tested ranging from psychosocial support¹⁰ through to more invasive procedures such as gastric banding surgery. 11 12 Currently, the treatment options reported to show improvements in FA symptoms are varied and include medication (combination of naltrexone and bupropion, as well as pexacerfont), ¹³ ¹⁴ bariatric surgery ¹¹ ¹² and lifestyle modification. 15 However, it is important to note that no studies to date ¹⁶ report engaging consumers with FA in the development of the intervention. Several studies in the areas of diabetes, ¹⁷ mental health, ¹⁸ asthma¹⁹ and stroke ²⁰ ²¹ have reported on the benefits of adopting a codesign approach to help generate more relevant and actionable intervention research. Within the context of FA, which has been found to be positively associated with co-occurring mental health conditions such as depression, anxiety, eating disorders⁷ ^{22–24} and severe mental illness including schizophrenia and bipolar affective disorder,²⁵ developing treatment options in combination with health professionals and consumers with lived overeating experiences through a codesign process may be of benefit, and assist with improving translation for clinical practice.

Codesign can take a number of forms, including the use of stakeholders such as knowledge users (ie, patients, caregivers, clinicians, policy-makers and health professionals), within an array of different frameworks.³ One such framework that is increasingly used and applied to health research codesign is integrated knowledge translation (IKT). This framework involves adopting a collaborative research approach with those people who will ultimately use the research outputs (eg, health professionals and consumers). ^{2 3 26 27} It includes researchers working in equal partnership with knowledge users and others who identify a problem and have the authority or ability to implement or use the research recommendations.² The aim of the IKT process is to produce and apply knowledge to address real-world needs, resulting in useful and useable recommendations that will more likely be applied in policy and practice. ^{2 3 26} The advantages of the IKT process over other codesign frameworks is that it is the only collaborative approach originally developed in a health research context, 28 while being an iterative process involving a range of people and knowledge users, all of whom are considered as equal partners regarding their views and values.^{3 27 28} Although the codesign approach has become more popular and frequently used, reviews have shown there is a lack of standard terminology, the method is rarely described in detail and outcomes are not well documented.1

Complex interventions are considered those that usually contain several interacting components, require new behaviours by those delivering or receiving the intervention, have a variety of outcomes or target a number of groups for the intervention. ^{29 30} While there are no specific therapeutic approaches, previous studies have

highlighted the diversity as well as the many elements required for a potentially successful FA intervention (eg, mindfulness, behavioural training, self-reflection, goal setting and physical activity) ^{10 15 31 32} and combinations of these. It is for these reasons that possible treatments for FA meet the definition of a complex intervention. ^{29 30} A number of frameworks have been proposed to address this need for better intervention development and documentation including the Medical Research Council's (MRC) guidelines for complex interventions, ²⁹ and the Template for Intervention Description and Replication (TIDieR) checklist. ³³ Both of these frameworks aim to improve research quality ³⁴ and allow researchers to choose appropriate methods ³⁵ increasing reproducibility and validity of studies. ²⁰ However, systematic reviews have indicated that few interventions are meeting these guidelines. ³⁶⁻³⁹

Given the few treatment options available for people with self-reported FA, a brief intervention was piloted by our research group in 2018. This pilot study included personality-based telehealth sessions with an Accredited Practising Dietitian for adults with symptoms of addictive eating. The unique approach of personalised feedback on personality profiles has been found to effectively target modifiable risk factors associated with the development of substance-use disorders and shown to be an economically viable alternative to face-to-face models of care. Telehealth may also help address barriers such as stigma and increased levels of anxiety that may be associated with appointments and FA, allow more individuals to access help from their own home and reduce geographical barriers, and facilitate equity in service delivery.

This study applies the IKT process to refine the previous pilot FA intervention by collaborating with researchers, clinicians and knowledge users, specifically consumers and health professionals, in an attempt to better meet the identified needs of individuals with FA, thus bridging the potential gaps in research translation. Specifically, the primary aim of this paper is to describe the step-by-step codesign and refinement of a complex intervention delivered via telehealth for adults with FA using an IKT approach. The secondary aim is to describe our intervention in detail according to the TIDieR checklist.

METHOD Study design

The current research applied an IKT methodology involving a series of meetings, workshops and interviews with knowledge users to adapt and refine a complex intervention for FA (figure 1). The meetings and workshops were structured around the relevant domains of the MRC guidelines³⁵ and TIDieR framework³³ for the development and evaluation of complex interventions, including developing, piloting, evaluating, reporting and implementation. Sessions were held between October 2020 and June 2021 with each of the sessions audiorecorded in order to review the summaries and outcomes as needed by the IKT research group.

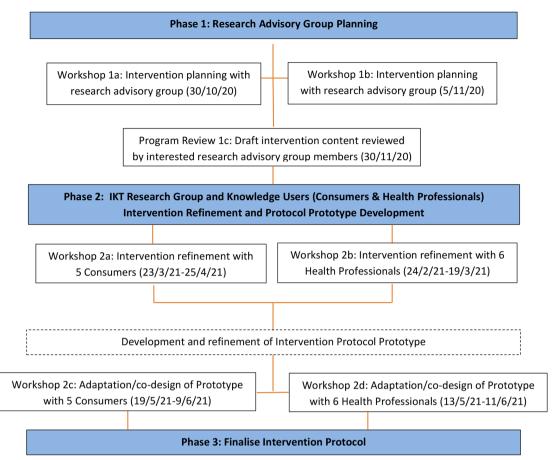


Figure 1 Overview of the major phases used in the integrated knowledge translation (IKT) framework.

The outcome of the current research was a refined intervention programme for use as an active treatment arm in a randomised controlled trial targeted at adults with FA which is currently at the pre-results stage (trial registration ACTRN12621001176853). For the purposes of reporting and to adhere to the IKT approach, the research was undertaken in three phases outlined in figure 1.

Participants and recruitment

For this study, three different groups were formed as follows:

The IKT Research Group

comprised of four core members (n=4) responsible for running the IKT study. This group was established prior to starting the IKT process and included key researchers (TB, JS, MCW and ML).

The research advisory group

The research advisory group comprised a broader range of researchers, experts and clinicians working in fields related to the programme and research area. This included addictive overeating, dietetics, eating disorders, psychiatry, neuroscience and addiction. The group consisted of 11 members including the four members from the IKT research group to help plan the programme outcomes, approach, efficacy and research question.

The knowledge users group

The knowledge users group comprised of six health professionals who worked in dietetics, psychology, mental health and disordered eating, as well as five consumers. The five consumers were not assessed for FA by the IKT research group, however, they reported lived overeating experience.

Members of both knowledge user groups were recruited through professional networks known to the IKT research group, previous addictive eating studies and social media. Informed consent was obtained from all knowledge users prior to the commencement of the study.

Measures

Demographics

Demographic information was collected from the knowledge user group only via an online survey. Specifically, for health professionals (n=6) this information included; gender, occupation, area of clinical specialisation, number of years specialising, location and primary work environment. Similarly, demographic information from consumers (n=5) was collected. This information included gender, age, geographical location, highest education qualification and types of treatment options undergone to manage addictive overeating.



| Phase | Elements identified | Consensus findings |
|-----------------------------|---------------------|---|
| Phase 1: (n=7 participants) | Research Question | What is the effectiveness of a personality targeted intervention on addictive overeating? |
| | Research Approach | Adopt a three arm randomised control trial comprising of an active intervention group, passive intervention group and passive control group ► Outcomes at baseline, 3 months and 6 months. ► Include participants from across the weight spectrum with BMI ≥18 kg/m². ► Exclude participants with a diagnosed eating disorder. |
| | Efficacy | Use the YFAS 2.0 ⁶⁴ to calculate sample size with stratification for weight status and mental health |
| | Outcomes | Primary outcome—Use the YFAS 2.0 symptom score |

Procedures

Phase 1: Start-up and planning meetings – the research advisory

The research advisory group met on two separate occasions via virtual workshops in October 2020 (six participants) and November 2020 (eight participants), each lasting 2 hours. The purpose of these workshops was to review updated programme content based on previous process evaluation⁴⁷ and feasibility trial.⁴⁰ More specifically, the workshops determined four factors necessary to ensure adherence to an IKT approach in relation to the development of an intervention. These included the research question/s, the research approach (and each project members' role within this), how efficacy would be ascertained and the outcomes that were to be sought (table 1).

Both workshops were facilitated by the same member of the IKT research group who helped to iteratively summarise the discussion and seek consensus on decisions around these four key areas. Any members that were unable to attend the scheduled workshop, were given the opportunity to review the notes from the workshop and provide comments for consideration by the team. On completion of the initial workshops (figure 1A,B, workshops 1a and 1b), members were asked to review draft content of the revised pilot programme (figure 1C). Those interested were given the option of reviewing some or all of the session content.

Phase 2: intervention refinement workshops and protocol prototype development

Each knowledge user participant was invited to two online semi structured interviews which were audio recorded (figure 1, workshops 2a, 2b, 2c and 2d), and lasted approximately 60 min each. The choice of an individual interview style approach rather than a group workshop was based on availability of both participants and IKT research group members as well as COVID-19 restrictions.

The first interviews (2a and 2b) were held between February 2021 and April 2021, and the second interviews (2c and 2d) were held between May 2021 and June 2021

(table 2). Each interview was facilitated by the same two members from the IKT research group. Prior to the first interview, participants were sent a broad list of preselected questions to assist in preparation for the interview, an overview of the revised programme content and various draft intervention handouts for discussion during the interviews.

The objectives of the interviews were to:

- 1. Capture the experience and knowledge of health professionals who work with people with FA, as well as consumers who have had experience either receiving or not receiving treatment for FA in the past. The aim was to elicit information on: (1) the perceived barriers and facilitators related to receiving/seeking out treatment for FA and providing treatment to adults who experience FA; (2) whether the use of an online platform (eg, telehealth) to deliver such a treatment was feasible and (3) to identify any key components important or missing from current treatments to ensure engagement, usability and uptake of an intervention.
- 2. Receive feedback on a range of drafted programme elements, such as terminology, content, concepts and materials that complement the study in order to finalise the intervention protocol.
- 3. Provide feedback to each knowledge user regarding the main results of the interviews.
- 4. To develop a protocol prototype of the intervention based on consensus and feedback from the previous phases.

Prior to the second interviews (2c and 2d), the IKT research group refined the intervention protocol prototype. They then consolidated this information and presented the main findings to the broader research advisory group for further feedback. The second interviews were attended by the same five consumers from 2a, and four of the six health professionals that participated in 2b. The two health professionals that were not available for interviews, provided written feedback via email.

Phase 3: finalise the intervention protocol

During phase 3, the IKT research group met on three occasions to consolidate the feedback, determine the



| Table 2 Summary | of the knowledge u | users' responses to the four main | rs' responses to the four main objectives from phase 2 a and 2B interviews | |
|---|------------------------|---|---|---|
| Phase | Objective | Thematic findings | | Verbatim evidence |
| Phase 2a and 2b: (n=11 participants) | Perceived barriers | Time (lack of time/time consumir readiness to change, stigma, pat need for ongoing follow-up and sof accountability, lack of practical | ient anxiety, limited structure, support between sessions, lack | "lack of time". (HP) "ongoing follow-up". (HP) |
| | Perceived facilitators | Ability to utililise various mediums behaviour change (eg, food moni eating, hunger/fulness scales, foo as part of a multi-disciplinary teatreatment. | itoring, self-reflection, mindful od/emotion diaries), working | "use of hunger and fullness scales are good". (HP) |
| | Delivery mode: | Positives | Negatives | |
| | Telehealth | Reduce patient anxiety Allows patients the option of video/no video Convenience Increases accessibility to treatment Anonymity means that patients may be more open | Some patients prefer face-to- face Difficulty for rapport building Increased nervousness due to lack of technology skills Dependent on reliable internet access Greater difficulty reading body language | "lack of skills". (HP) "it's more accessible". (HP) "allows people who struggle to travel to engage in these services". (HP) "anonymity behind a camera which allows them to speak out". (HP) |
| | Key components | Evidenced-based, focused on be terminology, include psychologic skills, clinicians trained in motiva mindfulness, adopt a holistic app | al support, provide practical tional interviewing, include | "give them practical skills". (HP) |
| HP, health profession | al. | | | |

outcomes, and focus on those areas in which there was no clear consensus by aligning with the four factors outlined and identified in Phase 1 (table 3). Each area of phase 1 and phase 2 as above was discussed and adaptations to the protocol prototype were made by the IKT research group based on the feedback from those knowledge users. The end result is the intervention outlined and described in table 4 of the TIDieR framework.

Analysis

Following each round of interviews and workshops, the audio recordings were listened to by at least one interviewer and one independent person not involved in the interviews to identify key elements raised by each participant. An inductive approach was taken to allow key elements to arise from the data. These were tabulated and grouped into themes by two reviewers, then reviewed by the IKT research group for consensus. The IKT research group identified 11 elements to be addressed in the codesign process and presented them as goals for refinement during the phase 2 interviews. These elements are displayed in table 3 and include: terminology, programme name, concepts, programme goal, materials, programme content, person with lived experience, character stories, support post programme, additional support and consent to contact participants' general practitioner. Feedback from the interviews and workshops were mapped to the TIDieR checklist to ensure complete intervention development (table 4).

Patient and public involvement

Five consumers with self-reported lived overeating were involved in the study throughout phase 2 of the IKT codesign process (see figure 1). They were recruited to be part of the 'Knowledge Users' group for the purpose of giving insight to what they perceived as the barriers and facilitators to receiving/seeking out treatment for FA, whether the use of an online platform (eg, telehealth) was feasible, to identify any key components important or missing from current treatments, and to give feedback regarding a range of refined handouts used in the intervention. Two of these consumers were later invited to become part of the larger research advisory group before the start of phase 3.

RESULTS

Knowledge users

Health professional demographic survey

All health professionals (n=6) were female with the majority (n=5) being dietitians and one a psychologist. However, the areas of specialisation reported were diverse spanning obesity management, eating disorders, overeating and mental health. The majority of health professionals worked in a metropolitan location including a hospital setting comprising inpatient and outpatient settings (n=4), private practice (n=1) or community/population health (n=1).



| Phase | Elements identified | Key findings | Verbatim evidence |
|--|------------------------------|--|--|
| Phase 2a and 2b: (n=11 participants) | | Avoid words such as 'good', 'bad', 'healthy', 'unhealthy'. Use neutral words to avoid stigmatising. | "make food terms more neutral". (HP) |
| | Programme name | The previous name 'FoodFix' was perceived negatively. | "sounds like there's something wrong with us that needs to be fixed". (C) |
| | Concepts | Exclude some concepts (eg, Good Eating Occasion) as they were deemed not necessary. | "I don't really relate to this". (C) "I prefer the foodline concept". (C) |
| | Programme goal | To improve the relationship with food. | "yesI think the relationship with food is under-emphasised for many people" (HP) |
| | Materials | Development of complementary materials (eg, participant workbook, website, telehealth and participant handouts) were viewed positively, however required editing to make them user friendly. | "the more mediums the better". (HP) "make sure the workbook and website aren't too text heavy". (HP) |
| | Programme content | Content of the programme to be delivered over the five telehealth sessions within 3 months was deemed appropriate. | "format of the content is good". (HP) |
| | Person with lived | Involve someone with lived overeating experience in the programme in some capacity. | "a peer with experience may be useful they have techniques" (C) |
| | Character stories | Deemed positive, however feedback on how to represent the characters was inconsistent. | "prefer it as a case study". (C) "present as small snippets". (C) |
| | Support post programme | Voluntary participation in a closed Facebook group offered to participants for additional support post-programme. | "some kind of facebook page to connect the participants". (HP) |
| Phase 2c and 2d: (n=11 participants) | Programme name | Consensus reached after phase 2. The IKT Research Group called the programme 'TRACE Programme: a personality-based eating awareness programme'. | |
| | Materials | Edited versions of the participant workbook, telehealth and participant handouts were deemed appropriate. | |
| | Additional support* | Links to additional Australian support services (eg, the butterfly foundation, mindspot and headspace) were added to the website and participant workbook. | |
| | Person with lived experience | Consumers with lived overeating experience (one male, one female) were added to the research advisory group and given the role to review programme materials. | |
| | Character stories | Include as a series of small snippets in the participant workbook and website. | |
| | Consent to contact GP* | Consent required from the participant to contact their GP or other health professional if there is an identified increased health risk of participating in the programme | |

Consumer demographic survey

Addictive and Compulsive Eating.

Of the five consumers who participated, the majority were female (n=4). They were 40 years of age or older (n=5), with the majority living in a metropolitan location (n=3). Two had completed an undergraduate university degree (n=2). Four of the five consumers

reported seeking previous treatment for their addictive overeating from four or more services which included but was not limited to: various health professionals (n=4), supplements (n=3), group support (n=3), meal replacements (n=2), smartphone apps (n=2) and books (n=2).

| Template for Intervention Description and Replication (TIDieR) item no | Description |
|--|--|
| Brief Name Provide the name or a phrase that describes the intervention | TRACE Programme: a personality-based eating awareness programme. To improve the relationship with food in adults with addictive overeating through a personality-based intervention. |
| 2. Why Describe any rationale, theory, or goal of the elements essential to the intervention | Rational: Previous reviews have identified self-reported FA affects 15%–20% of the adult population. ^{6 7} Further reviews on treatment show that no treatment options have been powered to detect changes in FA as a primary outcome. ¹⁶ Essential elements: Motivational interviewing (MI) based on the Patient Activation construct with open ended questions ⁶⁵ conducted via a telehealth platform (VSee) and delivered by a trained Accredited Practising Dietitian (APD). Personalisation of the intervention is based on feedback from validated surveys. Key areas of feedback include personality profiles, eating behaviours and lifestyle components including food, physical activity, sleep, alcohol and caffeine. Goal setting and behaviour tracking via checklists, diaries and rating scales will also be included. |
| 3. What: Materials Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can) be accessed. | Materials for the participant 1. Participant Workbook—140-page workbook provided to the participants to encourage reflective practice and increased mindfulness. Available as either a hard copy or pdf to download online via the website. The workbook mirrors the content of the online telehealth sessions and includes five key modules: personality, food, skills, confidence and moving forward. 2. Feedback of survey results including addictive eating, ⁶¹ personality, ⁶⁰ physical activity, ⁶¹ sleep, ⁶⁸ and dietary feedback, ⁶⁹ These results are emailed to participants before their first telehealth session and help to ensure the intervention is personalised. 3. How to get the most out of a telehealth consult resource – 1-page handout emailed to participants before their first telehealth session with tips on how to get the most out of a telehealth consult. 5. Website access—contains information to compliment the workbook Materials for the clinician 6. Website access—contains information to compliment the workbook Materials for the clinician 7. Fecilitator Manual—224-page manual provided to the APD to help facilitate treatment and ensure standardised delivery of the intervention across the five sessions of the programme. 8. Materials for participant and clinician 8. Materials for participant and clinician 9. Materials for participant and clinician 10. Materials for participant and clinician 11. Materials for participant and clinician 12. Materials for participant and clinician 13. Materials for participant and clinician 14. Materials for participant and clinician 15. Materials for participant and clinician 16. Materials for passion). Internet connection. Access to VSee platform. |

Continued

Continued

| Table 4 Continued | |
|---|--|
| Template for Intervention Description and Replication (TIDieR) item no | Description |
| 4. What: Procedures Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities | Prior to participation: - Prefer to transfer to undego eligibility screening if eligible, participants are asked to complete the electronic consent and baseline surveys. Intervendion details (including goals and main features). - Participants to undego eligibility screening if eligible, participants are asked to complete the electronic consent and baseline surveys. Intervendion details (including goals and main features). - Session I — Determine the participants main concerns with their food intake and addictive eating and major proveness. Impulsively proveness or Servation to root inside and addictive eating and major proveness in multism invariate to cold inside and addictive eating. - Bosus to we personant within invariate for to cold inside and addictive eating. - Bosus expension including that in my relates to cold inside and addictive eating. - Bosus expension including that in the "Addictive Eating Action Plan" (Session 2 - Loot. - Bosus expension and addictive eating and major expenses with coping strategies and electronic mental or or disease. In the "Addictive Eating Action Plan" (Session 2 - Loot. - Bosus expension and addictive eating behaviour. - Bosus expension and addictive eating behaviour. - Bosus Practical Strategies to Admine Fingers for Overearing Officialist. - Provide bedoack on ideatry with updated of Overearing Officialist. - Provide bedoack on ideatry with updated of Stategies to safe plan plan" (Session 2 - Indoor eating behaviour end and strategies to safe participant with session summary with updated 3 stategies to safe strategies to safe strategies to safe strategies to safe behavior behavior behavior to reprode participate with session summary with updated 3 stategies to safe participant with session summary with updated 3 stategies to safe participant with session summary with updated 3 stategies to safe participant with session summary with updated 3 stategies to safe participant with session summary with updated 4 stategies to safe participant with session summary wi |
| Who provided For each category of intervention provider, describe their expertise, background, and any specific training given. | Telehealth sessions—provided by an APD with training in MI, disordered eating, patient activation, and counselling expertise. The dietitians providing the telehealth sessions were also involved in the pilot study and have former research skills in this area and expertise with FA population groups. Dietitians could be trained/upskilled with the facilitator manual. Facebook closed group—monitored by IKT research group |



| Table 4 Continued | |
|--|--|
| Template for Intervention Description and Replication (TIDieR) item no | Description |
| 6. How Describe the modes of delivery of the intervention (was it provided individually or in a group) | Telehealth sessions with an APD will be provided individually via VSee platform or phone where this is not possible. The initial session will be booked with a member of the IKT research group, with subsequent sessions to be booked by the consulting dietitian after each appointment. |
| 7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features | Telehealth sessions will be with an APD in their place of work or home and participants in their own homes or a suitable alternative. Participant requirements: ► Internet connection, a device (desktop, laptop, computer tablet) with webcam and microphone capability and the TRACE participant workbook Clinician requirements: ► Internet connection and device with webcam and microphone capability and suitable place to deliver sessions and facilitator manual |
| 8. When and How Much Describe the number of times the intervention was delivered, over what period of time, number of sessions, schedule, duration, intensity, or dose | 5 sessions over 3 months: session 1 (week 1, 45–60 min), session 2 (week 2, 45–60 min), session 3 (week 4, 30–45 min), session 4 (week 8, 30–45 min), session 5 (week 12, 20–30 min) |
| 9. Tailoring If the intervention was personalised, titrated or adapted, describe what, why, when, how | The programme is tailored to an individual's dominant personality style with feedback provided on their major identified personality and how it may influence food intake. For consistency in intervention delivery, all participants received written feedback about all personalities (Anxiety proneness, Depression proneness, Impulsivity proneness and Sensation proneness). Participants will also receive feedback based on key lifestyle factors to set associated goals, the total number of goals are the same for each person however the content maybe different. |
| 10. Modifications If the intervention was modified during the study, describe the changes (what, why, when, how) | N/A |
| 11. How well: Planned If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them | A facilitator manual was developed and will be used in the intervention delivery to ensure standardisation. Timing of the intervention sessions were defined as adhering to schedule if within 1 week (before/after) of the scheduled date. Each participant will be provided login details for the website so the IKT research group can identify who has accessed the website. There is also a form for facilitators to complete after each intervention session to ensure the session was delivered as planned. This form includes elements such as a checklist of key content to be covered for the session and duration of the session. |

9

FA, Food Addiction; IRT, Integrated Knowledge Translation; N/A, not available; TRACE, Targeted Research on Addictive and Compulsive Eating.

the extent to which the intervention was delivered as planned

12. How well: Actual If intervention adherence or fidelity was assessed, describe



Phase 1: start-up and planning meetings – the research advisory group

These workshops were held to determine the four factors necessary to ensure adherence to an IKT approach in relation to the development of an intervention. These included the research question/s, the research approach, how efficacy would be ascertained and the outcomes that were to be assessed. The key factors identified from the research advisory group are presented in table 1.

Phase 2: intervention refinement workshops and protocol prototype development

These interviews were held to capture the experience and knowledge of both health professionals and consumers regarding the perceived barriers and facilitators related to receiving/seeking out treatment for FA, whether the use of an online platform to deliver such a treatment was feasible, and to identify any key components important or missing from current treatments.

Four of the identified 11 elements required further clarification in the second round of phase 2 interviews (2c and 2d) to obtain consensus. These included: 'programme name', 'materials', 'how to include a person with lived overeating experience' and 'character stories'. This consensus was obtained by the following:

Programme name: A draft list of possible names for the programme were developed by the IKT research group following phase 2a and 2b interviews and presented to the knowledge users for feedback during the phase 2c and 2d interviews. There was no consensus due to a range of participants and individual experiences, therefore the IKT research group proposed a programme name of 'Targeted Research on Addictive and Compulsive Eating (TRACE): a personality-based eating awareness programme' based on the name of our overarching research group, 'TRACE'. This name was deemed acceptable by the majority of knowledge users.

Materials: Draft versions of the participant workbook and various handouts were edited by the IKT research group based on feedback from the phase 2a and 2b interviews and presented to the knowledge users for further feedback in phase 2c and 2d.

How to include a person with lived overeating experience: There was consensus to include at least one person with lived overeating experience in the codesign and refinement process during phase 2a and 2b interviews. However, how this person would be involved needed to be finalised in phase 2c and 2d.

Character stories: Drafted character stories in the form of a long case-study and a series of small snippets were developed by the IKT research group following the phase 2a and 2b interviews and presented to the knowledge users for further feedback in phase 2c and 2d.

Results of phase 2a and 2b interviews including the perceived barriers, facilitators, feasibility of telehealth and key components important or missing from current FA treatments (table 2).

Consensus feedback from the knowledge users (n=11) of the 11 key elements identified during phase 2 interviews are displayed in table 3.

Phase 3: finalise the intervention protocol

The IKT research group combined the four key factors to ensure an IKT approach identified in phase 1 with feedback from the 11 key elements identified in phase 2 and mapped this to the TIDieR checklist. A complete description of the intervention developed by the IKT codesign process is outlined in the TIDieR checklist (table 4).

DISCUSSION

The current paper set out to describe the codesign and refinement of an online intervention for adults with symptoms of FA. Using an IKT approach and mapping with the TIDieR checklist³³ for complex interventions, allowed for a range of viewpoints, the identification of barriers and facilitators, as well as translation and scalability for a variety of practice settings and patient groups. Specifically, for the area of FA where complexity exists due to the nature of the condition, the IKT process enabled multiple professions and disciplines to engage in a semiformalised way to bring expertise to formulate a possible intervention approach. Using this framework permitted consensus to be achieved by knowledge users (health professionals and consumers), allowing for a detailed description of the intervention. The current study used a three-phase approach to engage a range of stakeholders to identify changes and adaptations related to the intervention components as well as the delivery method.

Specifically, during phase 2, consensus from the knowledge users highlighted eight perceived barriers and three facilitators to providing and receiving treatment, the feasibility of telehealth as a delivery platform, 8 key components needed or missing from current treatments and refinement of 11 identified key elements needed to ensure that the intervention was based on the real-world needs of those health professionals and consumers delivering and receiving treatments. During the phase 2 interviews, each knowledge user provided feedback regarding these key elements allowing the IKT research group to make the necessary changes to the draft intervention protocol. The barriers to providing or receiving treatment for FA identified during phase 2a and 2b included lack of resources, limited structure and need for ongoing follow-up and support between sessions as well as the reported negatives of using telehealth such as increased nervousness due to lack of technology skills. However, given the many positive applications of using telehealth including increased access and reach of services 47 48 particularly during the COVID-19 pandemic where social distancing restrictions were imposed, the IKT research group addressed these issues through the development of various resources including telehealth and participant handouts, participant workbook, facilitator manual and a closed Facebook support group post intervention.



Additional refinement came through consensus from the knowledge users regarding the identification of 11 key elements in phase 2. Each of these elements were identified as essential areas of the intervention that needed improving in order to enhance quality, useability and uptake for end-users. Consensus regarding how to refine these key elements was important to ensure adherence to the IKT process. ^{2 3 26 27} The incorporation of a second round of interviews during phase 2 allowed for consensus to be reached with three elements that was not achieved in the previous round of interviews, materials, person with lived experience and character stories. However, where consensus was not achieved as with the key element programme name, the IKT research group made the final decision. Successful use of the IKT process to increase intervention uptake and useability involved multiple opportunities for interaction, clear and agreed on goals, establishment of partnerships early and an openness of partners to listen, learn and adapt. 26 However, to enhance the implementation of interventions it is also important to accurately describe the intervention's content and delivery.49

To ensure effective replication or future modification and translation into clinical practice, it is essential that complex treatment options are reported in enough detail. However, previous studies report that this is rarely done.36-38 This study used the TIDieR framework33 to describe the resultant intervention from the IKT process in detail to ensure research quality and replication. Rather than develop a new intervention as with other IKT studies. 50-54 the IKT research group used a previously piloted brief intervention as the framework for redevelopment and refinement. 40 Adopting this approach allowed for a balanced method to codesign by combining evidence on behaviour change and components on lifestyle interventions for FA together with knowledge users. Holding separate workshops and interviews for the research advisory group and knowledge users, helped to streamline the codesign process, improved workshop focus, and allowed for detailed reporting. Furthermore, to ensure efficient use of time, the IKT research group sent each knowledge user a broad list of preselected questions that would be addressed at the upcoming interview. Given the varying knowledge and comfort level of consumers regarding research processes and likely unfamiliar approaches, providing participants the questions before their interview allowed them to better prepare and think about their responses. In addition, time was dedicated by the IKT research group to speak with consumers prior to recruitment to assist in understanding the approach and overall aim of what was trying to be achieved, which was beneficial to developing rapport.

The resultant intervention is a five session programme delivered by telehealth and considered quite brief especially when compared with other programmes for other health conditions that utilise psychological treatments such as cognitive–behavioral therapy. The intervention could be applied alone and increase an individuals'

awareness of their eating and help seeking behaviours, but could also be considered a dietary approach and be used alongside or in combination with other interventions or where in some cases more intensive treatments are required, or where individuals have multiple comorbidities or complex mental or emotional disorders.

At its core, IKT involves collaboration between various stakeholders such as researchers, health professionals and consumers throughout the codesign process.^{2 3 26–28} Given that FA may encompass a range of health professionals, disciplines and scientific areas including but not limited to mental health, ^{7 24 25} eating disorders ^{22 56} and neuroscience, ^{57 58} this study recruited and utilised the expertise and skills from a range of specialised health professionals. While the practice of involving consumers and members of the public in research is well established, ^{59 60} there is currently no universally accepted framework that describes the extent to which consumers or patients are to be engaged. 61 Engagement may occur as a means of providing indirect support to being consulted or involved as an external stakeholder, however, this type of engagement is not considered to align with the IKT process. 61 More direct forms of consumer engagement considered to align closely with the IKT process include collaborating with a team or being empowered to direct or lead a given component of the research.⁶¹ This study adopted the more direct method and encouraged collaboration between consumers and the IKT research group.

LIMITATIONS

Several limitations must be highlighted when interpreting the described study process. First, due to COVID-19, phase 2 was implemented as individual interviews rather than small workshops which may have prevented further group discussion suggested in the IKT codesign process. Second, there was an overall lack of male representation among both the consumers and health professionals. This is not surprising given women tend to be most interested in issues that affect the health and well-being of themselves, ⁵⁵ are more likely to seek help or treatment for disordered eating practices⁶² and make up the majority of the workforce in health professions such as dietetics. The lack of male participants with FA in this current study also aligns with other FA research where male representation is low. 6 7 10 Given the under-representation of males in this study as both consumers and health professionals, future IKT studies may need to identify more effective ways to attract and recruit male participants to ensure a more accurate representative sample. Third, while consumers with lived overeating experience were included in the knowledge user group from the beginning of the study, the larger research advisory group did not contain a consumer representative during phase 1. Due to the IKT process however, two consumers were identified during phase 2 and invited to be part of the research advisory group before the start of phase 3. Ideally, the IKT process would include consumers at conception (eg, defining the research question, research approach, efficacy and outcomes) through to applying and disseminating the findings.⁶³ Therefore, studies should



consider incorporating consumers within the larger research group earlier in the process to ensure adherence to the IKT process. Lastly, while FA is a transdiagnostic dimension, these results may not be generalisable to other overlapping conditions such as eating disorders or bipolar disorder. Future studies may wish to assess further and report outcomes by more specific stratifications or subtypes.

CONCLUSION

The findings from this study illustrate the benefits of the codesign approach and provide confidence at being able to bring useable, translational, evidence-based support to individuals with FA which may help bridge the potential gaps in research translation. To the authors knowledge, this is the first study to apply the IKT process to codesign and refine an intervention for managing symptoms of FA. Specifically, adopting an IKT approach and mapping the intervention plan to the TIDieR checklist for complex interventions, allowed for detailed description of the intervention and the identification of a number of areas that needed to be refined before development of the finalised intervention protocol.

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ORCID iDs

Mark Leary http://orcid.org/0000-0001-6175-8331 Phillipa Hay http://orcid.org/0000-0003-0296-6856

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