**WA HEALTH RESEARCH PROTOCOL**

**TEMPLATE FOR CLINICAL TRIALS**

**GUIDELINES**

This protocol template is provided as a guide for investigators and is based on the Therapeutic Goods Administration (TGA) [“Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)” 2000.](http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm) To meet Good Clinical Practice Guidelines the Protocol should contain, but not be restricted to, the information contained within this template.

A clinical trial is a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventative procedure, or a diagnostic device or procedure.

Some Heath Services provide access to statistical advice for investigators. Contact the relevant Research Governance Office for further advice; contact details are available on the Department of Health [Research Development](http://www.health.wa.gov.au/researchdevelopment/home/research_gov.cfm) website.

NB: Further information on clinical trial protocol/study report formats can be found in the ICH Guideline [“Structure and Content of Clinical Study Reports” 1995](http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/structure-and-content-of-clinical-study-reports.html) available on the ICH website.

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| **1. Trial Details** |

* 1. Trial Details.

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| **Protocol/Clinical Trial Title:** | Evaluating the efficacy of a brief intervention for the carers of individuals with eating disorders: A randomised controlled trial | | |
| **Protocol Number (Version and Date):** | Version 1, 12/10/2016 | | |
| **Amendment**  **(Number and Date):** |  | | |
| **Trial Start Date:** | December 2016 | **Trial Finish Date:** | December 2017 |
| **Coordinating Principal Investigator Name:** | Associate Professor Peter McEvoy | | |
| **Coordinating Principal Investigator Contact Details:** | Curtin University School of Psychology and Speech Pathology  Associate Professor  9266 5119  0402 456 495 | | |
| **Sponsor Name (if applicable):** |  | | |
| **Laboratory Name (if applicable):** |  | | |

* 1. Trial Summary (less than 300 words) including background, objectives and trial plan.

The carers of individuals with eating disorders report high levels of distress and perceived burden of care (Zabala, McDonald, & Treasure, 2008). The interpersonal maintenance model of eating disorders posits that high levels of carer unmet needs can lead to carers engaging in behaviours that can accommodate, enable, and maintain the eating disorder (Goddard, Macdonald, Sepulveda, Naumann, Landau, Schmidt, & Treasure, 2008). This study will involve evaluating a two-session group intervention for carers of individuals with eating disorders that aims to improve their knowledge, reduce their levels of burden and distress, and assist them to develop skills relevant to the interpersonal maintenance model of eating disorders. Participants will be randomised to either a waitlist control condition or intervention condition. Repeated measures of depression, anxiety, self-efficacy, knowledge, perceived burden of care, accommodating and enabling behaviours, level of expressed emotion, and interpersonal caregiver skills will be taken at pre, post, and follow-up intervals. It is hypothesised that participants will report reduced symptoms of depression, anxiety, perceived burden of care, accommodating and enabling behaviours, and level of expressed emotion at post intervention and follow-up, as well as improved knowledge, interpersonal skills and self-efficacy, relative to controls. People in the control condition will then be offered the intervention.

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| **2. RATIONALE / BACKGROUND** |

* 1. Summary of findings from previous clinical and non-clinical projects, relevant to this proposed trial. Include references to literature and data that are relevant to the trial and that provide background for the trial. *List references separately at the end of the protocol.*

The National Institute for Clinical Excellence (NCCMH, 2004) recommends that most individuals with anorexia nervosa should be managed on an outpatient basis. This places the primary responsibility for care onto family members. Zabala, Macdonald, and Treasure (2008) conducted a systematic review of twenty studies that examined the impact of eating disorders on family members, and found that the carers of individuals with eating disorders experienced high levels of burden and psychological distress. Specifically, carers have reported poor quality of life, high perceived burden of care, anxiety, depression, reduced ability to control their emotions and/or behaviour, and overall low psychological wellbeing (Sepulveda, Kyriacou, Treasure, 2009). Treasure, Murphy, Szmulker, Todd, Gavan, and Joyce (2001) found that levels of distress and difficulty across most areas of caregiving were higher amongst carers of individuals with eating disorders than for carers of individuals with schizophrenia.

In addition to the immediate distress associated with caring for someone with an eating disorder, carers can also become entangled in the social and emotional consequences of the illness. The interpersonal maintenance model of eating disorders posits that high levels of carer distress can deplete their coping resources such that they experience higher levels of psychopathology, which can in turn lead them to exhibit unhelpful behaviours and ineffective strategies in managing the eating disorder (Dimitropoulos, Carter, Schachter, & Woodside, 2008). Common unhelpful behaviours have been described as ‘accommodating and enabling’ behaviours, and ineffective coping strategies include emotional over-involvement and criticism, or ‘expressed emotion’. These behaviours and strategies have been implicated in the maintenance of eating disorders, highlighting the importance of developing interventions for the families of these individuals (Treasure, 2008).

Delivering psychoeducation to carers and clients with serious psychological disorders is considered to be an effective and economical method of modifying carers’ attitudes towards their loved one (Glick, Burti, Okonogi & Sacks, 1994), increasing their knowledge about illnesses, increasing family support, reducing family burden, increasing self-efficacy, and reducing relapse rates in psychiatric disorders (Eisner & Johnson, 2008). A number of interventions have been developed to address carers’ need for information and to reduce the level of burden associated with their role (Hibbs, 2015). A recent meta-analysis of 13 studies and found that most interventions directed at the carers of individuals with eating disorders produced a moderate reduction in carer distress, and a moderate sized reduction in carer burden and expressed emotion (Hibbs, 2015). However, the interventions evaluated in these studies varied significantly in length, method of delivery, and content. While there was a trend that suggested interventions with more therapeutic input may be more effective, the author stated that the optimum level of therapeutic input is unknown in terms of a cost benefit analysis. It is likely that many carers will benefit from brief interventions, with some requiring more intense interventions. Few of the studies included utilised a randomised controlled trial (RCT) design. To date, no RCTs appear to have been conducted to evaluate the effectiveness of a brief intervention that includes psychoeducation and skills-based training for the carers of individuals with eating disorders. It is predicted that such an intervention would be of significant benefit given the functional impact on the caregiver and the economical benefit of such brief interventions.

* 1. Name and description of the intervention or product(s) used in this trial, including investigational product(s) and comparator product/s (if applicable). Include status of product registration (i.e. registration on Australian Therapeutic Goods Registry, or equivalent).

CCI has been running two-session carers groups for eating disorders for several years. The aim of the proposed study is to evaluate the utility of this program in a RCT. This is a group psychoeducation and skills-based intervention targeting carers of individuals with eating disorders. Participants will be required to complete pre-intervention measures prior to the beginning of the first group session using Qualtrics online software (Time 1). After completing the measures, participants will be directed to a link containing basic psychoeducation about eating disorders (symptoms, diagnoses, bio-genetic model of eating disorders). Content for both group sessions has been adapted from *Skills-based learning for caring for a loved one with an eating disorder: the new Maudsley method* (Treasure, Smith, & Crane, 2007). The first session content will involve a summary of this information, focusing on the role of genetics, biological, and neurological factors (e.g. starvation syndrome). Participants will be invited to ask questions and discuss anything they found surprising. The role of environmental factors will also be discussed, and the interpersonal maintenance model of eating disorders will be introduced. Common communication "traps" will be discussed as a group (with participants providing personal examples). Homework between sessions will include approaching the individual with an eating disorder and agreeing upon a set time to have either a one-on-one or family ‘meeting’ in relation to the eating disorder. The second session will occur one week later and will also be 150-minutes in duration. The homework task will be reviewed, and participants will be introduced to a number of strategies they can utilise when difficult situations arise in relation to the individual with the eating disorder. Participants will be asked to role play difficult situations and practice using helpful phrases and simple techniques recommended by Treasure and colleagues (2008) in order to diffuse them. At the end of the second session participants will complete outcome measures again (Time 2). One-month post intervention, all participants will be sent a link to complete the final set of outcome measures online using Qualtrics (Time 3). Waitlist participants will be asked to complete the questionnaires one more time when they complete the intervention (Time 4), to ensure that they also benefit from the programme.

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| **3. TRIAL AIMS / OBJECTIVES / HYPOTHESES** |

* 1. Detailed description of the specific primary and secondary objectives and the purpose of the trial. Describe any hypotheses that will be tested.

To evaluate whether a two-session group psychoeducation and skills-based intervention for carers of individuals with eating disorders will improve carer knowledge, self-efficacy, and interpersonal skills whilst reducing their perceived burden of care, accommodating and enabling behaviours, and level of expressed emotion.

Five hypotheses are proposed:

H1: Reduction in carer burden will be greater in the intervention group compared to controls

H2: Intervention will result in positive changes in secondary outcomes of distress, level of expressed emotion, accommodating and enabling behaviours, caregiver interpersonal skills, coping self-efficacy, knowledge of eating disorders.

H3: Changes in carer interpersonal skills will be reported by the individual who has an eating disorder

H4: Changes in level of expressed emotion, accommodating and enabling behaviours, caregiver interpersonal skills, coping self-efficacy, and knowledge of eating disorders will mediate the effect of the intervention on carer burden.

H5: Intervention effects will maintain to one-month follow-up.

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| **4. TRIAL DESIGN** |

***The scientific integrity of the trial and the credibility of the trial data depend substantially on the trial design and methodology.***

* 1. Primary endpoints and the secondary endpoints, if any, to be measured during the trial and how they will be measured. *For further information refer to the TGA* [“Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)” 2000.](http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm)

Primary measures are: Carer level of perceived burden

Secondary measures are: Distress, level of expressed emotion, accommodating and enabling behaviours, caregiver interpersonal skills, coping self-efficacy, and knowledge of eating disorders.

Both primary and secondary outcome measures will be taken at three time intervals (pre-intervention, post-intervention, and one-month follow-up). Waitlisted participants will complete measures at the same time intervals as the immediate treatment group for direct comparison, but will also complete the measures after they complete the intervention.

* 1. Type (e.g. phase, pilot) and design (e.g. double-blind, placebo-controlled, parallel design) of the trial to be conducted and a schematic diagram of the trial design, procedures and stages (e.g. initial assessment, run-in, pre-randomisation assessment, randomisation, treatment phase, end-of-treatment assessment, washout, cross-over, alternative treatment, post-treatment assessments, trial exit).

Randomised controlled trial. Recruitment: February 2017- November 2017. Researcher (Targowski) will initially contact potential participants via phone to screen for exclusion criteria, gather demographic information, explain the nature of the study, and obtain informed consent.  
Measures taken to minimise/avoid bias, including randomisation and blinding.

One month follow-up

Participants complete measures (PROMIS Anxiety/Depression, BAS, Self-efficacy questionnaire, Knowledge of eating disorders scale, AESED, FQ, CASK)

One month follow-up

Participants complete measures (PROMIS Anxiety/Depression, BAS, Self-efficacy questionnaire, Knowledge of eating disorders scale, AESED, FQ, CASK)

**Waitlist control**

Wait period.

Complete measures 1 week after baseline and again 1 month later.

**Intervention condition**

Participants attend 2 x 150 minute group sessions spaced one week apart

Complete post intervention measures at the end of the second session (PROMIS Anxiety/Depression, BAS, Self-efficacy questionnaire, Knowledge of eating disorders scale, AESED, FQ, CASK)

Intervention

Participants attend 2 x 150 minute group sessions spaced one week apart

Complete post-intervention measures at the end of the second session (PROMIS Anxiety/Depression, BAS, Self-efficacy questionnaire, Knowledge of eating disorders scale, AESED, FQ, CASK)

**Eligible – YES** (meets inclusion criteria)

Participants are sent information sheet, consent form and pre-intervention measures (PROMIS Anxiety/Depression, BAS, Self-efficacy questionnaire, Knowledge of eating disorders scale, AESED, FQ, CASK)

**Eligible – NO** (meet exclusion criteria). Participants offered alternative support services by researcher

Randomisation

Participants will be randomly allocated to either an intervention condition or a waitlist control condition. Participants in the waitlist control condition will be offered the opportunity to complete the intervention within two months of being waitlisted.

* 1. Maintenance of any blinding records or randomisation codes and procedures for breaking codes.

The co-ordinating PI will generate a randomisation schedule (1:1). Participants will be randomised after their initial assessment of eligibility.

* 1. Method of tracking implantable medical devices (if applicable). N/A
  2. A description of the interventions or investigational product(s). For drug trials information regarding the dosage and dosage regimen, as well as a description of the dosage form, packaging, dispensing and labelling should be included.

CCI has been running two-session psychoeducation sessions for carers of individuals with eating disorders for several years but these have not yet been evaluated, which is the purpose of the current study. The current intervention involves attending two 150-minute group sessions at the Centre for Clinical Interventions. Content for both group sessions has been adapted from *Skills-based learning for caring for a loved one with an eating disorder: the new Maudsley method* (Treasure, Smith, & Crane, 2007). The first session content will involve a summary of psychoeducation information (sent out in an information pack prior to the intervention), focusing on the role of genetics, biological, and neurological factors (e.g. starvation syndrome). Participants will be invited to ask questions and discuss anything they found surprising. The role of environmental factors will also be discussed, and the interpersonal maintenance model of eating disorders will be introduced. Common communication "traps" will be discussed as a group (with participants providing personal examples). Homework between sessions will involve approaching the individual with the eating disorder and setting a time to discuss the eating disorder either one-on-one or with the family. The second session will occur one week later and will also be 150-minutes in duration. The homework task will be reviewed, and participants will be introduced to a number of strategies they can utilise when difficult situations arise in relation to the individual with the eating disorder. Participants will be asked to role play difficult situations and practice using helpful phrases and simple techniques recommended by Treasure and colleagues (2008) in order to diffuse them.

* 1. Accountability procedures for the investigational product(s) including the placebo(s) and comparator(s) (if applicable).
  2. Expected duration of the trial and participant participation, including a description of the sequence and duration of all techniques or assessments to be performed, including follow-up (e.g. interventions, procedures, measurements, observations, laboratory investigations). Provide a schedule of assessments in a table if possible.

Recruitment will commence upon ethics and governance approval and the study is expected to be completed by December 2017. Participation in the intervention condition will last two months, while participation in the waitlist control followed by intervention condition will last three months.

Schedule of Assessments: Intervention condition

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| Time | Assessments |
| Pre-intervention/baseline (T1) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |
| Post-intervention (T2) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |
| Four weeks after T2 (T3) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |

Schedule of Assessments: Waitlist condition (followed by intervention)

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| Time | Assessments |
| Pre Wait period (baseline, T1) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |
| Post 1-waiting period (T2) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |
| Four-weeks after T2 (T3) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |
| Post-intervention measures (T4) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |
| One-month follow-up T(5) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |

* 1. Criteria for the termination of the trial. Description of the discontinuation criteria for individual participants, parts of the trial and entire trial.

The two-session psychoeducation for carers sessions have been run at CCI for several years, but they have not yet been formally evaluated. The program will continue to run regardless of whether it is evaluated as part of a trial. The purpose of this application is to seek HREC permission to randomise participants to immediate vs. waitlist control groups. In practice, CCI only has capacity to run one group at a time, so some participants have had to wait anyway. As part of this study, waitlisted participants will be determined by the randomisation schedule rather than a ‘first come, first serve’ basis. If the findings are positive, the carers groups will be ongoing beyond this trial. Findings from this trial will be used as a benchmark for improving the program over time.

* 1. The identification of any data to be recorded directly on the Case Report Forms (CRFs) (i.e. no prior written or electronic record of data), and to be considered to be source data.

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| **5. SOURCE AND SELECTION OF PARTICIPANTS** |

* 1. Source of participants - research population, sample size, source, and sampling frame (if possible, split by site if multicentre trial).

Participants will be recruited using the Centre for Clinical Interventions’ (CCI) current referral pathway within the Perth metropolitan area. This involves the placement of advertisements at CCI and the dissemination of these fliers to other eating disorder specialist services in the state (Princess Margaret Hospital, Body Esteem) and a number of private practitioners. These services and practitioners will be contacted prior to the commencement of an intervention and asked to share this information with any clients they believe may be suitable. Radio advertisements and other methods (e.g., social media, email distributions to health professionals and services, university participant pools, community groups such as The Butterfly Foundation) will be used if required. However, CCI has been facilitating eating disorder carer groups for several years and it is expected that current referral pathways will be sufficient to achieve the required sample size. Potential participants will be contacted by the researcher (Targowski) to discuss details of the study and the nature of the intervention. The researcher will complete a brief phone interview (approximately 10 minutes) in order to screen participants for exclusion criteria and to gather demographic information. The demographic questionnaire is attached in the appendices.

* 1. Participant inclusion criteria. Describe appropriate criteria for special risk populations (e.g. women of reproductive age, participants with disease states or organ impairment).

Inclusion criteria for participants in the carers groups will be: 1) aged over 18 years; 2) able to speak and read English fluently, 3) currently care for someone with diagnosed eating disorder (either as a friend, family member or partner). Participants are also asked to invite the person with the eating disorder to complete a questionnaire on their perspective of their caregiver’s skills before and after the intervention. These participants may be under age 18, but will still receive an information sheet and consent form that will be co-signed by their parent/guardian.

* 1. Participant exclusion criteria. May include conditions that increase the risk to the participant, that interfere with the participants’ ability to give informed consent, or interfere with a participant’s ability to comply.

As has been standard practice at CCI for several years, no formal exclusion criteria will be applied for the carer groups.

* 1. Participant withdrawal criteria (i.e. terminating investigational product/trial treatment) and procedures specifying:

(a) when and how to withdraw participants from the investigational product/trial treatment;

(b) the type and timing of the data to be collected for withdrawn participant(s);

(c) whether and how participants are to be replaced; and

(d) the follow-up for participants withdrawn from the investigational product/trial treatment.

Participants will be informed verbally and via the Information Sheet that they are able to withdraw from the trial at any point and without reason. Participants are able to inform the researchers in person, via phone or email of their request to withdraw. Withdrawn participants will be informed that their de-identified data may still be utilised in the analysis, unless they inform the researchers prior to de-identification. Participants will not be replaced if they withdraw. A follow-up phone call will be offered to participants who withdraw to offer alternative services if requested.

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| **6. TREATMENT OF PARTICIPANTS** |

* 1. Description and justification for the treatments, interventions or methods to be utilised (including product name(s), dose(s), dosing schedule(s), route/mode(s) of administration and treatment period(s)) and the follow-up period(s) for participants for each investigational product/trial treatment group/arm of the trial.

No medication will be administered as part of this trial.

* 1. The medications/treatments permitted (including rescue medication) and not permitted before and/or during the trial.
  2. The procedures for monitoring participant compliance.

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| **7. ASSESSMENT OF EFFICACY** |

* 1. Specification of the efficacy parameters.

Efficacy of the protocol will be demonstrated if the intervention group demonstrate significantly greater changes in symptoms of depression, anxiety, perceived burden of care, self-efficacy, knowledge of eating disorders, accommodating and enabling behaviours, interpersonal skills, and level of expressed emotion than the waitlist control group. These gains are expected to be maintained at one-month follow-up. The following measures will be used in order to measure these outcomes.

1. Carer burden will be measured using the Burden Assessment Scale (BAS), which is a 19-item measure that assesses the objective and subjective consequences of providing on-going care to the seriously mentally ill. Objective burden refers to observable, behavioural effects of caregiving including; financial problems, limitations on personal activity, household disruption, and social interactions. Items measuring subjective burden include feelings, attitudes, and emotions expressed about the caregiving experience (Platt, 1985). The BAS is considered to be an internally reliable (α = .91) and conceptually meaningful tool that is useful for research and program evaluation (Reinhard et al., 1994).
2. Carer distress will be measured using the short form Patient Reported Outcomes Measurement Information System (PROMIS) for Depression and Anxiety, which are self-report measures containing eight items each (Cella, Riley, Stone, Rothrock, Reeve, Yount, Anthmann, Dagmar, Bode, Buysse, Choi, Seung, Cook, Devillis, Dewlat, Fries, Gershon, Hahn, Lai, Pilkonis, Revicki, Rose, Weinfurt, & Hays, 2010). The PROMIS Depression and Anxiety short-forms are considered to be reliable (α = .95; .93 respectively) and valid scales (Pilkonis, Choi, Reise, Stover, Riley, & Cella, 2011; Schalet, Cook, Choi, & Cella, 2014).
3. Changes in level of expressed emotion will be measured using the Family Questionnaire (FQ). The FQ is a 20-item self-report questionnaire that measures level of expressed emotion, as indicated by criticism and emotional over-involvement. It is also considered to be an internally reliable (α = .8 - .9) and conceptually meaningful tool and has been used in the context of schizophrenia (Wiedemann, Rayki, Feinstein, & Hahlweg, 2002) and eating disorders (Zabala, Macdonald, & Treasure, 2008).
4. Accommodating and enabling behaviours will be measured using the Accommodating and Enabling Scale for Eating Disorders (AESED) (Treasure, Smith, & Crane, 2007). The AESED is a 33-item self-report questionnaire that assesses accommodating and enabling behaviours commonly exhibited by carers of individuals with eating disorders. The AESED is considered to be an internally reliable tool (α = .92) that is sensitive to change and useful for program evaluation (Hibbs, Rhind, Salerno, Lo Coco, Goddard, Schmidt, Micali, Gowers, Beecham, Macdonald, Todd, Campbell, & Treasure, 2014).
5. Caregiver interpersonal skills will be measured using the CASK, which is a 27-item self-report questionnaire that caregiver skills in the context of the interpersonal maintenance model of eating disorders (Hibbs, et al., 2014). It is also considered to be internally reliable (α = .92) and has been found to be sensitive to change in the context of an intervention for carers of individuals with eating disorders (Hibbs, et al., 2014).
6. Changes in coping self-efficacy will be measured using the Self-Efficacy Scale for Eating Disorders (attached as an appendix), which was created with the assistance of staff who specialise in eating disorders at the Centre for Clinical Interventions.
7. Changes in knowledge of eating disorders will be measured using a brief version of the Carer’s Needs Assessment Measure (Haigh & Treasure, 2003). This is a self- report measure that assesses areas such as knowledge of local support groups and treatment options.
8. Changes in carer interpersonal skills will be measured by administering a version of the CASK that has been modified (with permission of the authors) to be suitable for use with the individual who has the eating disorder.
   1. The methods and timing for assessing, recording, and analysing efficacy parameters.

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| Time | Assessments |
| T1: Pre-intervention/baseline (prior to first session) | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |
| T2: Post-intervention (at the end of the second session) or post-waitlist | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |
| T3: Four weeks after T2 | PROMIS (Anxiety)  PROMIS (Depression)  Self-efficacy Burden Assessment Scale  Knowledge of eating disorders  Accommodating and Enabling Scale for Eating Disorders  Family Questionnaire  The Caregiver Skills |

People in the waitlist condition will complete an extra set of measures (T4) post-intervention and at one-month follow-up (T5) to determine whether any benefits received from the immediate intervention group are replicated in the waitlisted participants.

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| **8. ASSESSMENT OF SAFETY** |

* 1. Summary of known and potential risks and benefits, if any, to research participants.

The intervention is expected to be beneficial to participants in that they will develop better coping strategies for supporting themselves and their loved one with an eating disorder. Adverse events are considered to be highly unlikely, however, it is possible that participants may become distressed when discussing difficulties they have encountered during their experience of caring for someone with an eating disorder.

* 1. The safety parameters and the methods and timing for assessing, recording, and analysing safety parameters. Include a description of emergency procedures if applicable.

An experienced clinical psychologist employed by the Centre for Clinical Interventions with specialist knowledge of eating disorders and their treatment will be present during both sessions of the intervention condition to provide support to distressed individuals if required. There will always be at least two facilitators present so that one is able to take a distressed participant out of the group for a private consultation if required. The student researcher (Targowski) is a registered provisional psychologist.

* 1. Details of the Data and Safety Monitoring Board, or equivalent. *For further information refer to the* *TGA* [*“Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)” 2000.*](http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm)

n/a

* 1. The procedures for eliciting reports of and for recording and reporting adverse events. Include definitions of adverse events. *For further information on adverse events refer to the* *TGA* [*“The Australian Clinical Trial Handbook” 2006.*](http://www.tga.gov.au/industry/clinical-trials-handbook.htm)

n/a

* 1. The type and duration of the follow-up of participants after adverse events.

Although unlikely, should participants become distressed they will be supported by the senior clinical psychologist facilitating the group and will be referred for on-going services if deemed appropriate.

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| **9. DATA MANAGEMENT, STATISTICAL ANALYSIS AND RECORD KEEPING** |

* 1. Description of the statistical methods to be employed, including timing of any planned interim analysis.

Hypotheses 1, 2, 3 and 5 will be tested with a series of Generalised Linear Mixed Models (GLMMs) – one for each outcome measure. For the GLMMs, there is one nominal random effect (participant), one nominal fixed effect of group (intervention, waitlist), and one ordinal fixed effect (time: pre, post, follow-up). H1, H2, H3, and H5 predict a significant Group by Time interaction effect.

The indirect effect hypothesis 4, where changes in carer burden from pre-post intervention are mediated by changes in the mediators, will be tested using path analysis in Mplus (Muthén & Muthén, 1998-2015). Post-scores on carer burden (controlling for pre-scores) will be regressed on the hypothesised post-scores (controlling for pre-scores) on the mediators (self-efficacy, knowledge, perceived burden of care, accommodating and enabling behaviours, level of expressed emotion, and interpersonal caregiver skills), controlling for the pre-scores, which will be regressed on Condition (intervention vs. waitlist). Bootstrapping using 1000 resamples will be used to estimate indirect effects with 90% confidence intervals.

* 1. The number of participants planned to be enrolled (if possible, include number at each site). Document the reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.

A power analysis using G\*Power software was conducted assuming a low to medium effect size (f = .20), an alpha of .05, power of .80, an autocorrelation of .5, and three measurement occasions. This analysis suggested that a minimum of 42 participants were required, however based on participation rates over previous years it is expected that between 45 and 60 will actually be recruited. Each individual group will have a minimum of six participants and a maximum of 20. It is noteworthy that a two-session carer’s psychoeducation programme for bipolar disorder we recently evaluated yielded large effects on caregiver burden, self-efficacy, and knowledge (Hubbard, McEvoy, Smith, & Kane, 2016), which increases our confidence that this study will be sufficiently powered to detect effects.

* 1. The level of significance to be used.

A 0.5 level of significance will be used.

* 1. Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in the protocol and/or in the final report, as appropriate).

This project is using a relatively simple design and analytic plan. No changes are foreseeable, but will be reported as post-hoc analyses if appropriate.

* 1. The selection of participants to be included in the analyses (e.g. all randomised participants, all dosed participants, all eligible participants, or all evaluable participants).

All randomised participants who meet inclusion criteria and attend at least the first carers’ session will be included in the analysis.

* 1. Information on how data will be managed, including coding for computer analysis and data handling (collection, storage, maintenance, security and archiving). Include details regarding these processes if the data is sent off-site (e.g. encryption). *Clinical trial records should be retained for a minimum of 15 years from the completion of the trial.*

Although the intervention is occurring at a North Metropolitan Mental Health Service location, the data will not be utilised by this service as it is being collected as part of a Masters project. All data obtained from participants will be managed by the Curtin University Masters student (Katharina Targowski). Questionnaires will be collected by Katharina and held at Curtin University in a locked filing cabinet. The only people who will have access to this cabinet will be Katharina and the Coordinating Investigator (Peter McEvoy). In line with data storage policies held by Curtin University, the de-identified data will be held securely for a minimum of seven years, and may be securely retained longer on Curtin University’s data repository.

Participants will be allocated a sequential participant number, which will be kept securely in a password protected electronic documents on Associate Professor Peter McEvoy’s password protected folder on the School of Psychology and Speech Pathology’s common drive. The data collected as part of the study will be entered into a separate password-protected database with the participant numbers but not their name. Only this de-identified database will be used for analysis by the masters student.

* 1. Procedure for accounting for missing, unused, and spurious (*false*) data.

All data will be screened for aberrant responding (e.g. all scores at maximum, minimum, or the same values). Invalid responding will be reported in publications and excluded from formal analyses. GLMM is less sensitive to participant attrition because it does not rely on participants providing data at every assessment point. The GLMM maximum likelihood procedure is a full information estimation procedure that uses all the data present at each assessment point. This reduces sampling bias and the need to replace missing data. GLMM is able to use the data present at each assessment point because time (pre, post, follow-up) is interpreted as a Level 1 variable that is nested within participant at Level 2.

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| **10. MONITORING / AUDIT** |

* 1. Statement that the trial investigators/institutions will permit trial-related monitoring, audits, and regulatory inspections, providing direct access to source data/documents. This may include, but not limited to, review by external sponsors, Human Research Ethics Committees and institutional governance review bodies.

The researchers agree to permit trial-related monitoring, audits, and regulatory inspections and provide direct access to source data/documents. This includes: a review by external sponsors, Human Research Ethics Committees and institutional governance review bodies.

* 1. Description of the procedures for monitoring and auditing. *The clinical trial sponsor may nominate the form of monitoring and auditing and will indicate the times of audit visits.*

Group sessions will be audio-recorded and an independent assessor will rate the recordings for compliance with the protocol.

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| **11. QUALITY CONTROL AND QUALITY ASSURANCE** |

* 1. Statement that the trial will be conducted in compliance with the protocol, Good Clinical Practice and the application regulatory requirements.

The proposed trial will be conducted in compliance with the protocol, Good Clinical Practice and the application regulatory requirements.

* 1. Quality control & quality assurance measures to ensure quality of data.

Participants will complete self-report questionnaires. Data will be entered into a database and 20% of participants will be randomly selected for an audit to identify transcription errors. If errors are detected all data will be checked by a second researcher (Peter McEvoy).

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| **12. ETHICS** |

* 1. Description of ethical considerations related to the trial with particular reference to participant consent (including Participant Information and Consent Forms).

Caring for someone with an eating disorder is associated with increased rates of psychopathology (Hibbs, Rhind, Sallis, Goddard, Raenker, Ayton, Bamford, Arcelus, Boughton, Connan, Goss, Lazlo, Morgan, Moore, Roerstoon, Schrieber-Kounine, Sharma, Whitehead, Lacey, Schmidt, & Treasure, 2014). Participants’ symptomology will be monitored throughout the intervention through outcome measures (Patient Reported Outcomes Measurement Information System scale of Anxiety and Depression). The intervention in this study will aim to reduce participants’ symptoms of anxiety and depression via the provision of psychoeducation, self-care strategies, and communication strategies. The intervention will also inform participants about support services they can access for on-going support after the intervention.

As part of the study, participants are required to complete a number of self-report questionnaires. In order to ensure that confidentiality is maintained, all participant information will be kept in a locked filing cabinet at Curtin University and in password protected databases. These will only be accessible by Katharina Targowski and Peter McEvoy. The data will be securely stored for a minimum of seven years, after which it may be securely retained longer on Curtin University’s data repository.

Potential participants will be given an information sheet outlining the details of the study. They will also be offered the opportunity to ask any questions of the researcher via phone to clarify any concerns and to ensure they are able to make an informed decision regarding their participation. Participants will complete a consent form prior to the commencement of the study. Participation is voluntary and participants may withdraw from the study at any time without prejudice. All participants will be aware that they can attend the intervention sessions without participating in the research if they wish.

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| **13. BUDGET, FINANCING, INDEMNITY AND INSURANCE** |

* 1. Budget, financing, indemnity and insurance, if not addressed in a separate agreement.

There are no anticipated costs associated with this trial. The carers groups have been running at CCI for several years, and it is not expected that this study will increase workload for CCI clinicians.

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| **14. PUBLICATION** |

* 1. Publication and dissemination of trial results (including any limitations), if not addressed in a separate agreement. *In accordance with the Declaration of Helsinki (2008) every clinical trial must be registered in a publicly accessible database before recruitment of the first participant.*

The proposed trial will be registered in the Australian New Zealand Clinical Trial Registry (ANZCTR) and the results are expected to be published in an academic journal, and may be presented at academic conferences.

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| **15. REFERENCES** |

* 1. A list of articles from the literature pertinent to the evaluation of the trial. Include references that have been cited in the protocol.

Cella, D., Riley, W., Stone, A., Rothrock, N., Reeve, B., Yount, S., Hays, R. (2010). The patient- reported outcomes measurement information system (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. Journal of Clinical Epidemiology, 63, 1179- 1194. doi:10.1016/j.jclinepi.2010.04.011

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National Collaborating Centre for Mental Health. (2004). National Clinical Practice Guideline. Eating disorders: Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders. National Institute for Clinical Excellence. (Online). Available http://www.nice.org.uk

Pilkonis, P. A., Choi, S. W., Reise, S. P., Stover, A. M., Riley, W. T., & Cella, D. (2011). Item banks for measuring emotional distress from the patient-reported outcomes measurement information system (PROMIS): Depression, anxiety, and anger. Assessment, 18, 261-283. doi: 10.1177/1073191111411667

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Treasure, J., Smith, G., & Crane, A. (2007). Skills-based learning for caring for a loved one with an eating disorder: The new Maudsley method. Routledge.

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Zabala, M. J., Macdonald, P., & Treasure, J. (2009). Appraisal of caregiving burden, expressed emotion and psychological distress in families of people with eating disorders: A systematic review. European Eating Disorders Review, 17(5), 338-349.

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| **16. APPENDICES** |

* 1. List all appendices. Including an Investigator’s Brochure or Device Manual (if applicable). *All trials involving unregistered drugs must be accompanied by an investigator’s brochure which is a compilation of the clinical and non-clinical data available on the experimental products intended for use in the trial. Clinical investigations involving devices should include an Investigator’s Brochure or Device Manual.*

1. Demographic Questionnaire (for screening purposes)
2. Participant Information Sheet (Carer)
3. Participant Consent form (Carer)
4. Participant Information Sheet (person with the eating disorder)
5. Participant Consent form (person with the eating disorder)
6. Example advertisement
7. PROMIS (Anxiety)
8. PROMIS (Depression)
9. Burden Assessment Scale (BAS)
10. Self-efficacy Scale
11. Accommodating and Enabling Scale for Eating Disorders (AESED)
12. Knowledge of Eating Disorders Questionnaire
13. Family Questionnaire (FQ)
14. The Caregiver Skills (CASK)
15. The Caregiver Skills modified for use with the individual with the eating disorder (CASK-E)
16. List of additional Mental Health services (for referral)
17. Outline of the group sessions

APPENDIX A:

**Eating Disorder Carers’ Group - Demographic and screening form completed via phone interview**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DOB: \_\_\_\_\_\_\_\_\_\_ Gender: \_\_\_\_\_\_\_\_\_\_\_\_ Ethnicity: \_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to individual with eating disorder: (circle all that apply)

Friend Sibling Parent Partner Other\_\_\_\_\_\_\_\_\_\_\_\_\_

Time since their diagnosis:

In the last month Less than 12 months 1-5 years 5-10 years >10 years

History of support services/interventions you have accessed in relation to supporting someone with an eating disorder (including; number of services, type of service and professional e.g. psychologist, social worker, and number of sessions):

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Age of person with an eating disorder \_\_\_\_\_\_\_\_\_\_\_

How would you rate the severity of (\_\_\_\_\_\_\_’s) problems over the last month?

0 (no problem) 1 (mild) 2 (moderate) 3 (high) 4 (severely incapacitating)

Are you currently accessing any support services for yourself about your caregiving role?

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Do you have any past or current mental health diagnoses?

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Are you able to commit to attending 2 x 2.5-hour sessions and completing questionnaires?   
  
 YES NO

Are you coming alone? YES or if NO, with whom\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Suitable (please circle): YES NO If no, offer alternative services.

APPENDIX B

INFORMATION SHEET



GROUP WORKSHOP FOR CARERS OF INDIVIDUALS WITH EATING DISORDERS

You are invited to take part in a research project which is being undertaken as part of a Masters of Clinical Psychology degree at Curtin University. The information generated by this project will be used by the associate investigator (Katharina Targowski) to obtain a Masters of Clinical Psychology degree.

**What is the study about?**

Being a caregiver of someone with an eating disorder can have a big effect on life quality, mood, relationships, and performance. The best practice guidelines for the treatment of eating disorders recognise the significant impact the illness can have on the individual and those around them. They recommend that family, friends and carers (referred to as ‘carers’) access services that provide education about the illness and promote the development of self-care strategies. This study aims to evaluate a brief group intervention targeted specifically at caregivers of individuals with eating disorders. It is hoped that carers’ knowledge of the illness will improve as well as their coping skills and overall well-being.

**Who can participate?**

We are looking for participants who are relatives, partners, or friends of an individual with a diagnosed eating disorder.

**What will the study involve?**

Once you have registered your interest in the study by contacting the number below or emailing your details to the address below, Katharina will contact you via phone to discuss your interest and conduct an initial interview.

*Initial Interview*

Via phone, Katharina Targowski will conduct a brief interview (approx. 10 minutes) that will involve answering a series of demographic questions (name, date of birth, ethnicity, address) and questions about the person you support with an eating disorder (date of diagnosis, past and current interventions or supports they and you have received, how severe you would rate their illness). If we believe the program could be helpful and you would like to participate you will be sent a series of questionnaires and a consent form. The questionnaires should take about 30 minutes to complete.

*Allocation to waitlist or intervention*

If you choose to participate in the study you will be randomly allocated to either a waitlist or immediate intervention.

**Waitlist** – Those on the waitlist will again complete the questionnaires 1 and 5 weeks after being allocated. Katharina will collect the questionnaires via post or online and will ensure they are safely secured in a locked filing cabinet at Curtin University. The data from the questionnaires will be used to compare to the data collected from those who were allocated to the immediate intervention. This will help the researchers determine whether the group is successful. Once you have completed the questionnaires after 5 weeks you will be allocated a place in the next scheduled group session.

**Immediate intervention –** Those allocated to the immediate intervention condition will be contacted via phone and informed of the details (time, date, location) of the first and second group sessions to attend.

*First Group Session*

The first session will be two and a half hours in duration and cover the following topics; the bio-genetic link in eating disorders, the family’s role, and common communication pitfalls. Between the first and second sessions you will be asked to plan either a one-on-one or family ‘meeting’ with your loved one to discuss their eating disorder.

*Second Group Session*

The second group session will be held one week later and will focus on refining communication skills and practicing some useful techniques that can help to diffuse difficult situations that can arise with your loved one. Both sessions will be interactive and provide you with the opportunity to meet other caregivers and ask any questions you may have related to you caregiving role. You will be asked to again complete the questionnaires at the end of the second session.

*Follow-up questionnaires*

To monitor the helpfulness of the program over time, you will be asked to complete the questionnaire one final time, one month after the completion of the second session.

*Questionnaire for the person you support*

In addition to any benefits you might receive, we are interested in the impact the intervention might have on the person with the eating disorder. We will be inviting the person you support to also complete a brief questionnaire before and after the intervention, to see if they notice any benefits from their perspective. This is not necessary for you to participate in the study.

**Confidentiality**

All information will be treated in the strictest of confidence. Documents and questionnaires will be coded with an ID number and kept by Katharina in a locked filing cabinet. By signing the Consent Form, you also agree to keep confidentiality within the group sessions, if you are allocated to the treatment group. This means that you will be asked not to talk about other group members or about the session discussions with people outside the group.

The results of the study may be published in scholarly journals. Your name, or any other identifying information, will not be mentioned in any written reports of this study.

**Risks**

There are no foreseeable risks to your participation in this study, except that you might experience some distress during the group as you reflect on any difficulties you have experienced in your caring role. The facilitators will be available to assist you if this occurs. The time commitment of attending two, 2.5 hour sessions may also be inconvenient.

**Withdraw**

You are free to withdraw from the study at any point and need give no reason or justification for your decision. If you wish to withdraw please inform Katharina or Peter in person or via the contact details below. If you choose to withdraw your de-identified information from completed questionnaires may still be used by Katharina Targowski in her analysis. A follow-up phone call will be provided to you to provide you with other support services if you require. All participant data will be stored at Curtin University for a minimum of seven years following the study, after which it will be destroyed. A de-identified electronic database may be stored at the Curtin University data repository. If this occurs, this de-identified database may be used by other researchers to verify the findings, to combine data with studies conducted by other researchers to compare outcomes, or to conduct additional analyses that answer additional questions that can inform future services for carers.

**Audio-recording**

The group sessions will be audio-recorded to ensure the group facilitators adhere to the treatment protocol. The recordings will be stored at Curtin University for seven years following the study, after which they will be destroyed.

**How do I sign up for the study?**

If you would like to take part in this study, kindly contact Katharina or Peter via the contact details below. Upon receiving your interest you will be contacted to arrange the phone interview.

If you require further details about the study, please contact:

Katharina Targowski (co-investigator) [Katharina.targowski@postgrad.curtin.edu.au](mailto:Alison.miller@postgrad.curtin.edu.au) or 0402 748 886

OR

Peter McEvoy (principal investigator) [peter.mcevoy@curtin.edu.au](mailto:peter.mcevoy@curtin.edu.au) or 9266 5110

*Approval to conduct this research has been provided by Curtin University and the Human Research Ethics Committees of the North Metropolitan Mental Health Service Research Ethics and Governance Office (NHMS MH REGO) in accordance with their ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time.* *In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the NMHS MH REGO Executive Officer on (08) 9347 6502 or* [*NMAHSMHREGO@health.wa.gov.au*](mailto:NMAHSMHREGO@health.wa.gov.au) *or the Human Research Ethics Office at Curtin University on (08) 9266 9223 or by emailing to* [*hrec@curtin.edu.au*](mailto:hrec@curtin.edu.au)*. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.*

APPENDIX C:

CONSENT FORM



**Group Workshop for Carers of Individuals with Eating Disorders**

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(the participant) have read the Information Sheet and any questions I have asked have been answered to my satisfaction. I agree to participate in this activity, realising that I may withdraw at any time without reason and without prejudice.

I understand that all information provided is treated as strictly confidential and will not be released by the investigator unless required to do so by law. I have been advised as to what data are being collected, what the purpose is, and what will be done with the data upon completion of the research.

I understand and agree for all the group sessions to be audiotaped for treatment integrity, and am aware that all recordings will be kept securely for 7 years upon project completion and will be securely disposed thereafter.

I agree to maintain the confidentiality within the group I am allocated to for the group sessions.

I agree that research data gathered for the study may be published as long as my name, or any identifying data, is not used in any publication

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Date

**Chief Investigator Co-Investigator**

Associate Professor Peter McEvoy Katharina Targowski

Senior Clinical Psychologist [Katharina.targowski@postgrad.curtin.edu.au](mailto:Katharina.targowski@postgrad.curtin.edu.au)

Centre for Clinical Interventions &

Curtin University

[peter.mcevoy@curtin.edu.au](mailto:peter.mcevoy@curtin.edu.au)

*Approval to conduct this research has been provided by Curtin University and the Human Research Ethics Committees of the North Metropolitan Mental Health Service Research Ethics and Governance Office (NHMS MH REGO) in accordance with their ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time.* *In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the NMHS MH REGO Executive Officer on (08) 9347 6502 or* [*NMAHSMHREGO@health.wa.gov.au*](mailto:NMAHSMHREGO@health.wa.gov.au) *or the Human Research Ethics Office at Curtin University on (08) 9266 9223 or by emailing to* [*hrec@curtin.edu.au*](mailto:hrec@curtin.edu.au)*. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.*

APPENDIX D

INFORMATION SHEET



GROUP WORKSHOP FOR CARERS OF INDIVIDUALS WITH EATING DISORDERS:

THE PERSPECTIVE OF THE PERSON WITH THE EATING DISORDER

You have received this information sheet because a family member, friend, or partner (referred to as ‘carer’) is participating in a group to learn more about eating disorders, and how to help you in your recovery. In addition to assessing any benefits the carer receives from this group, we are also interested in your perspective – in particular, whether you notice any helpful changes in the way the eating disorder is managed.

You are therefore invited to take part in a research project which is being undertaken as part of a Masters of Clinical Psychology degree at Curtin University. The information generated by this project will be used by the associate investigator (Katharina Targowski) to obtain a Masters of Clinical Psychology degree.

**What is the study about?**

Being a caregiver of someone with an eating disorder can have a big effect on life quality, mood, relationships, and performance. The best practice guidelines for the treatment of eating disorders recognise the significant impact the illness can have on the individual and those around them. They recommend that family, friends and carers (referred to as ‘carers’) access services that provide education about the illness and promote the development of self-care strategies. This study aims to evaluate a brief group intervention targeted specifically at caregivers of individuals with eating disorders. It is hoped that carers’ knowledge of the illness will improve as well as their coping skills and overall well-being. We also hope that the carer program will help the person with the eating disorder feel that their relationships, and the way the eating disorder is managed, improve.

**Who can participate?**

We are hoping that people with eating disorders, who have family members, friends, or partners attending the carers groups, will agree to complete a brief questionnaire so that we can assess any benefits for the person with the eating disorder. Your decision on whether or not to provide your perspective will not impact on whether your carer can attend the group.

**What will the study involve?**

Some carers will receive the intervention immediately, whereas others will receive the intervention after a waiting period. We request that you complete a brief questionnaire about how you relate to the person (or people) attending the group before and after the group. For people with carers attending the immediate group, this will involve completing the questionnaire before the first group, again one week later, and then a final time one month later (3 times). For people with carers attending the group after a waiting period, this will involve completing the questionnaires before the waiting period, one week later, one month later, and then one final time after the carer attends the group (4 times). The questionnaire should not take more than 15 minutes to complete on each occasion. Your answers to this questionnaire will help us determine whether the carers groups are beneficial from the perspective of the individual with the eating disorder.

**Confidentiality**

All information will be treated in the strictest of confidence. Documents and questionnaires will be coded with an ID number and kept by Katharina in a locked filing cabinet. By signing the Consent Form, you also agree to keep confidentiality within the group sessions, if you are allocated to the treatment group. This means that you will be asked not to talk about other group members or about the session discussions with people outside the group.

The results of the study may be published in scholarly journals. Your name, or any other identifying information, will not be mentioned in any written reports of this study.

**Risks**

There are no foreseeable risks to your participation in this study, except that you might experience some distress as you reflect on any difficulties you have experienced with eating or with the person completing the group. If this occurs, you can contact the Butterfly Foundation (1800 33 4673) for support. The time commitment of completing the questionnaires may also be inconvenient.

**Withdraw**

You are free to withdraw from the study at any point and need give no reason or justification for your decision. If you wish to withdraw please inform Katharina or Peter in person or via the contact details below. If you choose to withdraw your de-identified information from completed questionnaires may still be used by Katharina Targowski in her analysis. A follow-up phone call will be provided to you to provide you with other support services if you require. All participant data will be stored at Curtin University for a minimum of seven years following the study, after which it will be destroyed. A de-identified electronic database may be stored at the Curtin University data repository. If this occurs, this de-identified database may be used by other researchers to verify the findings, to combine data with studies conducted by other researchers to compare outcomes, or to conduct additional analyses that answer additional questions that can inform future services for carers.

**How do I sign up for the study?**

If you would like to take part in this study, kindly contact Katharina or Peter via the contact details below. Upon receiving your interest you will be contacted to arrange the phone interview.

If you require further details about the study, please contact:

Katharina Targowski (co-investigator) [Katharina.targowski@postgrad.curtin.edu.au](mailto:Alison.miller@postgrad.curtin.edu.au) or 0402 748 886

OR

Peter McEvoy (principal investigator) [peter.mcevoy@curtin.edu.au](mailto:peter.mcevoy@curtin.edu.au) or 9266 5110

*Approval to conduct this research has been provided by Curtin University and the Human Research Ethics Committees of the North Metropolitan Mental Health Service Research Ethics and Governance Office (NHMS MH REGO) in accordance with their ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time.* *In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the NMHS MH REGO Executive Officer on (08) 9347 6502 or* [*NMAHSMHREGO@health.wa.gov.au*](mailto:NMAHSMHREGO@health.wa.gov.au) *or the Human Research Ethics Office at Curtin University on (08) 9266 9223 or by emailing to* [*hrec@curtin.edu.au*](mailto:hrec@curtin.edu.au)*. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.*

APPENDIX E:

CONSENT FORM



**Group Workshop for Carers of Individuals with Eating Disorders:**

**The perspective of the person with the eating disorder**

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(the participant) have read the Information Sheet and any questions I have asked have been answered to my satisfaction. I agree to participate in this activity, realising that I may withdraw at any time without reason and without prejudice.

I understand that all information provided is treated as strictly confidential and will not be released by the investigator unless required to do so by law. I have been advised as to what data are being collected, what the purpose is, and what will be done with the data upon completion of the research.

I agree that research data gathered for the study may be published as long as my name, or any identifying data, is not used in any publication

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant (person with an eating disorder) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian (if person with an eating disorder is under 18 years) Date

**Chief Investigator Co-Investigator**

Associate Professor Peter McEvoy Katharina Targowski

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*Approval to conduct this research has been provided by Curtin University and the Human Research Ethics Committees of the North Metropolitan Mental Health Service Research Ethics and Governance Office (NHMS MH REGO) in accordance with their ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time.* *In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the NMHS MH REGO Executive Officer on (08) 9347 6502 or* [*NMAHSMHREGO@health.wa.gov.au*](mailto:NMAHSMHREGO@health.wa.gov.au) *or the Human Research Ethics Office at Curtin University on (08) 9266 9223 or by emailing to* [*hrec@curtin.edu.au*](mailto:hrec@curtin.edu.au)*. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.*

APPENDIX F:

Example advertisement

**GROUP WORKSHOP FOR CARERS OF INDIVIDUALS WITH EATING DISORDERS**

|  |  |
| --- | --- |
| **Chief Investigator**  Associate Professor Peter McEvoy  [peter.mcevoy@curtin.edu.au](mailto:peter.mcevoy@curtin.edu.au) | **Co-Investigator**  Katharina Targowski  [Katharina.targowski@postgrad.curtin.edu.au](mailto:Katharina.targowski@postgrad.curtin.edu.au)  M: 0428 687 626 |

**Purpose of the research**

We are interested in finding out whether a brief group workshop for carers of individuals with eating disorders will help carers to better cope with supporting their loved one. Participants will attend two 150-minute group sessions at the Centre for Clinical Interventions. Participants will be required to complete a number of brief questionnaires throughout the study.

Group Sessions:

The first session will cover the following topics; the bio-genetic link in eating disorders, the family’s role, and common communication pitfalls. Between the first and second sessions you will be asked to plan either a one-on-one or family ‘meeting’ with your loved one to discuss their eating disorder.

The second group session will be held one week later and will focus on refining communication skills and practicing some useful techniques that can help to diffuse difficult situations that can arise with your loved one. Both sessions will be interactive and provide you with the opportunity to meet other carers and ask any questions you may have related to you caregiving role. You will be asked to again complete the questionnaires at the end of the second session.

**Consent to Participate**

Participation in the study is entirely voluntary and you are free to withdraw from the study at any time without prejudice. You do not need to give a reason for not completing the study. If you decide not to participate, or want to leave the study at a later stage, and would like to receive help from outside of the study, then we will be happy to provide you with a list of experienced mental health professionals and services.

**Confidentiality**

All personal information collected during the study will be kept confidential and remain in a locked filing cabinet at Curtin University. Information will only be viewed by those connected with the study and if the research is published, the names of participants will not be used.

**Ethics**

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR XXX/2015) and the *Human Research Ethics Committees of the North Metropolitan Mental Health Service Research Ethics and Governance Office (NHMS MH REGO).* The committees are comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or emailing [hrec@curtin.edu.au](mailto:hrec@curtin.edu.au). Verificaion from the NMMHS can be obtained by contacting the *NMHS MH REGO Executive Officer on (08) 9347 6502 or* [*NMAHSMHREGO@health.wa.gov.au*](mailto:NMAHSMHREGO@health.wa.gov.au)*.*

APPENDIX G:

PROMIS (Anxiety)

*In the past seven days…*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Never | Rarely | Sometimes | Often | Always |
| I felt fearful |  |  |  |  |  |
| I found it hard to focus on anything other than my anxiety |  |  |  |  |  |
| My worries overwhelmed me |  |  |  |  |  |
| I felt uneasy |  |  |  |  |  |
| I felt nervous |  |  |  |  |  |
| I felt like I needed help for my anxiety |  |  |  |  |  |
| I felt anxious |  |  |  |  |  |
| I felt tense |  |  |  |  |  |

APPENDIX F:  
PROMIS (Depression)

*In the past seven days…*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Never | Rarely | Sometimes | Often | Always |
| I felt worthless |  |  |  |  |  |
| I felt helpless |  |  |  |  |  |
| I felt depressed |  |  |  |  |  |
| I felt hopeless |  |  |  |  |  |
| I felt like a failure |  |  |  |  |  |
| I felt unhappy |  |  |  |  |  |
| I felt that I had nothing to look forward to |  |  |  |  |  |
| I felt that nothing could cheer me up |  |  |  |  |  |

APPENDIX I:

Burden Assessment Scale (BAS)

Please read the list of things which other people have found to happen to them because of their relative’s illness. Please choose and circle to what extent you have had any of the following experiences in the past one month.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Because of ( ‘s) illness, to what extent have you:*** | Not at all | A little | Some | A lot |
| Had financial problems | 1 | 2 | 3 | 4 |
| Missed days at work (or school) | 1 | 2 | 3 | 4 |
| Found it difficult to concentrate on your own activities | 1 | 2 | 3 | 4 |
| Had to change your personal plans like taking a new job, or going on vacation | 1 | 2 | 3 | 4 |
| Cut down on leisure time | 1 | 2 | 3 | 4 |
| Found the household routine was upset | 1 | 2 | 3 | 4 |
| Had less time to spend with friends | 1 | 2 | 3 | 4 |
| Neglected other family members’ needs | 1 | 2 | 3 | 4 |
| Experienced family frictions and arguments | 1 | 2 | 3 | 4 |
| Experienced frictions with neighbours, friends, or relatives outside the home | 1 | 2 | 3 | 4 |
| Became embarrassed because of (\_\_\_\_\_)’s behaviour | 1 | 2 | 3 | 4 |
| Felt guilty because you were not doing enough to help | 1 | 2 | 3 | 4 |
| Felt guilty because you felt responsible for causing (\_\_\_\_\_)’s problem | 1 | 2 | 3 | 4 |
| Resented (\_\_\_\_\_) because s/he made too many demands on you | 1 | 2 | 3 | 4 |
| Felt trapped by your caregiving role | 1 | 2 | 3 | 4 |
| Were upset about how much (\_\_\_\_\_) had changed from his/her former self | 1 | 2 | 3 | 4 |
| Worried about how your behaviour with (­­\_\_\_\_\_) might make the illness worse? | 1 | 2 | 3 | 4 |
| Worried about what the future holds for (\_\_\_\_\_) | 1 | 2 | 3 | 4 |
| Found the stigma of the illness upsetting | 1 | 2 | 3 | 4 |

APPENDIX J:

Self-efficacy Scale

At present, how confident are you in performing each of the following activities in relation to your loved one with an eating disorder? For each of the statements, please use the following scale to rate your level of confidence with respect to the person in your life with an eating disorder?

0 1 2 3 4 5 6 7 8 9 10

I cannot I am moderately confident I am certain I can

do this at all I can do this do this

|  |  |
| --- | --- |
|  | Rating 0-10 |
| Identify early warning signs of an increase in eating disorder behaviours (e.g., dieting, binge-eating, vomiting, laxative misuse, driven exercise) |  |
| Take action in response to early warning signs of an increase in eating disorder behaviours |  |
| Identify the types of stressful events that might trigger an increase in eating disorder behaviours |  |
| Cope with stressful situations in relation to their disordered eating |  |
| Communicate with this person about their illness |  |
| Communicate with others about eating disorders |  |
| Maintain satisfactory relationships with this person |  |
| Remain calm when facing difficulties in relation to the eating disorder because I can rely on my coping abilities |  |
| Seek medical attention for this person if I become concerned about the impact of the eating disorder on his/her physical health? |  |

APPENDIX K:

Accommodating and Enabling Scale for Eating Disorders (AESED)

The following items contain a number of statements that commonly apply to the family members who live with a relative or a friend with an eating disorder. We would like you to read each one and decide how often it has applied to your family members over the **past one month.** It is important to note that there are no right or wrong answers. Your first reaction will usually provide the best answer.

**0 = never : 1 = rarely : 2 = sometimes : 3 = often : 4 = every day**

*During the past month how often have you thought about :*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| The choices of food that you buy? | 0 | 1 | 2 | 3 | 4 |
| What other family members do and for how long in the kitchen? | 0 | 1 | 2 | 3 | 4 |
| Cooking practice and ingredients you use? | 0 | 1 | 2 | 3 | 4 |
| What other family members eat? | 0 | 1 | 2 | 3 | 4 |

*Does your relative engage any family member in repeated conversations:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Asking for reassurance about whether she/he will get fat? | 0 | 1 | 2 | 3 | 4 |
| About whether it is safe or acceptable to eat a certain food? | 0 | 1 | 2 | 3 | 4 |
| Asking for reassurance about whether she/he looks fat in certain clothes? | 0 | 1 | 2 | 3 | 4 |
| Their ingredients and amounts, possible substitutes for ingredients? | 0 | 1 | 2 | 3 | 4 |
| About negative thoughts and feelings? | 0 | 1 | 2 | 3 | 4 |
| About self-harm? | 0 | 1 | 2 | 3 | 4 |

*Do any family members have to accommodate to the following?*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| What crockery is used? | 0 | 1 | 2 | 3 | 4 |
| How crockery is cleaned? | 0 | 1 | 2 | 3 | 4 |
| What time food is eaten? | 0 | 1 | 2 | 3 | 4 |
| What place food is eaten? | 0 | 1 | 2 | 3 | 4 |
| How the kitchen is cleaned? | 0 | 1 | 2 | 3 | 4 |
| How food is stored? | 0 | 1 | 2 | 3 | 4 |
| The exercise routine of the relative with an ED? | 0 | 1 | 2 | 3 | 4 |
| Your relative’s checking their body shape or weight? | 0 | 1 | 2 | 3 | 4 |
| How the house is cleaned and tidied? | 0 | 1 | 2 | 3 | 4 |

*Do you choose to ignore aspects of your relative’s eating disorder that impinge on your family’s life in an effort to reconcile or make it tolerable for the rest of the family such as if:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Food disappears? | 0 | 1 | 2 | 3 | 4 |
| Money is taken? | 0 | 1 | 2 | 3 | 4 |
| The kitchen is left a mess? | 0 | 1 | 2 | 3 | 4 |
| The bathroom is left a mess? | 0 | 1 | 2 | 3 | 4 |

*In general, to what extent would you say that the relative with an eating disorder controls family life and activities?*

*None at all About half Completely*

0 1 2 3 4 5 6 7 8 9 10

**To continue answering the questionnaire, please bear in mind the following:**

If it has never happened, you would circle the number 0. If it has happened 1-3 times per month, you would circle the number 1. If it has happened 1-2 times per week, you would circle the number 2. If it has happened 3-6 times per week you would circle the number 3. If it happens daily, you would circle the number 4. Over the ***past one month:***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| How often did you participate in behaviours related to your relative’s compulsions? | 0 | 1 | 2 | 3 | 4 |
| How often did you assist your relative in avoiding things that might make her/him more anxious? | 0 | 1 | 2 | 3 | 4 |

**To continue answering:**

If the answer is NO, you would circle the number 0. If the answer is MILD, you would circle the number 1. If the answer is MODERATE, you would circle the number 2. If the answer is SEVERE, you would circle the number 3. If the answer is EXTREME, you would circle the number 4. Over the **past one month:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Have you avoided doing things, going places, or being with people because of your relative’s eating disorder? | 0 | 1 | 2 | 3 | 4 |
| Have you modified your family routine because of your relative’s symptoms? | 0 | 1 | 2 | 3 | 4 |
| Have you modified your work schedule because of your relative’s needs? | 0 | 1 | 2 | 3 | 4 |
| Have you modified your leisure activities because of your relative’s needs? | 0 | 1 | 2 | 3 | 4 |
| Has helping your relative in the before-mentioned ways caused you distress? | 0 | 1 | 2 | 3 | 4 |
| Has your relative become distressed/anxious when you have not provided assistance? | 0 | 1 | 2 | 3 | 4 |
| Has your relative become angry/abusive when you have not provided assistance? | 0 | 1 | 2 | 3 | 4 |

APPENDIX L:

Knowledge of Eating Disorder Questionnaire

Please rate your response to the following statement “Right now, I believe I have enough information about…” using the scale provided below:

1 2 3 4 5 6 7   
Strongly disagree Disagree Agree Strongly  
 agree

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Eating disorders in general | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Local self-help groups | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Individual/family support groups | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Help lines | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Where to get help and/or advice | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Counselling/psychotherapy opportunities available to you | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Coping strategies | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| ‘Success stories’ i.e. people who have recovered from an eating disorder | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Different treatment options | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Prognosis of the person you are caring for | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| How to meet others ‘in the same boat’ | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| What to do/who to contact in the case of a relapse | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

APPENDIX M:

Family Questionnaire (FQ)

**Family Questionnaire:** This questionnaire lists different ways in which families try to cope with everyday problems. For each item please indicate how often you have reacted to the patient in this way. There are no right or wrong responses. It is best to note the first response that comes to mind. Please respond to each question, and mark only one response per question.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Never/ very rarely | Rarely | Often | Very often |
| I tend to neglect myself because of him/her | 0 | 1 | 2 | 3 |
| I have to keep asking him/her to do things | 0 | 1 | 2 | 3 |
| I often think about what is to become of him/her | 0 | 1 | 2 | 3 |
| He/she irritates me | 0 | 1 | 2 | 3 |
| I keep thinking about the reasons for his/her illness | 0 | 1 | 2 | 3 |
| I have to try not to criticise him/her | 0 | 1 | 2 | 3 |
| I can’t sleep because of him/her | 0 | 1 | 2 | 3 |
| It’s hard for us to agree on things | 0 | 1 | 2 | 3 |
| When something about him/her bothers me, I keep it to myself | 0 | 1 | 2 | 3 |
| He/she does not appreciate what I do for him/her | 0 | 1 | 2 | 3 |
| I regard my own needs as less important | 0 | 1 | 2 | 3 |
| He/she sometimes gets on my nerves | 0 | 1 | 2 | 3 |
| I’m very worried about him/her | 0 | 1 | 2 | 3 |
| He/she does some things out of spite | 0 | 1 | 2 | 3 |
| I thought I would become ill myself | 0 | 1 | 2 | 3 |
| When he/she constantly wants something from me, it annoys me | 0 | 1 | 2 | 3 |
| He/she is an important part of my life | 0 | 1 | 2 | 3 |
| I have to insist that he/she behave differently | 0 | 1 | 2 | 3 |
| I have given up important things in order to be able to help him/her | 0 | 1 | 2 | 3 |
| I’m often angry with him/her | 0 | 1 | 2 | 3 |

APPENDIX N:

The Caregiver Skills (CASK)

We are interested in your thoughts on some areas of caregiving. Please be as frank and honest as you can. The statements below describe situations that are commonly associated with eating disorders. For each situation please rate how confident your carer could respond in the way described.

**Rate your degree of confidence from 0 to 100 using the scale given below.**

**0 10 20 30 40 50 60 70 80 90 100**

**Almost never Occasionally Frequently Almost Always**

For example, a rating of 100 means that you are absolutely, 100% confident that you could perform the activity whenever you wished. For each scenario, please circle the number that you feel best reflects your confidence.   
You can choose any score between 0 and 100 (10, 20, 30, etc.)  
**Please make all your ratings based on what you could do THIS WEEK** as the person you are NOW rather than on the person you used to be or the person you would like to be. This is very important. If you feel some of the questions aren’t applicable to you, try to rate how confident you would be should the situation arise.

The blank spaces refer to your loved one with an eating disorder. You do not need to fill in the gaps.

**How confident are you that you can…**

|  |  |
| --- | --- |
|  | **Rating (0-100)** |
| Keep doing the things that you enjoy whilst caring for \_\_\_\_\_\_\_\_\_ |  |
| Discuss and explain your own feelings about the eating disorder openly with \_\_\_\_\_\_\_\_\_ |  |
| Discuss the eating disorder openly with *all* other immediate family members involved? |  |
| Be understanding towards \_\_\_\_\_\_\_\_\_, even when you are angry or frustrated with them? |  |
| Avoid getting drawn into arguments about the eating disorder with \_\_\_\_\_\_\_\_\_? |  |
| Be calm when dealing with difficult behaviours associated with the eating disorder? |  |
| Take some time for yourself when you need a break? |  |
| Talk and listen with \_\_\_\_\_\_\_\_\_ about difficult and complex emotions that s/he is feeling? |  |
| Be reassured by even the smallest signs of improvement? |  |
| Keep hope that \_\_\_\_\_\_\_\_\_ will recover? |  |
| Step back and trust that \_\_\_\_\_\_\_\_\_ will cope with day to day challenges themselves? |  |
| Agree boundaries, plans, or household rules in collaboration with \_\_\_\_\_\_\_\_\_? |  |
| Uphold boundaries/rules consistently in a compassionate tone, even with \_\_\_\_\_\_\_\_\_ is arguing with you? |  |
| Control the urge to argue against the eating disorder behaviours, even though you believe your argument to be logical? |  |
| Have pleasant verbal interactions with \_\_\_\_\_\_\_\_\_, not related to the eating disorder? |  |
| Control the urge to keep enquiring or checking on \_\_\_\_\_\_\_\_\_’s behaviour even when you are very worried? |  |
| Praise change or attempts at change by \_\_\_\_\_\_\_\_\_ even if the effects/results were less than what you were hoping for? |  |
| Resist constantly reminding/asking about agreed behaviour targets? |  |
| Avoid getting caught in repetitive conversations with \_\_\_\_\_\_\_\_\_ about food and eating? |  |
| Keep your eye on \_\_\_\_\_\_\_\_\_’s overall progress/the bigger picture? |  |
| Resist solely on weight as a marker of how s/he is doing? |  |
| Separate \_\_\_\_\_\_\_\_\_ as a person from the illness? |  |
| Reflect and understand the effect of your behaviour on \_\_\_\_\_\_\_\_\_? |  |
| Accept that the eating disorder is not your fault? |  |
| Accept that the one cause or trigger for the eating disorder may not be the solution to recovery? |  |
| Find time to spend with other members of the family? |  |
| Manage your anxiety levels so that you don’t feel overwhelmed? |  |

APPENDIX O:  
The Caregiver Skills (CASK) Modified for use with the individual with the eating disorder

We are interested in your thoughts on some areas of caregiving. Please be as frank and honest as you can. The statements below describe situations that are commonly associated with eating disorders. For each situation please rate how confident you are that your carer could respond in the way described.

**Rate your degree of confidence from 0 to 100 using the scale given below.**

**0 10 20 30 40 50 60 70 80 90 100**

**Almost never Occasionally Frequently Almost Always**

For example, a rating of 100 means that you are absolutely, 100% confident that your carer could perform the activity whenever you wished. For each scenario, please circle the number that you feel best reflects your confidence.   
You can choose any score between 0 and 100 (10, 20, 30, etc.)  
**Please make all your ratings based on what your carer could do THIS WEEK** as the person they are NOW rather than on the person they used to be or the person they would like to be. This is very important. If you feel some of the questions aren’t applicable, try to rate how confident you would be should the situation arise.

**How confident are you that your carer can…**

|  |  |
| --- | --- |
|  | **Rating (0-100)** |
| Keep doing the things that they enjoy whilst caring for you |  |
| Discuss and explain their feelings about the eating disorder openly with you |  |
| Discuss the eating disorder openly with *all* other immediate family members involved? |  |
| Be understanding towards you even when they are angry or frustrated with you? |  |
| Avoid getting drawn into arguments about the eating disorder with you |  |
| Be calm when dealing with difficult behaviours associated with the eating disorder? |  |
| Take some time for themselves when they need a break? |  |
| Talk and listen with you about difficult and complex emotions that you are feeling? |  |
| Be reassured by even the smallest signs of improvement? |  |
| Keep hope that you will recover? |  |
| Step back and trust that you will cope with day to day challenges yourself? |  |
| Agree boundaries, plans, or household rules in collaboration with you |  |
| Uphold boundaries/rules consistently in a compassionate tone, even when you are arguing with them? |  |
| Control the urge to argue against the eating disorder behaviours, even though you believe your argument to be logical? |  |
| Have pleasant verbal interactions with \_\_\_\_\_\_\_\_\_, not related to the eating disorder? |  |
| Control the urge to keep enquiring or checking on \_\_\_\_\_\_\_\_\_’s behaviour even when you are very worried? |  |
| Praise your change or attempts at change even if the effects/results were less than what they were hoping for? |  |
| Resist constantly reminding/asking about agreed behaviour targets? |  |
| Avoid getting caught in repetitive conversations with you about food and eating? |  |
| Keep their eye on your overall progress/the bigger picture? |  |
| Rely solely on weight as a marker of how you are doing? |  |
| Separate you as a person from the illness? |  |
| Reflect and understand the effect of their behaviour on you? |  |
| Accept that the eating disorder is not their fault? |  |
| Accept that the one cause or trigger for the eating disorder may not be the solution to recovery? |  |
| Find time to spend with other members of the family? |  |
| Manage their anxiety levels so that they don’t feel overwhelmed? |  |

APPENDIX P:

List of additional Mental Health services (for referral)

|  |  |
| --- | --- |
| **Emergency Contact Numbers Mental Health Emergency Response Line (MHERL)** | 1300 555 788 |
| Department of Health’s metropolitan emergency mental health service. They can refer you to an appropriate service during normal business hours or provide after-hours help. | |
| **RuralLink** | 1800 552 002 |
| Department of Health’s after-hours emergency mental health service for regional areas. | |
| **Acute Response Team (Child & Adolescent)** | 1800 048 636 (metro area) |
| **Crisis Care** (24 hour): | 9223 1111 |
| 1800 199 008 (freecall STD) | |
| **Lifeline** (24-hour): | 13 11 14 |
| **Suicide Call Back Service** (24-hour): | 1300 659 467 |
| **Samaritans** (24-hour): | 135 247 |
| **Kids Helpline** (24-hour): | 1800 551 800 |
| **Poisons Information Centre** (24-hour): | 13 11 26 |

**Emergency Departments**

You can also present to a hospital emergency department if you are finding it difficult to cope at any time. There are Emergency Departments at the following major hospitals:

**Royal Perth Hospital** 9224 2244

**Sir Charles Gairdner Hospital** 6457 3333

**Fiona Stanley Hospital** 6152 2222

**And at the following local hospitals …**

**Midland Public Hospital** 9462 4000

**Bentley Hospital** 9334 3666

**Joondalup Health Campus** 9400 9400

**Armadale Health Service** 9391 2000

**Peel Health Campus** 9531 8000

**Rockingham General Hospital** 9599 4000

|  |
| --- |
| **Community Services**  **UWA Eating Disorders Service: 6488 8079**  www.psychology.uwa.edu.au/community/uwa-eating-disorders-service  The University of Western Australia Eating Disorders Service (UWA EDS) is a private, outpatient treatment service for children, adolescents and adults with anorexia nervosa, bulimia nervosa, binge eating disorder, other mixed symptom eating disorders, and obesity. |
| **The Body Esteem Program 9300 1566**  www.womenshealthworks.org.au/programs/eating-disorders-body-esteem/  The Body Esteem Program is a service provided by WOMEN’S Healthworks (WHW) which offers support for women suffering from eating disorders, such as anorexia nervosa, bulimia nervosa, binge eating disorder and compulsive overeating. The program supports and assists women to make informed decisions about their health and wellbeing and to make and sustain positive change through a 20-week recovery focused group based on the self-help model. |
| **The Hollywood Clinic 9346 6801**  www.thehollywoodclinic.com.au  The Hollywood Clinic provides inpatient treatment for individuals experiencing severe eating disorders. They also offer day-patient programs for patients with Anorexia Nervosa and Bulimia Nervosa, and evening-based multifamily therapy group for young people (and their families) who are experiencing an eating disorder. |

|  |
| --- |
| **Websites**  **Centre for Clinical Interventions website**  [www.cci.health.wa.gov.au](http://www.cci.health.wa.gov.au)  Information for both consumers and health professionals about eating disorders and mental health. Provides self-guided information packages and handouts for eating disorders, emotional disorders as well as perfectionism and low self-esteem. |
| **Butterfly Foundation** Support line: 1800 ED HOPE / 1800 33 4673  [www.thebutterflyfoundation.org.au](http://www.thebutterflyfoundation.org.au)  Aims to increase the understanding and awareness in the community in relation to eating disorders, through the support of existing services, education and research projects. Website provides extensive information on eating disorders, treatment, and support services available for those affected by eating disorders and negative body image and their families. |
| **The National Eating Disorders Collaboration (NEDC)**  [www.nedc.com.au](http://www.nedc.com.au)  NEDC brings research, expertise and evidence from leaders in the field together in one place. It's a one stop portal to make eating disorders information a lot more accessible for everyone. |

APPENDIX Q:

Outline of the group sessions

**PSYCHOEDUCATION PACKS:**

* Clarify objectives of the group
* Types of eating disorders and their symptoms, briefly explain that individuals with eating disorders may move between the different types
* Common myths
* Possible causes (genetics, role of the brain, environmental factors)
* Warning signs for medical risk and who to call
* Available treatment options

**SESSION ONE:**

* Summary of psycho-education: focus on the role of genetics, biological/neurological factors
  + Starvation syndrome (video)
  + The catch-22 of re-feeding: strengthens the individual but also strengthens the ED voice. Briefly summarise stages of change and the fact that individuals will go through each one more than once
    - Introduce the fear of change and reasons for it (getting better feels bad)
  + Participants asked to comment on anything they found surprising or confusing
  + Introduce the cancer metaphor: when someone is diagnosed, we don’t spend our time worrying about the cause, we just jump straight to treating it
* Families are our greatest asset: introduce homework task and rationale
* Role of environmental factors: (this could potentially be moved to session two)
  + Interpersonal maintenance model of eating disorders
  + Participants asked to provide examples of common communication traps they can get ‘stuck’ in (e.g. getting stuck in eating disorder talk, reassurance seeking, escalating).
  + Show slide of Treasure’s communication ‘animals’ and ask participants to think about which one they identify with most
  + Participants asked to provide examples of times they have accommodated their loved one’s eating disorder
* The effect on carers:
  + Importance of self-care

**HOMEWORK TASK:**

* Self-care task (20 minutes)
* Approach the individual with the eating disorder and set a time for an eating disorder ‘meeting’ (either whole family, or one-on-one). Task could simply be setting this meeting or actually following through before next session)

*Set aside time for yourself, and other involved close family members, to have a meeting with Edi when you can talk about your feelings and needs as well as giving Edi time to describe what help and support she or he needs and wants from family members. Schedule the meeting so that everyone has time to prepare, to think about what problems they might want to raise. During this meeting, do:*

* Let Edi present the arguments for change, give the opportunity to talk about (and hopefully resolve) ambivalence
* Focus on your loved ones’ concerns
* Emphasise that Edi has the choice and responsibility for deciding future behaviour
* Explore and reflect upon Edi’s perception of the situation
* Reflect what you think you have heard with statements starting with ‘you’. (“You feel…”, “You think…”)

*Try to avoid:*

* Arguing, lecturing, or persuading with logic
* Assuming an authoritatian role
* Ordering, directing, warning, and threatening
* Doing most of the talking
* Making moral statements, criticizing, preaching, or judging
* Asking a series of three or more questions in a row
* Telling Edi they have a problem
* Prescribing solutions or a certain course of action.

**SESSION TWO:**

* Review homework task
* Introduction to strategies and helpful phrases from Treasure book (handouts provided)
* Participants to role play difficult situations (communication ‘traps’ identified in session one) and practice using the helpful phrases to diffuse them

**POSSIBLE TOOLS FOR COMMUNICATION:**

**Sidestepping food and weight talk:**

* It sounds as if your anorexic anxiety is strong
* You seem frightened
* That is your eating disorder speaking to you
* Be brave, it will pass
* I have read that if I reassure you it will keep your fear flourishing
* If I join in with food or weight talk I will lock you deeper into your eating disorder
* I do not enter into discussions about food or calories. We will change the subject
* As we have discussed, speaking to the ‘eating disorder’ voice is harmful
* I will listen to you talk to me for five minutes about food/shape/weight, but that will be it for the day
* It sounds as if you might be confused about making changes

**Helpful coaching comments during mealtimes:**

* It is not helpful if you focus on the detail of what sort/what calories/what amount
* Let’s stick to the plan – we are interested in nutrition for health and quality of life
* What is more helpful is to keep your eye on what we want to achieve in terms of your life story
* I would like your life to be more than eating
* Let’s zoom out to connections to people and the world rather than being stuck on nutritional basics
* I know that there is more to you than food and weight. Let’s move on and get there

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| *Things to try not to say. Think of your tone of voice* | *Things to say calmly* |
| Why haven’t you eaten it all? | You told me you would eat it. Please do it- I know you can |
| Surely you can eat that last bit? | I know you need support and I know you can do it |
| Come on, you have not finished that bit, time is running out and I’ve got things to do- get on with it! | It is hard but you have the courage within you to do it |
| What a waste! | Try hard not to listen to the anorexic ‘minx’ |
| I have spent hours getting that ready! | We need to take steps to improve your nutrition safety |
| Think about the children in Africa | I am not going to get into a debate now. Let’s get on with the nutritional treatment |
| It’s disgusting to see you cut up your food like that! | In the plan we agreed, we said that dinner would last less than 45 minutes. You have 15 minutes left, can I help? Should I heat it up again? |
| Look at how little you have taken! What do you think you are, a mouse? | That portion size is not big enough. Please can you try again? |

**Positive statements:**

* Edi, you must be pleased that you have managed to…
* Edi, it must have been difficult to take that step…I really appreciate how hard you are trying
* Thank you for…
* I noticed that you…
* I really like it when you (name it: help me tidy up, keep your room tidy, bring in the washing, put out the bins. *Anything* you can praise it useful, no matter how small.)

**When the situation is escalating:**

* I don’t think this is a good time to discuss the matter. Let’s talk about it later when we are both calm
* We’ve both said what we think, now I’m going to…
* My emotions are too intense to think clearly at the moment. Let’s come back to it later

**When Edi is upset:**

* Look and listen for signs of anger and hurt, validate these emotions: “I might be wrong, but it seems like you are…”
* Encourage Edi to voice the emotion they are experiencing
* Listen carefully to painful thoughts: don’t prematurely reassure
* Don’t over-identify with Edi’s feelings
* Ensure that you don’t get into a self-defensive pattern- take any negative feedback on the chin
* Give positive feedback about their expression of their feelings: “I’m very impressed that you were able to tell me how you were feeling. Well done for having the courage to do that”

**Guide to medical risk:**

<http://www.kcl.ac.uk/ioppn/depts/pm/research/eatingdisorders/resources/GUIDETOMEDICALRISKASSESSMENT.pdf>

**Script for approaching ‘Edi’ when medical risk is a concern:**

“I have noticed several things which have made me worry about your health. First, you are very sensitive to cold- you have the fire turned on in your room so that it feels like a furnace. Also, I’ve noticed that you find opening heavy doors difficult. I’d like you to go and have a medical check-up to put my mind at rest. Could I help my making you an appointment with our GP? If you want me to, I’d be happy to come with you.”