Treating anxiety and depression in older adults: randomised controlled trial comparing guided v. self-guided internet-delivered cognitive–behavioural therapy

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Background
Symptoms of anxiety and depression are prevalent in older adults.

Aims
To compare clinician-guided and self-guided versions of a transdiagnostic internet-delivered cognitive–behavioural therapy (iCBT) intervention for adults aged 60 years and above.

Method
Adults (n=433) with symptoms of anxiety and depression were randomly allocated to: (1) clinician-guided treatment (n=153); (2) initial clinician interview followed by self-guided treatment (n=140); or (3) self-guided treatment without interview (n=140).

Results
Large reductions (d ≥1.00) in symptoms of depression and anxiety were observed across groups, and sustained at follow-up. No differences were observed in clinical outcomes or satisfaction ratings. Age did not affect outcomes.

Conclusions
Carefully developed iCBT interventions may significantly reduce symptoms of anxiety and depression in older adults when delivered in either clinician-guided or self-guided formats.

Declaration of interest
N.T. and B.F.D. developed the Wellbeing Plus Course but derive no financial benefit from it.

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Clinical and subclinical levels of depression and anxiety are common in older adults, and are associated with reduced quality of life, increased disability and increased risk of suicide.

Treatments such as cognitive–behavioural therapy (CBT) are known to be effective, but only a small proportion of older people with depression and anxiety seek or receive evidence-based treatment. Barriers to care include stigma, costs of treatment, mobility limitations and the limited number of trained therapists, which can all be reduced using internet-delivered CBT (iCBT). iCBT can be supported by a clinician, provided as a self-guided treatment with an initial interview followed by monitoring of outcomes, or provided in a fully automated manner without contact or monitoring. In studies conducted to date, clinician-guided iCBT has been associated with superior outcomes relative to self-guided and fully automated iCBT. However, recently developed self-guided iCBT, which include automated prompts and other strategies designed to increase completion rates, has shown levels of clinical improvement equivalent to clinician-guided treatment. Whereas several studies have demonstrated the efficacy of iCBT in treating anxiety and depression in older adults, there have been no trials directly comparing guided and self-guided iCBT with this population. The comparison is warranted because we do not know whether older adults require additional support to benefit from self-guided iCBT, which can in turn affect the cost of making this treatment widely available.

The present study compared the efficacy and acceptability of an iCBT intervention delivered with varying levels of clinician guidance. The Wellbeing Plus Course is a transdiagnostic intervention designed for adults aged 60 years and above with anxiety or depression. Participants were randomised to clinician-guided or self-guided iCBT groups, with the latter receiving either an orientation interview or no interview. It was hypothesised that all groups would report significant improvements on measures of anxiety and depression but that the clinician-guided group would obtain superior outcomes, and that the outcomes of the self-guided group which received an orientation interview would be superior to the other self-guided group. It was also hypothesised that outcomes would be maintained from post-treatment to 3-month follow-up.

Method

Participants
The study was promoted in newspapers and online, and participants were recruited via a specialist research unit (www.centreclinic.org) that provides information about common mental and chronic health conditions and offers free psychological treatment via participation in clinical trials. The CONSORT flowchart for the trial is displayed in Fig. 1. A total of 563 individuals applied to participate in the study and 459 met the criteria for inclusion. The inclusion criteria were: (a) resident of Australia, (b) at least 60 years of age and (c) a principal complaint of symptoms of anxiety or depression. The exclusion criteria were: (a) current participation in CBT and (b) very severe symptoms of depression (defined as a total score ≥24 or responding >2 to Question 9 on the 9-item Patient Health Questionnaire (PHQ-9)). Questions pertaining to the inclusion and exclusion criteria were assessed via an online application form.

Applicants meeting inclusion criteria were randomly allocated at the point of application to one of three treatment groups, using a permuted block randomisation sequence generated by B.F.D.: (a) interview plus clinician-guided group (ICG; n=158); (b) interview plus self-guided group (ISG; n=147); or (c) self-guided
group (SG; n=154). The randomisation sequence was created by B.F.D. using an online randomiser (www.random.org) and participants were masked to group allocation until the participants had any contact with the researchers or the researchers had the opportunity to review the details of participants’ applications. Thus, the researchers were masked to group allocation until the participants were deemed to have made a successful or unsuccessful application. The study was approved by the Human Research Ethics Committee (HREC) of Macquarie University, Sydney, Australia, and the trial was registered on the Australian and New Zealand Clinical Trials Registry (ANZCTR) as ACTRN12613000958785.

Design and measures

The study employed a three-arm CONSORT-revised compliant randomised controlled trial (RCT) comparing an internet-delivered treatment for older adults provided with three levels of support. The researchers sought to recruit at least 450 participants, which, with alpha set at 0.05 and a power of 0.80, would enable the detection of small effect size differences (i.e. Cohen’s d≥0.35) between groups. All outcome measures were collected via online questionnaires. The primary measures of anxiety and depression were administered weekly to monitor participants’ progress and safety throughout treatment. The secondary and tertiary measures were administered at pre-treatment, post-treatment and 3-month follow-up, and the acceptability and satisfaction questions were administered post-treatment.

Primary measures

Two primary measures were used to assess the presence and severity of depression and anxiety: the PHQ-9, a 9-item measure of the presence and severity of symptoms of depression, based on the DSM-IV diagnostic criteria for major depressive disorder;23 and the 7-item Generalised Anxiety Disorder scale (GAD-7), a 7-item measure of the presence and severity of symptoms of general anxiety, which is based on the DSM-IV diagnostic criteria for GAD.24

Secondary measures

Two secondary measures were used: the Geriatric Depression Scale (GDS), a 15-item short-form screening measure for the assessment and detection of depression among older adults. The GDS employs a simple ‘Yes’ or ‘No’ response, and places less emphasis on the somatic symptoms of depression, which are often confounded in older adults by other physical conditions.25 The 10-item Kessler Psychological Distress Scale (K-10) was used to measure general psychological distress, with total scores ≥22 associated with a diagnosis of anxiety and depressive disorders.26

Fig. 1 Participant flow from application to 3-month follow-up. CBT, cognitive–behavioural therapy; PHQ-9, 9-item Patient Health Questionnaire.
Table 1 Demographic characteristics and treatment and symptom histories of the treatment groups

| Variable                  | Clinician-guided with interview (n=153) | Self-guided with interview (n=140) | Self-guided without interview (n=140) | Overall (n=433) | Statistical comparison between groups |
|---------------------------|----------------------------------------|-----------------------------------|---------------------------------------|-----------------|--------------------------------------|
| Gender                    |                                        |                                   |                                       |                 |                                      |
| Male                      | 53                                     | 50                                | 52                                    | 36              | 155 (n=20), P=0.905                  |
| Female                    | 100                                    | 90                                | 88                                    | 63              | 278 (n=64)                           |
| Age, years                |                                        |                                   |                                       |                 |                                      |
| Mean (s.d)                | 65 (3.8)                               | 66 (4.6)                          | 67 (5.6)                              | 66 (4.7)        | F<sub>2,430</sub>=4.73, P=0.009     |
| Range                     | 60–78                                  | 60–80                             | 60–93                                 | 60–93           |                                      |
| Age frequency             |                                        |                                   |                                       |                 |                                      |
| 60–64 years               | 78                                     | 51                                | 69                                    | 49              | 210 (n=49), P=0.578                  |
| 65–74 years               | 74                                     | 48                                | 64                                    | 46              | 201 (n=46), P=0.829                 |
| 75 years and above        | 1                                      | 1                                 | 7                                     | 14              | 22 (n=5), P=0.013                    |
| Marital status            |                                        |                                   |                                       |                 |                                      |
| Single/rever married      | 8                                      | 5                                 | 8                                     | 6               | 3 (n=3), P=0.35                      |
| Married/de facto          | 96                                     | 63                                | 98                                    | 70              | 293 (n=68), P=0.269                  |
| Separated/divorced/widowed/other | 49                                      | 32                                 | 34                                    | 24              | 121 (n=28), P=0.328                  |
| Education                 |                                        |                                   |                                       |                 |                                      |
| High school or less       | 32                                     | 21                                | 27                                    | 21              | 85 (n=20), P=0.674                  |
| Certificate/ diploma/other | 43                                    | 28                                | 37                                    | 27              | 127 (n=29), P=0.389                 |
| University                | 78                                     | 51                                | 76                                    | 54              | 221 (n=51), P=0.561                  |
| Vocational status<sup>a</sup> |                                        |                                   |                                       |                 |                                      |
| Full-time/part-time employment | 84                                   | 55                                | 76                                    | 54              | 225 (n=52), P=0.168                 |
| Full-time/part-time student | 1                                     | 1                                 | 4                                     | 3               | 7 (n=2), P=0.367                    |
| Unemployed/seeking employment | 9                                    | 6                                 | 8                                     | 6               | 26 (n=6), P=0.966                   |
| Registered disability     | 4                                      | 3                                 | 5                                     | 4               | 13 (n=3), P=0.885                   |
| Retired                   | 83                                     | 54                                | 86                                    | 61              | 256 (n=59), P=0.311                 |
| Age at symptom onset, years: mean (s.d.) | 33 (19) | 33 (18) | 35 (20) | 33 (19) | F<sub>2,430</sub>=0.50, P=0.609 |
| Treatment in previous 12 months |                                        |                                   |                                       |                 |                                      |
| Yes                       | 53                                     | 35                                | 45                                    | 32              | 149 (n=34), P=0.750                  |
| No                        | 100                                    | 65                                | 95                                    | 68              | 284 (n=66), P=0.780                  |
| Health professionals seen for treatment |                                        |                                   |                                       |                 |                                      |
| General practitioner      | 87                                     | 57                                | 81                                    | 58              | 250 (n=58), P=0.975                 |
| Psychiatrist              | 9                                      | 6                                 | 7                                     | 5               | 108 (n=25), P=0.901                 |
| Psychologist/counsellor   | 39                                     | 26                                | 36                                    | 26              | 23 (n=5), P=0.966                   |
| Other                     | 14                                     | 9                                 | 10                                    | 7               | 34 (n=8), P=0.760                    |
| Taking prescription medication |                                        |                                   |                                       |                 |                                      |
| No                        | 101                                    | 66                                | 89                                    | 65              | 288 (n=67), P=0.516                  |
| Anxiety                   | 12                                     | 8                                 | 16                                    | 11              | 40 (n=9), P=0.544                   |
| Depression                | 19                                     | 12                                | 19                                    | 14              | 53 (n=12), P=0.764                  |
| Both anxiety and depression | 21                                | 14                                 | 16                                    | 11              | 52 (n=12), P=0.708                  |
| Distribution of symptoms at assessment |                                        |                                   |                                       |                 |                                      |
| Anxiety symptoms (GAD-7)  |                                        |                                   |                                       |                 |                                      |
| Minimal anxiety           | 18                                     | 12                                | 8                                     | 6               | 10 (n=7), P=0.36                    |
| Mild anxiety              | 57                                     | 37                                | 51                                    | 36              | 161 (n=37), P=0.970                |
| Moderate anxiety          | 50                                     | 33                                | 54                                    | 39              | 155 (n=36), P=0.565                |
| Severe anxiety            | 28                                     | 18                                | 27                                    | 19              | 81 (n=19), P=0.976                  |
| Depression symptoms (PHQ-9) |                                        |                                   |                                       |                 |                                      |
| No depression             | 13                                     | 9                                 | 15                                    | 11              | 39 (n=9), P=0.683                   |
| Mild depression           | 56                                     | 37                                | 50                                    | 36              | 159 (n=37), P=0.933                |
| Moderate depression       | 47                                     | 31                                | 48                                    | 34              | 146 (n=34), P=0.578                |
| Moderately severe depression | 29                                 | 19                                 | 24                                    | 17              | 70 (n=16), P=0.261                 |
| Severe depression         | 8                                      | 5                                 | 9                                     | 4               | 19 (n=4), P=0.279                   |

Tertiary measures

Two tertiary measures were used: the Sheehan Disability Scale (SDS), a 3-item measure of disability and functional impairment in work, study, social life and family life and household responsibilities, and the Satisfaction with Life Scale (SWLS), a 5-item measure of judgements of subjective well-being.

Acceptability and satisfaction

Treatment satisfaction and acceptability were assessed at post-treatment using two questions taken from other studies: (1) ‘Would you feel confident in recommending this course?’ and (2) ‘Was it worth your time doing the course?’ Participants responded with a ‘Yes’ or ‘No’ response.
The Wellbeing Plus Course is an 8-week intervention that teaches core transdiagnostic psychological principles and skills such as cognitive challenging, exposure and behavioural activation that have been found to be effective at reducing symptoms of depression and anxiety in older adults.\textsuperscript{16,17,20} The Wellbeing Plus Course consists of five online lessons, homework assignments and case-enhanced stories, which detail the experiences of older adults recovering from symptoms of depression and anxiety (Table 2). Each lesson is presented in a slide show format that combines didactic material (i.e. text-based instructions and information) with case-enhanced stories. Participants are instructed to read the lessons over 8 weeks according to a timetable. Participants also receive regular automatic emails which notify them of new course materials, reinforce completion of materials and practice of skills.

Participants are encouraged to complete one lesson every 7–10 days and to attempt to regularly practice the skills covered within the lesson summaries.

### Clinician contact

Participants in the iCG and iSG groups received a brief telephone interview from one of the clinicians. This call was scripted and aimed to: (a) discuss the aims of treatment; (b) convey hope by describing the results of previous participants; (c) emphasise the importance of consistent practice of the skills over time; and (d) answer questions about the treatment. The interview calls were designed to take between 10 and 20 min.

Participants in the iCG group also received weekly contact from clinicians during treatment. Two registered and experienced psychologists (V.F. and L.J.) provided all clinical contact with participants, via telephone or a secure email system. In accordance with previous research,\textsuperscript{29} clinicians were instructed to: (a) answer participants’ questions; (b) summarise content; (c) encourage skills practice; (d) resolve difficulties applying skills; and (e) reinforce progress. Clinicians were instructed not to introduce therapeutic skills not covered within the course and, unless clinically indicated, to limit the time spent in contact or contacting participants to approximately 10–15 min per week.

Participants in the iSG and SG groups were informed via the online application system that they would not receive clinical contact throughout treatment unless their symptoms became more severe. The symptom questionnaire responses of participants in these groups were monitored weekly by the clinicians, but contact was only initiated if a deterioration in their mental health (i.e. defined as an increase in PHQ-9 total score of ≥5 with a total score ≥15 or a PHQ-9 question 9 score of 3) was observed. This contact involved the administration of a risk assessment and, if needed, referral to appropriate crisis services.

### Statistical analysis

All analyses were conducted using SPSS version 21. Group differences in demographic variables and diagnostic variables were analysed using binomial and multinomial logistic regression and general linear models analyses. The alpha significance level for the preliminary analyses was adjusted from 0.05 to 0.01 as a partial control for the number of analyses conducted. Participants who did not start the interventions were not included in any analyses.

A generalised estimation equation (GEE) modelling technique was employed to examine changes in the measures over time. An unstructured working correlation structure was selected, coupled with a robust error estimation, for GEE analyses. GEE models specified a gamma distribution with a log-link response scale to address skewness in the dependent variable distributions. Symptom scores at the time of completing the online application were employed as baseline for the primary measures. However, for the secondary and tertiary outcomes, which were not assessed at initial application, pre-treatment was used as baseline. SPSS
pairwise comparisons were used to examine significant main and interaction effects. To determine whether the age of older adults affected clinical outcomes, GEE analyses were repeated on the primary outcomes using participant age as a model covariate.

In addition, three different statistics were calculated for comparison and benchmarking purposes. First, the average percentage change across time was calculated from the GEE analyses for each of the outcome variables with 95% confidence intervals. Second, Cohen’s d effect sizes and 95% confidence intervals were calculated for the between-groups effects based on the estimated marginal means derived from the GEE models. To provide data about negative outcomes, the numbers of participants reporting symptom deteriorations ≥30% and symptoms in the clinical ranges at post-treatment (i.e. above recognised clinical cut-offs on the GAD-7 and PHQ-9) on the primary outcome measures were also calculated.

### Results

#### Baseline data, adherence and attrition

The demographic characteristics of the sample are shown in Table 1. Participant flow, treatment attrition, lesson completion and questionnaire response are shown in Fig. 1. As shown in Table 1, participants reported having had symptoms for several decades and the majority had not sought professional help in the past 12 months. No differences were found between the groups on the demographic variables. A minimum of 95% of participants in each group completed questionnaires at post-treatment compared with a minimum of 90% at 3-month follow-up. No differences were found between participants who completed and did not complete questionnaires at post-treatment (P > 0.01). The means, percentage reductions and effect sizes for the groups are shown in Table 3.

#### Primary outcomes

The primary outcomes were depression and anxiety symptom levels, which were assessed with the PHQ-9 and GAD-7 respectively. The GEE analyses indicated a significant effect for time (PHQ-9: Wald’s χ²=738.80, P < 0.001; GAD-7: Wald’s χ²=682.88, P < 0.001) but no significant time × group interactions (PHQ-9: Wald’s χ²=4.34, P = 0.362; GAD-7: Wald’s χ²=4.43, P = 0.351). Pairwise comparisons indicated that on the PHQ-9, all groups reduced their symptoms from assessment to post-treatment (P < 0.001) but not from post-treatment to 3-month follow-up (P = 0.761). On the GAD-7, all groups reduced in their symptoms from assessment to post-treatment (P < 0.001) and from post-treatment to 3-month follow-up (P = 0.002).

#### Secondary outcomes

The secondary outcomes were geriatric-specific depression symptoms and general psychological distress, as measured by the GDS and K-10 respectively. The GEE analyses indicated a significant effect for time (GDS: Wald’s χ²=731.43, P < 0.001; K-10: Wald’s χ²=793.60, P < 0.001) but no significant time × group interactions (GDS: Wald’s χ²=6.52, P = 0.164; K-10: Wald’s χ²=5.58, P = 0.233). Pairwise comparisons indicated that on both measures, all groups showed significant symptom reduction from assessment to post-treatment (P < 0.001) and from post-treatment to 3-month follow-up (P < 0.001).

#### Tertiary outcomes

The tertiary outcomes were disability and satisfaction with life, assessed with the SDS and SWLS respectively. Analyses indicated a significant effect for time (SDS: Wald’s χ²=282.31, P < 0.001; SWLS: Wald’s χ²=241.25, P < 0.001). All groups showed symptom reduction from assessment to post-treatment (P < 0.001) and from post-treatment to 3-month follow-up in both disability and satisfaction (P < 0.009).

There was no significant time × group interaction for disability (SDS: Wald’s χ²=1.71, P = 0.790) but there was evidence of an interaction for satisfaction with life (SWLS: Wald’s χ²=12.34, P = 0.015). Pairwise comparisons indicated that the iSG group did not improve in satisfaction with life from post-treatment to 3-month follow-up (P = 0.363), whereas the iCG and SG groups did improve (P < 0.003). However, there were no overall differences in satisfaction with life between the three groups at either post-treatment (P range: 0.334–0.780) or at 3-month follow-up (P range: 0.642–0.981).

#### Age and clinical outcomes

The GEE analyses revealed no significant effect for age (GAD-7: Wald’s χ²=0.57, P = 0.449; PHQ-9: Wald’s χ²=0.28, P = 0.591) or significant interactions on the primary outcomes (GAD-7: Wald’s χ²=3.24, P = 0.518; PHQ-9: Wald’s χ²=0.33, P = 0.988) when age was entered into the analyses as a covariate.

#### Clinician time

There were significant differences in clinician contact time between groups (F = 415.50, P < 0.001). The iCG group received more clinician time than the iSG and SG groups (P < 0.001), but there were no differences between the iSG and SG groups (P = 0.483). The mean total clinician time per participant in the iCG group was 68.47 min (s.d. = 34.35), which was comprised of answering and making calls (total = 1320; M = 8.63 min; s.d. = 28.0; range 0–20) as well as reading, sending and responding to secure emails (total = 750; M = 4.90; s.d. = 2.78; range 0–12). Because of technical difficulties and deterioration, 52% (73/140) of the iSG group and 56% (79/140) of the SG group received one or more contacts via email or telephone during treatment. The mean total clinician time per participant in the iSG group was 46.61 min (s.d. = 8.08) and the mean total clinician time per participant in the SG group was 6.43 min (s.d. = 10.24).

#### Negative outcomes

Less than 1% (1/150), 3% (3/136) and 2% (2/133) in the iCG, iSG and SG groups respectively had increases in depression scores ≥30% and also scored above clinical cut-off at post-treatment. None of the iCG group, 3% (4/136) of the iSG and 2% (2/133) of the SG groups respectively had increases in anxiety scores ≥30% and scored above the clinical cut-off at post-treatment. No participants reported symptom deteriorations or changes in personal safety requiring referral to crisis services.

#### Treatment completion and satisfaction rates

There was no difference between groups in the number of lessons completed at post-treatment (F = 1.12, P = 0.326) or follow-up (F = 2.18, P = 0.114). Of the participants who completed the evaluation questions at post-treatment, 95% (132/139), 94% (117/124) and 91% (112/123) of participants in the iCG, iSG and SG groups respectively, responded that they ‘would recommend the course’ to others. Similarly, 94% (131/139), 92% (115/124) and 95% (117/123) of participants in the iCG, iSG, and SG groups respectively responded that the course was ‘worth their time’. There were no differences between groups in the proportions reporting they would recommend the course (F = 0.92, P = 0.398) or that it was worth their time (F = 0.41, P = 0.668).

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### Table 3
Means, s.d.s, percentage change and effect sizes (Cohen’s d) for the primary and secondary outcome measures

|                          | Estimated marginal mean (s.d.) | Percentage change from assessment (95% CI) | Within group effect size from assessment (95% CI) | Between group effect size at post-treatment (95% CI) | Between group effect size at 3-month follow-up (95% CI) |
|--------------------------|-------------------------------|------------------------------------------|-------------------------------------------------|---------------------------------------------------|------------------------------------------------------|
|                          | n                             | Assessment                                | Post-treatment                                  | 3-month follow-up                                 | Post-treatment                                      | 3-month follow-up                                    |
| **Primary outcomes**     |                               |                                          |                                                 |                                                   |                                                     |                                                     |
| Depression (PHQ-9)       | ICG 153                       | 10.74                                    | 4.30                                            | 4.30                                              | 59                                                  | 60                                                   | 1.45                                                | 1.54                                              | –                                                   | 0.01                                                 | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
|                          | ISG 140                       | 10.43                                    | 4.44                                            | 4.71                                              | 57                                                  | 55                                                   | 1.44                                                | 1.36                                              | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
|                          | SG 140                        | 10.43                                    | 4.78                                            | 4.75                                              | 54                                                  | 54                                                   | 1.30                                                | 1.33                                              | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
| Anxiety (GAD-7)          | ICG 153                       | 9.86                                     | 3.73                                            | 3.73                                              | 58                                                  | 62                                                   | 1.33                                                | 1.57                                              | –                                                   | 0.14                                                 | 0.26                                                 | –                                                   | 0.41                                                 | –                                                   | 0.22                                                 | –                                                   | –                                                   |
|                          | ISG 140                       | 10.45                                    | 4.74                                            | 4.36                                              | 55                                                  | 58                                                   | 1.36                                                | 1.47                                              | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
|                          | SG 140                        | 10.44                                    | 5.19                                            | 4.50                                              | 50                                                  | 57                                                   | 1.29                                                | 1.50                                              | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
| **Secondary outcomes**   |                               |                                          |                                                 |                                                   |                                                     |                                                     |
| Geriatric depression (IQDS) | ICG 153                       | 8.07                                     | 4.83                                            | 4.41                                              | 40                                                  | 45                                                   | 0.90                                                | 1.04                                              | –                                                   | 0.03                                                 | 0.15                                                 | –                                                   | 0.02                                                 | –                                                   | 0.02                                                 | –                                                   | –                                                   |
|                          | ISG 140                       | 7.82                                     | 4.73                                            | 4.35                                              | 40                                                  | 44                                                   | 0.85                                                | 0.94                                              | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
|                          | SG 140                        | 7.72                                     | 5.36                                            | 4.50                                              | 31                                                  | 42                                                   | 0.67                                                | 0.89                                              | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
| Psychological distress (K-10) | ICG 153                       | 24.92                                    | 17.01                                           | 16.05                                             | 32                                                  | 36                                                   | 1.22                                                | 1.44                                              | –                                                   | 0.11                                                 | 0.23                                                 | –                                                   | 0.12                                                 | –                                                   | 0.19                                                 | –                                                   | –                                                   |
|                          | ISG 140                       | 24.97                                    | 17.69                                           | 16.76                                             | 29                                                  | 33                                                   | 1.17                                                | 1.32                                              | –                                                   | 0.13                                                 | 0.27                                                 | –                                                   | 0.07                                                 | –                                                   | 0.31                                                 | –                                                   | –                                                   |
|                          | SG 140                        | 25.09                                    | 18.50                                           | 17.21                                             | 26                                                  | 31                                                   | 1.05                                                | 1.26                                              | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
| **Tertiary outcomes**    |                               |                                          |                                                 |                                                   |                                                     |                                                     |
| Disability (SGS)         | ICG 153                       | 11.51                                    | 6.17                                            | 5.53                                              | 46                                                  | 52                                                   | 0.77                                                | 0.83                                              | –                                                   | 0.02                                                 | 0.06                                                 | –                                                   | 0.03                                                 | –                                                   | 0.00                                                 | –                                                   | –                                                   |
|                          | ISG 140                       | 11.47                                    | 6.31                                            | 5.76                                              | 45                                                  | 50                                                   | 0.74                                                | 0.82                                              | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |
|                          | SG 140                        | 11.50                                    | 6.63                                            | 6.74                                              | 35 to 54                                            | 40 to 59                                            | 0.50 to 0.98                                         | 0.57 to 1.06                                       | –                                                   | 0.27 to 0.20                                       | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   | –                                                   |

**Note:** Table sourced from Trichili and colleagues, reference provided.
Table 3 (Continued)

| Within group effect size (95% CI) at post-treatment | Between group effect size (95% CI) | Self-guided with interview | Pure | Clinician
|-----------------------------------------------|----------------------------------|---------------------------|-------|-----------|
| Life satisfaction (SWLS)                      |                                  | 6.54 (5.22 to 8.09)       | 5.19  | 6.63 (4.92 to 8.49) |
| iCG                                           |                                  | 5.34 (4.05 to 6.56)       | 4.12  | 5.55 (3.93 to 7.18) |
| SG                                            |                                  | 6.30 (5.09 to 7.60)       | 5.09  | 6.69 (5.00 to 8.63) |
| iSG                                           |                                  | 5.81 (4.52 to 7.24)       | 4.50  | 6.15 (4.21 to 8.30) |
| Satisfaction with life (SWLS)                 |                                  | 19.63 (18.01 to 21.16)    | 19.89 | 20.46 (18.74 to 22.17) |
| iCG                                           |                                  | 20.36 (18.67 to 22.05)    | 20.46 | 20.36 (18.67 to 22.05) |
| SG                                            |                                  | 20.24 (18.52 to 21.96)    | 20.46 | 20.24 (18.52 to 21.96) |
| iSG                                           |                                  | 19.73 (18.01 to 21.45)    | 20.46 | 19.73 (18.01 to 21.45) |

Notes:
- Self-guided with interview
- Pure
- Clinician

Discussion

The present study compared the efficacy and acceptability of three support levels for a new transdiagnostic internet-delivered intervention, the Wellbeing Plus Course, for adults aged 60 years and above with symptoms of depression and anxiety. No differences were found between the groups. High completion and acceptability rates were achieved in all three groups. All groups were associated with significant reductions in symptoms and very low rates (i.e. <4%) of symptom deterioration.

Similarly, large reductions in symptoms of depression (Cohen’s $d \geq 1.30$; average reduction $\geq 54%$) and anxiety (Cohen’s $d \geq 1.29$; average reductions $\geq 50%$) were observed across the three treatment groups and were maintained or improved at follow-up. The magnitude of the observed reductions are comparable with other studies that have evaluated the efficacy of psychological treatments for older adults when administered face to face$^{31,32}$ and via the internet.$^{19-28}$ Significant improvements were also observed on secondary and tertiary outcome measures, which included satisfaction with life, improvements in psychological distress and disability.

The present findings extend the literature in several ways. First, the results from this large RCT augment existing studies indicating that transdiagnostic treatments for symptoms of anxiety or depression are not only effective for younger adults$^{31,32}$ but also older adults.$^{14,17}$ Second, the results of this study indicate that clinician guidance or a pre-treatment telephone interview with a clinician may not be necessary to achieve strong clinical outcomes among older adults. This finding contributes to a growing body of evidence indicating that carefully designed self-guided treatments, which include automated prompts and other features that improve engagement are able to produce high rates of engagement and large clinical benefits.$^{11-15}$ It is important to note that the results of the present trial have been partially replicated in an online national mental health service in Australia which used the clinician-guided iCBT model described here.$^{53}$

High rates of course completion, satisfaction and strong clinical outcomes were observed in that sample of patients in routine clinical care, indicating the intervention can be successfully translated from a research setting into a routine clinical environment. This is consistent with recent results from other clinics indicating that both younger and older adults can benefit from iCBT when administered as part of routine clinical care.$^{34,36}$ It is also notable that participants in the present study reported having had symptoms for several decades ($M$ onset=33 years; $s.d.=19$) and many ($\geq66%$) had not sought professional help in the past 12 months, which highlight the public health potential of internet-delivered psychological treatments to the large number of older adults with untreated anxiety and depression.

This study has a number of limitations. First, the absence of a control group means it is not possible to control for the effects of spontaneous remission. However, controlled trials using similar methods have found very little change in control groups (e.g. Cohen’s $d<0.15$) without active intervention,$^{16,28}$ which may reflect the chronicity of symptoms. Second, the present trial was designed as a superiority trial and consequently caution is needed in concluding any statistical findings as supporting clinical equivalence, which requires the use of specific equivalence trial analyses. Third, the results are based on self-reported symptom scores. The absence of a formal diagnostic interview means that some care is needed in generalising the results of the current study to older adults meeting diagnostic criteria for anxiety and depressive disorders. Fourth, it is unclear whether the current results would be maintained beyond the 3-month follow-up period, although the improvements in similar studies were still
evident at 12-month follow-up.16,20 A further limitation of the current study is that it used a sample of older adults who were both seeking psychological treatment and were comfortable enough with the use of computers to participate in the study. Some caution is therefore needed in generalising the results to older adults presenting to other settings and who may not be interested in psychological treatment or are not sufficiently confident with computers.

Two further considerations are the nature of the intervention and the nature of support that was available to patients if needed. The Wellbeing Plus Course has been carefully developed over several phases of research, with each version evaluated in clinical trials and modified with the help of feedback from large numbers of participants. Moreover, the self-reported symptoms of all participants were carefully monitored during treatment and half of those in the self-guided groups were contacted, even if only briefly, by a clinician to check their safety or assist with technical difficulties during treatment. Hence, this model of self-guided treatment differs from fully automated interventions in facilitating the safety and engagement of participants, whereas still representing a cost-effective method of administration.

In conclusion, these results extend evidence indicating that CBT can help older adults recover from symptoms of anxiety and depression. The results also indicate that carefully developed clinician-guided and self-guided iCBT interventions, delivered either with and without a clinical interview, can result in similarly high treatment completion rates, levels of satisfaction and large clinical outcomes. The findings of the current trial further highlight the considerable potential of iCBT and interventions like the Wellbeing Plus Course to improve access to treatment for older adults with anxiety and depression who might otherwise never receive treatment.

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