

GROUPS 4 HEALTH reduces loneliness and social anxiety in adults with psychological
distress: Findings from a randomized controlled trial

Catherine Haslam¹, Tegan Cruwys², Melissa X-L Chang¹, Sarah V. Bentley¹, S. Alexander
Haslam¹, Genevieve A. Dingle¹, and Jolanda Jetten¹

¹School of Psychology, University of Queensland, Brisbane, Australia

²Research School of Psychology, The Australian National University, Australia

Submission to *Journal of Consulting and Clinical Psychology*

First submission: 2/10/2018

Revision 1: 15/2/2019

Revision 2: 18/4/2019

Revision 3: 11/6/2019

Address correspondence to:

Catherine Haslam, School of Psychology, University of Queensland, Brisbane, Australia, 4072

Phone: + 61 733467565

Email: c.haslam@uq.edu.au

Abstract

Objective: Loneliness is a key public health issue for which various interventions have been trialled. However, few directly target the core feature of loneliness—lack of belonging. This is the focus of GROUPS 4 HEALTH (G4H), a recently developed intervention that targets the development and maintenance of social group memberships to support health.

Method: To investigate the efficacy of this intervention, a randomized controlled trial was conducted with participants ($N=120$) assigned to G4H or treatment-as-usual (TAU) by computer software. Assessment of primary (loneliness) and secondary (depression, social anxiety, general practitioner visits, multiple group membership) outcomes was conducted at baseline and 2-month follow-up using mixed-model repeated-measures analyses.

Results: G4H produced a greater reduction in loneliness ($d = -1.16$) and social anxiety ($d = -0.53$) than TAU ($ds = -0.36, 0.03$, respectively). G4H was also associated with fewer general practitioner visits at follow-up ($d = -0.21$) and a stronger sense of belonging to multiple groups ($d = 0.96$) relative to TAU ($d = 0.21, d = 0.42$, respectively). Depression declined significantly in both G4H ($d = -0.67$) and TAU ($d = -0.35$), but follow-up analyses showed this was greater in G4H among those not receiving adjunct psychopharmacological treatment and whose symptoms were milder.

Conclusions: Findings suggest that G4H can be a useful way to treat loneliness and highlight the importance of attending to group memberships when tackling this important social challenge.

Key words: Loneliness, social anxiety, social identity, GROUPS 4 HEALTH

Public Health significance: This study demonstrates how an intervention derived from social identity theorizing can target social isolation and in so doing reduce loneliness and symptoms of depression, and social anxiety.

Social isolation is experienced by a large number of people, and is particularly common in vulnerable populations — for instance, people who are socially disadvantaged such as immigrants and minority groups, or those with disability. If isolation leads to a subjective sense of loneliness, it can be toxic to health with wide ranging consequences on people's mental health (e.g., Cacioppo, Hughes, Waite, Hawkley, & Thisted, 2006; Hawkley & Cacioppo, 2010), physical health, and mortality (e.g., Cacioppo et al., 2002; Holt-Lunstad et al., 2010). These various outcomes therefore make it a priority for intervention.

Approaches to managing loneliness are diverse, though not all are informed by theory, and evidence of their effectiveness is mixed (Mann et al., 2017; Masi, Chen, Hawkley, & Cacioppo, 2011). However, a recently developed psychoeducational intervention — GROUPS 4 HEALTH (G4H) — seeks to address this theory–practice gap by drawing on evidence of the role that people's group-based social identifications play in supporting health (Haslam, Jetten, Cruwys, Dingle, & Haslam, 2018), whilst also providing a novel approach to managing loneliness. In this paper, we report on a randomized controlled trial (RCT) of G4H involving adults presenting with psychological distress in association with loneliness.

Loneliness interventions

Loneliness is essentially unwanted social isolation, and has been characterized as the discrepancy between a person's actual social relationships and those they desire. Its prevalence is high and, some authors argue, is growing (e.g., Cacioppo et al., 2015). In a UK survey one in ten people reported feeling lonely often, and about 42% reported being depressed because they felt alone (Griffin, 2010). Figures from other surveys conducted in the United States and Australia indicate that one in three adults over 45 years of age (Wilson & Moulton, 2010), and 60% of adults in general (Lifeline, 2016), often reported feeling lonely. Loneliness is commonly associated with a range of chronic mental health conditions — including depression, psychosis, and social anxiety — and is reported to be more

prevalent in some populations (e.g., vulnerable older adults). It is also associated with increased risk of mortality and morbidity (see Holt-Lunstad, Smith, & Layton, 2010; Lim, Rodebaugh, Zyphur, & Gleeson, 2016). As these data suggest, loneliness is therefore a major public health issue that is widely understood to warrant both research attention and practical intervention.

To this end, a range of interventions have been developed to reduce loneliness (see Mann et al., 2017; Masi, Chen, Hawkley, & Cacioppo, 2011). These essentially fall into one of three categories. The first and most basic approach targets the development and mastery of social skills, which are thought to be deficient in people who are lonely (e.g., Twentyman & Zimering, 1979). The second approach focuses directly on increasing social contact, interaction, and support. Interestingly, a meta-analysis of loneliness interventions found that these approaches were less effective than those in a third category, which target cognitive biases (Masi et al., 2011). The latter were found to be associated with a moderate effect size ($d=.598$), but were also rather diverse in content, making it difficult to establish the particular cognitive processes responsible for improvement.

Of these approaches, only the third category — those targeting cognitive biases — is derived from a coherent body of theory. Informed by principles of cognitive behaviour theory, social-cognitive interventions attribute the cause of loneliness to cognitive biases (e.g., irrational, self-defeating thoughts) that result from increased vigilance to social threats (Cacioppo, Cacioppo, & Boomsma, 2014; Cacioppo & Hawkley, 2009). Were this sufficient as a target for intervention, then we might expect greater consistency in their effectiveness. Yet, the meta-analysis by Masi and colleagues revealed a wide range in the effect sizes of social-cognitive interventions for loneliness; from -4.81 to 0.12 when all study designs are considered and -0.97 to -0.32 in the more rigorous randomized group comparison studies. This raises the question of whether we can improve these outcomes by targeting another core

feature of loneliness: people's sense of wider connectedness to others in society — to which social group-based belonging is integral. This is the focus of a recent body of research that applies social identity theorizing to a broad range of health challenges.

The Social Identity Approach to Health

Similar to the social-cognitive perspective on loneliness, an understanding that humans are social animals is central to social identity theorising (Tajfel & Turner, 1979; Turner, Hogg, Oakes, Reicher, & Wetherell, 1987). However, this approach differs in its emphasis on the importance of social *groups*, and on people's sense of connectedness, through *social identification*, with those groups. This approach recognizes that the self is comprised not only of those attributes and traits that are unique to an individual (i.e., a person's *personal identity* as “I” or “me”; e.g., a sense of one's unique interests or attributes; Turner, 1982), but also by the social groups to which he or she belongs (i.e., a sense of social identity; e.g., as “us women”, “us Londoners”, or “us cyclists”). Critical here is the idea that the group memberships that form part of our social identities have the power to influence the way we think, feel and act in different situations. So, for example, membership in groups can affect our response to stress and challenge, who we turn to for support, and whether we engage (or do not engage) in particular health behaviours (e.g., smoking, exercise). Group memberships have this impact in part because they are an important psychological resource — providing a framework within which our sense of who we are is constructed. Amongst other things, this means that group memberships provide us with a sense of meaning, purpose and belonging, the means to enhance self-esteem and perceived control, as well as access to social support (see Haslam et al., 2018; Jetten et al., 2012, for reviews).

The Social Identity Approach to Health (SIAH; Haslam et al., 2018) takes this argument a step further to provide an integrated socio-psychological account of the role that group memberships play in the development and management of a broad range of health

conditions and contexts (Haslam, Jetten, Postmes, & Haslam, 2009). This framework is built on two key hypotheses: *the social identity hypothesis*, which proposes that because social identity is the basis for meaningful group life, it is central to good and ill health, and *the identification hypothesis* that a person will generally experience the health-related benefits or costs of a given group membership only to the extent that they identify with that group (see Haslam et al., 2018). From these hypotheses, we predict that it is only when people identify with a given group that it has potential to impact on their health. Amongst other things, this means that the curative potential of groups is out of reach for those who experience loneliness — because their sense of social disconnection precludes them from accessing the range of psychological resources that flow from social group belonging.

The above reasoning provides the basis for a novel approach to managing loneliness — one that is focused on efforts to build and sustain social identities and social identification. This is the purpose of the GROUPS 4 HEALTH (G4H) program — a structured and manualized intervention that seeks to translate insights from the SIAH into practice. G4H has previously been described in a published Phase I pilot study (Haslam et al., 2016; see also Chapter 15 in Haslam et al., 2018) and aims to build people’s social identity capital in the context of an in-vivo group experience. The program raises awareness of the ways that group memberships influence health, whilst at the same time helping people to develop bespoke strategies to harness existing group ties as well as develop new ones to support connectedness (and thereby, health).

The previously reported pilot study, conducted with 83 young adults experiencing social isolation and associated psychological distress, found that those who received the program reported reduced symptoms of depression, anxiety and loneliness relative to a group of 75 matched (but not randomly assigned) controls, with benefits sustained at six-month follow-up. As the social identity approach to health would predict, among those who took

part in G4H, these changes were also associated with an increased sense of connectedness to multiple groups. Yet while these findings were encouraging, greater rigour is clearly required to established G4H's efficacy. This is the primary purpose of the present study, which evaluates G4H by means of a Phase II clinical trial.

The present research

There are numerous interventions to tackle loneliness and considerable variability in their effectiveness (Cacioppo et al., 2015; Masi et al., 2011). By targeting problems of social identification, G4H provides a unique theory-based strategy for addressing the lack of belonging and social disconnection central to loneliness (Haslam et al., 2018). To test this strategy, the primary objective of the present study was to examine the effectiveness of G4H relative to treatment-as-usual (TAU) in a sample of adults presenting with loneliness in association with clinically severe psychological distress or a diagnosed mental illness.

Participants were randomly assigned to receive G4H or TAU. Those in receipt of other mental health treatments were not excluded from the study. While the mental health presentations in the sample were diverse in some cases they were severe, and so we could not ethically dissuade participants from seeking appropriate care elsewhere in addition to their participation in the trial. Our primary hypothesis (H1) was that perceived loneliness would be significantly reduced among G4H recipients, relative to those receiving TAU. This is because loneliness is the explicit focus of the G4H program, but is rarely the primary target of TAU, despite it sometimes being an element of TAU.

Several secondary outcomes measures were also included with the aim of evaluating the efficacy of the G4H intervention more broadly. These included symptoms of social anxiety and depression, which are two mental health presentations commonly associated with loneliness (e.g., Lim, Rodebaugh, Zyphur, & Gleeson, 2016). Additionally, we included measures of multiple group membership, which had been found to be associated with change

in health outcomes in a pilot study of the intervention (Haslam et al., 2016), and self-reported General Practitioner (GP) visits, given evidence of the link between loneliness and frequent use of primary care services, including those offered by GPs (e.g., Cruwys, Wakefield, Sani, Dingle, & Jetten, 2018). Drawing on previous research, we predicted that while G4H and TAU would reduce depression symptoms (H2) and general practitioner visits (H3), G4H would be more effective in reducing social anxiety (H4) and increasing multiple group membership (H5). These latter predictions reflect the fact that the primary focus of G4H is on social factors known to be associated with loneliness — notably, processes involved in actively building and strengthening social group memberships (e.g., identifying groups that are a good fit, compatible, and likely to endure) — that contribute to the social anxiety seen in people who are lonely (Lim et al., 2016).

Method

Study design and power

This study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12617001602314) and used an unblinded RCT design with participants assigned to G4H or to a control condition by computer software. The control condition, as reported in the trial registration, was intended as a wait-list. Participants on this wait-list were offered access to G4H after the completion of the follow-up timepoint. However, as over half the participants in this condition were in receipt of adjunct evidence-based mental health care (most commonly for depression), it was decided that TAU more accurately characterized this condition. Assessments were conducted at baseline and then at two month follow-up.

Power analyses used the pre-post treatment group effect size for the primary outcome (loneliness) found in the Haslam et al. (2016) pilot study of G4H ($d = 0.86$)¹. This suggested

¹ For comparative purposes, the mean effect sizes for loneliness interventions found in the Masi et al. (2011) meta-analysis were lower: $d = -0.367$ (range = -4.81 to 0.12) for single group pre-post designs, $d = -0.459$ (range = -1.88 to 0.11) for non-randomised group

that a minimum of 23 participants would need to be retained in each condition at follow-up for 80% power (Lehr, 1992). This figure was doubled to account for expected change in the TAU condition ($n = 46$), and increased further to 65 per condition to allow for attrition (based on an expected retention rate of 67% in the G4H pilot study; Haslam et al., 2016). This figure ($n = 65$ in the G4H condition) also functioned as a stopping criterion for recruitment to the intervention.

Participants

Participants were recruited from both the community as well as university health services through self and clinician referrals between April 2015 and February 2017. All were invited to complete a screening questionnaire if they were subjectively experiencing social isolation, and were eligible if either (a) diagnosed with a mental illness by a health professional or (b) reported symptoms that met the criteria for clinical depression (i.e., ≥ 5 on the Patient Health Questionnaire-9, PHQ-9). Despite the latter being lower than the Manea et al. (2012) criteria for diagnosis of major depressive disorder (i.e., a score falling between 8-11 on the PHQ-9), in the present research we were interested in recruiting people with clinically impairing levels of depression, and this includes those with at least mild depression. No-one was excluded on the basis of comorbid conditions that are common in mental illness (e.g., anxiety, autism spectrum disorders), or in receipt of alternative treatment. Those presenting with moderate to severe mental illness symptoms were informed about, and encouraged to seek, adjunct treatment while completing the trial, if they were not doing so already. Assessment of eligibility was undertaken for 199 people. Of these, 79 people did not meet inclusion criteria, declined or were unable to participate, did not complete screening/baseline measures, or could not be contacted after completing screening and

comparisons, and $d = -0.198$ (range = -0.79 to 0.40) for randomised group comparisons. This is likely a reflection of the wide variation in the context of these interventions, many of which did not have a significant effect on outcomes.

baseline measures (see Figure 1). A range of reasons were provided by those who declined to participate ($n = 24$) and these included being unsure the program was for them, wanting to check with their psychologist/psychiatrist, wanting individual therapy, or finding the location of the clinic where the program was offered too far from home.

Table 1 provides descriptive statistics for the final randomized sample at baseline ($N=120$). The mean age of participants was 31.06 years ($SD = 12.80$) and the majority in each condition were female (64%), Australian (69%), and Caucasian (74%). Among these participants, 59% had a formal mental health diagnosis, and 59% were receiving some form of adjunct mental health treatment (pharmacological and/or psychological)².

Intervention

Groups 4 Health (G4H). This social identity theory-derived intervention focuses on the building and maintenance of positive social group identifications, as a theoretical agent of change in enhancing health and well-being. It targets specific social identity processes of multiple group membership, group identification, group maintenance, group gain, and group compatibility. All of these factors have been shown to protect health and well-being, particularly under conditions of challenge and vulnerability — whether this be due to illness, trauma, social disadvantage, diagnosis, or life change (Drury, Cocking & Reicher, 2009; Haslam et al., 2008; Iyer, Jetten, Tsivrikos, Postmes, & Haslam, 2009; Muldoon & Downes, 2007; Walter, Jetten, Dingle, Parsell, & Johnstone, 2015). In doing so, the G4H program offers an in-vivo group experience where participants learn about tackling social disconnection with others who face similar challenges. By drawing on each other's

² We do not report baseline differences between G4H and TAU in Table 1, given this is not recommended for RCT trials. Previous authors have argued that this is inappropriate because any such differences should be a chance occurrence (Pocock, McMurray & Collier, 2015). In fact, the only difference that was found, after Bonferroni correction for use of multiple tests, was on the demographic variable education, $\chi(4) = 18.85, p = .001$; with those allocated to G4H having a slightly lower level of education at baseline than those in TAU. In line with Pocock and colleagues' argument that this is likely to be a chance result, no further analysis was conducted.

knowledge and resources, the group's membership as a collective is as much a part of the intervention as the content of the program itself.

The five-module program is manualized (Haslam et al., 2015a) and comes with an associated workbook (Haslam et al., 2015b) that supports participants through various program activities and exercises. G4H has been described in a number of previous publications (Haslam, 2018; Haslam et al., 2016, 2018), so here we only summarize its aims and content. Module 1, *Schooling*, is psychoeducational and aims to raise people's awareness of the social groups in their lives and the role they play in health. In this, education is targeted not only at helping people harness those groups that enhance health, but also at increasing recognition of those group ties that can undermine and harm health. Module 2, *Scoping*, uses a Social Identity Mapping tool (Cruwys, Steffens, Haslam, Haslam, Jetten, & Dingle, 2016; Bentley et al., 2019) to help people create a visual illustration of their social group world. This is used as a basis for reflecting on the different groups in their life and how they relate to those groups. It also provides a basis from which to build and enhance group networks in the next two sessions. In Module 3, *Sourcing*, activities focus on maximising a person's existing group relationships where they are positive, which involves brainstorming ways to reconnect with existing groups, recognizing and overcoming barriers to strengthening those bonds, and managing the give and take in relationships in order to help them endure. Module 4, *Scaffolding* uses the G4H group (which is a new group for all participants) as a platform from which participants can build on their existing relationships, where needed, to join new groups. As part of this module, people learn how to extend their group memberships in ways that are more likely to be compatible with their existing social identity network and they develop a social plan that they are encouraged to trial to achieve this. These first four sessions take place weekly, and each lasts between 60 to 90 minutes. The final module, *Sustaining*, takes place one month later to provide time and opportunities for people to trial their social

plans and focuses on them reporting back on their experiences of doing so. This fifth module is built upon both celebrating successes but also troubleshooting challenges, and also involves people revisiting their social identity map in order to reflect on ways this might have changed as a result of taking part in the program.

In the present study, the program was administered in groups comprising between five and nine participants and facilitated by two provisionally registered psychologists completing supervised graduate training in the psychology clinic of the researchers' university. Facilitators were trained in program delivery and received weekly group supervision, which, in addition to the use of a manualized program, contributed to treatment fidelity. This training included detailed discussion of the program background, content, and materials required for each session, as well as process issues involved in running a group program. Facilitators were asked to complete a checklist at the end of each session to determine compliance to the protocol.

Measures

These comprised scales to screen for psychological distress and mental health diagnosis prior to randomization, demographic information collected prior to study commencement, and primary and secondary outcome measures collected before, at completion and two months following G4H for those assigned to this intervention or during the same time period for those assigned to TAU.

Demographics and screening. Participants were asked to indicate their gender, years of education, nationality, ethnicity, and current adjunct psychopharmacological and psychological treatment for mental health concerns (e.g., use of prescription medication, medical or psychological treatment). For the purposes of screening, participants were asked to complete the following measure of depression that differed from the outcome measure, and also to indicate if they had any mental health diagnoses.

Patient Health Questionnaire-9. (PHQ-9; Kroenke, Spitzer, & Williams, 2001). This comprised 9 items (e.g., feeling down, depressed, or hopeless), with participants asked to rate how frequently they had experienced symptoms in the last 2 weeks on a 4-point scale (0 = Not at all to 3 = Nearly every day; $\alpha = 0.85$). The measure has excellent validity, with the test discriminating well between those with and without major depressive disorder (Kroenke et al., 2001). It also has good internal reliability ($\alpha = .86$ and $.89$ in obstetric and primary care settings; Blackwell & McDermott, 2014) and test-retest reliability ($r = 0.84$ over 48 hours; Kroenke et al., 2001). At baseline, the mean PHQ-9 score of participants was 12.85 ($SD = 6.08$); falling in the moderate depression range.

Mental Health Diagnosis. Participants were asked if they had been diagnosed with a mental illness by a health professional, and if so, to indicate their diagnosis and the profession of the person who provided the diagnosis (e.g., GP, psychiatrist).

Primary outcome.

Loneliness. This was assessed using the *Roberts UCLA Loneliness Scale (RULS-8)* which has good construct validity, sound internal consistency ($\alpha = .78$ in adolescents), and moderate test-re-test reliability ($r=0.48$ in non-clinical samples) (Goosens, Klimstra, Luyckx, Vanhalst, & Teppers, 2014; Roberts, Lewinsohn, & Seeley, 1993). The eight items in this scale (e.g., How often do you feel.... : isolated from others? part of a group of friends?) were rated on a 4-point scale ($\alpha=0.70$ for the present study; 1 = Never, 4 = Always). Items were summed to yield a scale with scores ranging from 8-32, with higher values indicating greater perceived loneliness.

Secondary outcomes.

Depression. Participants completed the seven-item depression subscale of the *Depression, Anxiety, and Stress Scale-21 (DASS-21; Lovibond & Lovibond, 1995)*. The depression subscale has excellent internal consistency (e.g., $\alpha = .94$) and concurrent validity

(correlating positively and highly with other measures of depression e.g., the Beck Depression Inventory) in clinical samples (Antony, Bieling, Cox, Enns, & Swinson, 1998; Crawford & Henry, 2003). Participants rated how frequently in the preceding week they had experienced depression symptoms (e.g., I felt down-hearted and blue) on a 4-point scale (0 = Did not apply to me at all, to 3 = Applied to me very much, or most of the time; $\alpha = 0.90$). In line with recommendations for scoring, responses were summed and multiplied by two. At baseline, mean scores were in the “extremely severe” clinical range ($M = 20.32$, $SD = 9.69$). While this differs from the PHQ-9 at screening, this could be explained by the DASS-21 being recorded subsequently in which presentation of symptoms were targeted in the previous week (as opposed to two weeks).

General Practitioner (GP) visits. This was measured with a single item: “How many times have you been to see a general practitioner (medical doctor) in the last month” (as used in Vedsted & Christensen, 2005). At baseline, participants reported seeing a GP on average 1.12 times in the last month ($SD = 1.41$, range = 0-6).

Social anxiety. This was assessed with the short version of the Social Phobia Inventory (mini-SPIN; Connor, Kobak, Churchill, Katzelnick, & Davidson, 2001), comprising three items (e.g., “Being embarrassed or looking stupid are among my worst fears”; $\alpha = 0.83$). The mini-SPIN discriminates well between those with and without social anxiety disorder, and has strong internal consistency ($\alpha = .90$) and test-retest reliability ($r = .82$; Fogliati et al., 2016). Each item is rated on a 5-point scale (1 = not at all, 5 = extremely), with higher scores indicating greater social anxiety.

Multiple group memberships. People’s sense of belonging to multiple groups was assessed using a standard 4-item multiple group membership scale (Haslam et al., 2008; e.g., “I have strong ties with lots of different groups”) which has good internal consistency ($\alpha = .78 - .93$, see Haslam et al., 2018), but no reported test-retest reliability. Each item was rated

on a 5-point scale (1 = do not agree at all, 5 = agree completely; $\alpha = 0.87$) with higher scores indicating stronger connectedness with multiple groups. The baseline mean of 1.79 ($SD = 0.85$) in this sample was lower than that reported in other vulnerable populations (e.g., homelessness; Jetten et al., 2015).

Program adherence. At the end of each session, facilitators were asked to rate the extent to which they covered key issues and activities in each session. The number of elements ranged between 6 to 10 across sessions, with some repeated items (e.g., establishing session goals, reviewing homework/reflection) and others unique to specific sessions (e.g., positive features of social identity maps, development of social plans). Ratings for each item ranged from 1 to 7 (1 = not done, 7 = extensively covered). To reduce the likelihood of facilitators giving socially desirable responses, these ratings were completed anonymously and facilitators were encouraged to be honest in their responses and told that their feedback was being used to assess the program content.

Procedure

Ethical approval for the study was granted by the researchers' university. Recruitment notices were distributed via letters and flyers to community and university service providers (e.g. General Practitioners, psychologists, counsellors, psychology interns, and other health professionals) and their clinics. These notices offered free participation in a 5 X 1.5-hour group program suitable for people experiencing social isolation and disconnection. Participants were randomized to receive either G4H or TAU by one research assistant using a computer-generated random number sequence. Allocated numbers were not held equal between conditions, but were fully random, resulting in slightly more participants being allocated to G4H. The TAU participants were offered the G4H intervention after completing the follow-up measures.

As shown in the CONSORT diagram (see Figure 1), 199 participants were assessed

for eligibility and 141 completed the screening measures to determine eligibility. Those eligible, once condition allocation had been made, were contacted by the research assistant team, and were informed about the timeframe to receive the intervention — either less than 2 weeks for those in the G4H condition, or a minimum of four months for those wishing to receive the intervention but allocated to TAU.

G4H was delivered in the Psychology Clinic of the researchers' university. The first group commenced in May 2015 and the final group in February 2017, after the projected number of participants ($N = 65$) had been allocated to the intervention. Participants completed baseline measures at the time of allocation, and follow-up measures were taken approximately four months after baseline. All data collection was completed in June 2017. For participants receiving G4H, the intervention occurred over a period of eight weeks, and the follow-up measures were completed about two months after the program ended. Our priority was to collect follow-up data from all participants who consented, and so flexibility in the timing was allowed to include participants who were travelling, moving overseas, or completing university exams. As a result, the follow-up period ranged between 55 days to 204 days and most participants completed these measures online. The average time between baseline and follow-up was 119 days ($SD = 29.46$) in TAU and 128 days ($SD = 31.16$) in G4H, with no significant difference between conditions, $t(76) = -1.35, p = .182$.

An additional timepoint was available for 56 participants, taken immediately following completion of the program in the G4H condition ($n = 37; M = 77$ days from baseline; $SD = 15.30$) and immediately prior to commencing G4H for those in the TAU condition who took up the option of receiving G4H after a waitlist period ($n = 19; M = 183$ days from baseline; $SD = 20.45$). These supplementary data were included in follow-up analyses reported below that replaced the *time* predictor with an indicator of *days since baseline* and include all available measurements.

Analysis strategy

Mixed-effects repeated-measures analyses were conducted to test the primary hypotheses (Donohue & Ainsen, 2012; Mallinckrodt, Clark & David, 2001; Molenberghs et al., 2004). This approach honours the intention-to-treat principle by including (i) baseline data for all randomized participants ($N = 120$), (ii) follow-up data for those allocated to G4H who did not complete the intervention, and (iii) those in both conditions who did not have follow-up data ($n = 38$). The mixed-effects model included time, condition and their interaction as fixed effects, with participant and group as random effects. Data were analysed in R using the *lmer* and *emmeans* packages (Bates et al., 2014; Lenth, et al., 2019).

A number of follow-up analyses were also conducted. First, we conducted a mixed-effects analysis that excluded participants whose adjunct treatment status changed ($n = 15$) and investigated the moderating effect of adjunct treatment, focusing on pharmacological treatment which was slightly higher in the G4H group at baseline. Second, a multivariate analysis of covariance (MANCOVA) was conducted that assessed the five outcome measures in the same model, with baseline measures of each variable included as covariates. A final mixed-effects analysis that replaced the predictor of *time* with the continuous predictor *days since baseline* was also conducted. This analysis allowed all available data to be included in the analysis (up to three timepoints per participant). Within-subjects effect sizes were calculated as recommended by Masi and colleagues (2011), with the pre-post difference in each condition divided by the pooled standard deviation. Clinically significant change was calculated as the proportion of participants in each condition who experienced reliable improvement using the reliable change index (RCI; as recommended by Jacobson & Truax, 1991).

Results

Intervention characteristics

As indicated in Figure 1, of the 120 participants allocated to a condition, 36% of G4H participants were lost to follow-up; more than a third of these were lost due to the protocol requirement of attending a minimum of 3/5 sessions. This largely accounts for the difference in attrition between this condition and TAU, which was 24%.

The mean adherence ratings on session content (from 1-7) were 5.4_{Session 1} ($SD=0.58$), 5.1_{Session 2} ($SD=1.08$), 5.3_{Session 3} ($SD=0.89$), 5.2_{Session 4} ($SD=1.22$), and 5.9_{Session 5} ($SD=0.67$). These indicate that facilitators were typically able to engage in “considerable discussion” of the key elements of each session, thereby providing evidence of good adherence to program content.

Primary analysis

The primary findings are summarized in Table 2. Figures 2 to 6 show the estimated marginal means and SEs from the output of these analyses.

Loneliness. Both the main effect of time, $\beta = -.35, p < .028$, and the time \times condition interaction were significant, $\beta = -.74, p < .001$. The interaction is shown in Figure 2, with further analysis indicating that loneliness decreased significantly in G4H, $t(97.0) = 7.27, p < .001$, but not in TAU, $t(90.8) = 2.23, p = .098$. This decline was an average of 3.83 points ($SE = 0.53, d = -1.16$) in G4H vs. 1.23 points ($SE = 0.55, d = -0.36$) in TAU. Reliable improvement was observed in 35.7% of the G4H group and 12.5% of the TAU group.

Depression. The main effect of time was significant, $\beta = .39, p = .009$, but the time \times condition interaction was not, $\beta = -.33, p = .108$ (see Figure 3). Depression symptoms decreased significantly in the G4H condition, $t(96.8) = -5.10, p < .001$, and also in the TAU condition, $t(91.7) = -2.65, p = .035$. This corresponded to an average decrease of 7.29 points in the G4H condition ($SE = 1.43; d = -0.67$) and an average of 3.94 points in the TAU condition ($SE = 1.49, d = -0.35$). Reliable improvement was observed in 45.2% of the G4H group and 25% of the TAU group.

GP visits. As illustrated in Figure 4, The main effect of time was not significant, $\beta = .36, p = .053$, but the time X condition interaction was, $\beta = -.75, p = .004$. This interaction reflected a non-significant decrease in GP visits in the G4H condition, $t(98.8) = -2.23, p = .098$, and a non-significant increase in GP visits in the TAU condition, $t(91.3) = 1.96, p = .172$, GP visits decreased an average by 0.53 visits per month in the G4H condition ($SE = 0.24, d = -0.21$), and increased by an average of 0.49 visits per month in the TAU condition ($SE = 0.25, d = 0.42$). A reliable reduction was observed in 19% of the G4H group and 5% of the TAU group.

Social anxiety. The main effect of time was non-significant, $\beta = .03, p = .803$, but the time X condition interaction was, $\beta = -.53, p = .003$. This effect is shown in Figure 5, with further analysis indicating that social anxiety decreased significantly for those in receipt of G4H, $t(85.9) = -4.22, p < .001$, but not in the TAU condition, $t(83) = .25, p = .993$. This corresponded to an average decrease of 0.50 points in the G4H condition ($SE = .12, d = -0.53$) and a non-significant increase of 0.03 points in the TAU condition ($SE = .12, d = .03$). Reliable improvement was observed in 21.4% of the G4H group and 5% of the TAU group.

Multiple group memberships. Both the main effect of time, $\beta = .37, p < .010$, and the time X condition interaction were significant, $\beta = .52, p = .009$ (see Figure 6). Further analysis showed that group memberships increased significantly in G4H, $t(95.8) = 6.57, p < .001$, and also increased significantly in TAU, $t(91.1) = 2.64, p = .036$. This corresponded to an average increase of 0.56 points in the G4H condition ($SE = .14, d = 0.96$), and of 0.32 points in the TAU condition ($SE = .14, d = 0.44$). Reliable improvement was observed in 47.6% of the G4H group and 32.5% of the TAU group.

Follow-up analyses

Stability of adjunct treatment. Almost 60% of participants were in receipt of some form of adjunct treatment (psychopharmacological or psychological) at baseline, with no

significant differences between conditions, $t(116) = .92, p = .362$. Overall, only 13% of participants (15 people) reported some change in adjunct treatment across the course of the trial, with the remaining 87% indicating no change in their receipt (or not) of adjunct treatment for mental health concerns. Of these 15, five ceased adjunct treatment (two in the G4H condition) and 10 commenced adjunct treatment (six in the G4H condition). There was no significant difference between conditions in the likelihood of changing adjunct treatment status, $t(118) = -.43, p = .669$.

Adjunct psychopharmacological treatment. Although participants were randomly allocated to condition, there was a slightly higher proportion of participants in the G4H condition who were in receipt of psychopharmacological treatment at baseline. The difference between G4H and TAU in use of such treatment at baseline was significant without Bonferroni correction for multiple comparisons, $t(118) = 2.24, p = .026, d = .43$, but non-significant when such correction was applied (revised significance criterion of $p < .004$). Furthermore, as described above, 15 participants reported some change in their adjunct treatment status over the course of the trial.

To investigate this further, a post-hoc mixed-effects analysis was conducted, in which these 15 participants were excluded and psychopharmacological treatment status was added as a moderator (0 = No; 1 = Yes). These analyses revealed only two significant effects of adjunct treatment status. First, there was a main effect of treatment status on loneliness, with those in receipt of psychopharmacology reporting higher levels of loneliness across timepoints, $\beta = .60, p = .039$. Second, there was a three-way interaction between treatment status, time, and condition on depression ($p = .024$, see Figure 7). This indicated that participants in receipt of psychopharmacology tended to have more severe depression symptoms at baseline and to show moderate improvement in depression symptoms over time, regardless of whether they were in the TAU or G4H condition, $t(132.97) = 0.63, p = .997$.

However, participants not in receipt of psychopharmacology tended to have lower depression scores at baseline (albeit still in the ‘moderate’ clinical range), and those in the G4H condition showed greater improvement than those in the TAU condition, $t(79.31) = 4.83$, $p < .001$.

Multivariate analysis of covariance (MANCOVA). A more traditional approach to analysing clinical trial data uses MANCOVA, an analysis which allows for examination of interrelationships among all outcome variables; five in this case. In order to mirror our mixed-effects intention-to-treat analyses as closely as possible, we specified a MANCOVA model that included the five outcome measures at follow-up as dependent variables, with baseline measures of each included as covariates. Condition was the between-subjects independent variable. Multiple imputation was used to handle missing data at follow-up, with five imputations conducted using the monotone method in SPSS v.25, estimated using the five outcome variables at both timepoints as well as treatment condition, adjunct treatment status, and the number of days from baseline to follow-up (Havati Rezvan, Lee, & Simpson, 2015). The results of this analysis are reported in Table 3. Overall, the findings were similar to those of the mixed-effects model, with G4H leading to significant reductions in loneliness and social anxiety relative to TAU. G4H also predicted a significant increase in multiple group memberships relative to TAU. However, the results for depression and GP visits were not significant.

Number of days from baseline to follow-up. Finally, a follow-up analysis was conducted in which the predictor variable of timepoint (0=baseline; 1 = follow-up) was replaced in the model with a continuous measure of the number of days since baseline. This allowed all the available data to be analysed for those participants who completed additional measures (typically between baseline and follow-up in the G4H condition, and after follow-up in the TAU condition). The results of this analysis are presented in Table 4. To

summarize, the focal effects (i.e., interaction of “days since baseline” and condition) were significant, and had the same pattern of means, for loneliness, social anxiety, GP visits, and multiple group memberships as in the primary analysis.

Discussion

This RCT examined the efficacy of a novel group intervention targeting social group connectedness, GROUPS 4 HEALTH (G4H), relative to treatment-as-usual (TAU). Confirming the efficacy of G4H, findings from our analysis largely supported predictions. Specifically, there was evidence that compared to TAU, G4H was associated with a greater reduction in symptoms of loneliness (H1) and social anxiety (H4). Evidence of a significant interaction in GP service use provided partial support for H3, and showed that G4H was better than TAU in reducing visits. Also as predicted, we found evidence of a decline in depressive symptoms in both conditions (supporting H2), indicating that G4H and TAU were equally effective on this outcome. Post-hoc follow-up analyses exploring the contribution of adjunct psychopharmacological treatment showed that G4H was significantly better than TAU in reducing depression among those who were not taking medication. Finally, partial support was found for H5 in which we predicted that increased strength of belonging would be specific to G4H. Here we found evidence of a significant increase in multiple group membership in both G4H and TAU.

As this summary indicates, the present results provide full support for predictions regarding the efficacy of G4H over TAU in reducing perceived loneliness. These findings extend those reported in a previous pilot study (Haslam et al., 2016), and further demonstrate the value of targeting positive group identification as a strategy for reducing loneliness. The moderate-to-large effect sizes associated with G4H in the present study also compare favourably with those from Masi et al.’s (2011) meta-analysis which found a small overall effect size for randomized group comparison studies (i.e., $d = 0.198$), but a moderate effect

size of $d = 0.598$ for social-cognitive interventions within this category of study design. Moreover, the G4H program also had a significant effect in reducing social anxiety, which previous research has shown to be not only co-morbid with loneliness (Teo, Lerrigo, & Rogers, 2013), but also to predict the development of loneliness better than depression (Lim et al., 2016). Indeed, based on the latter findings, Lim and colleagues (2016) conclude that failure to manage symptoms of social anxiety alongside loneliness is likely to result in suboptimal outcomes. As G4H had a positive effect on both these symptoms, it offers a substantive advance on existing approaches.

Our follow-up analyses, albeit post-hoc, revealed a main effect of adjunct psychopharmacological treatment on loneliness and a three-way interaction between time, condition, and medication use on depression. The former indicated that those in receipt of any form of adjunct psychopharmacological treatment reported greater perceived loneliness, and this was evident in both G4H and TAU. This, in and of itself, is not surprising as social disconnection and associated loneliness is common in a range of health conditions and contexts (Haslam et al., 2018). What was more interesting, in terms of potentially differentiating the effects of G4H and TAU, was the three-way interaction on depression. This indicated that among those not in receipt of psychopharmacology, G4H produced a greater reduction in depression symptoms than TAU. These participants tended to have more moderate symptoms and received greater benefit from G4H in management of depression than those in TAU. For those people in receipt of psychopharmacology, symptoms were more severe at baseline (which presumably is why they were prescribed medication), and moderate improvement was observed across conditions making it difficult to tease apart the effects of G4H and TAU.

The evidence in relation to multiple group membership was more mixed, with improvement in both conditions; not just in G4H as predicted. Although it is unlikely that

TAU targets multiple group membership as directly as G4H, it nevertheless treats depression, and, to the extent that reduced group membership is symptomatic of depression (as argued in Cruwys et al., 2014), the improvement associated with TAU on this outcome should not be that surprising. Nevertheless, effect sizes also indicated that the magnitude of the treatment effect associated with G4H was greater than that for TAU ($d = 0.96$, $d = 0.44$, respectively), which suggests that the former should be the treatment of choice where multiple group belonging is the target of intervention. The evidence was also more mixed for GP visits, where the predicted decline was not found in either condition. However, a significant interaction indicated that the trajectories of change differed between conditions, with visits tending to decline among those who received the G4H program, and tending to increase for those receiving TAU. This suggests that participants may have been less likely to utilize health services if their needs were met by the G4H program. This can only be speculation at present, given that GP service use was numerically (but not significantly) higher at baseline for G4H than TAU recipients. Accordingly, there is clearly a need for future research to identify the nature of GP visits (for adjunct treatment monitoring or other reasons) in addition to their number, and to extend the evaluation timeframe to gain a better picture of primary care use.

Effect sizes provide one indication of the clinical significance of treatment effects, and, on this indicator, we found that the magnitude of the effect associated with G4H was consistently greater than TAU (with effect sizes ranging from 0.21 to 1.16 and from 0.03 to 0.44, respectively). Beyond this though, we calculated the RCI for all outcomes and here too, we found that evidence of reliable improvement was greater in response to G4H (with reliable change for 21.4% to 47.6% of G4H vs. 5.0% to 32.5% of TAU participants). Added to evidence of statistical change, these indices provide further support for G4H's capacity to make a meaningful improvement in the lives of people who are experiencing loneliness.

There are also theoretical implications of our findings. The social identity approach, unlike most others applied to health, stresses the value of working with social groups that are already, or have the capacity to become, a part of people's lives, and in so doing, draws effectively on the resources they can provide to protect health. This suggests that *social identity management* of the form that G4H promotes can be helpful not only in overcoming loneliness, as demonstrated here, but also in managing the social disconnection that is common in a range of health conditions and contexts.

Limitations and future research

As in many clinical trials, the present study has its limitations, and several are particularly noteworthy. First, receipt of adjunct treatment was not an exclusion criterion, largely for ethical reasons, and the fact that diverse interventions were offered in TAU was not ideal. While this contributed to the study having an active control, it raises questions about the extent to which the G4H program was exclusively responsible for observed outcomes. Over half the participants were in receipt of evidence-based treatment of a diverse nature; most commonly antidepressant medication or psychological therapy targeting depression. Our analysis of these data was not *a priori* and thus, would benefit from replication. In particular, future studies might use a single adjunct treatment as a control and ensure no adjunct treatment for those in receipt of G4H to differentiate treatment effects more clearly, particularly among those with more severe symptomatology. Alongside medication, the most obvious would be cognitive behaviour therapy, as this has the strongest evidence-base of psychological therapies to date, and elsewhere its principles have been found to be an effective component of loneliness interventions (Masi et al., 2011). An RCT comparing G4H and CBT for depression is currently underway. In this trial we expect that CBT and G4H will be equally effective in reducing symptoms of depression (as in the present study), but that G4H may be more effective in reducing loneliness and associated social anxiety, which is a

key predictor of longer term loneliness (Lim et al., 2016).

Second, while the present paper focused on the effect that G4H had on outcomes, questions remain about mechanisms. Notably, having found that G4H was better than TAU in reducing loneliness and improving depression when G4H was the sole form of treatment (i.e., in the absence of adjunct treatment) how is it that it achieves these outcomes? Theoretically, the social identity approach predicts that one mechanism through which this may occur is the building and strengthening of people's sense of belonging to multiple social groups; something that is explicitly targeted in the G4H program. In line with this reasoning, our published pilot data show that G4H was associated with increased strength of belonging to multiple groups both on program completion and six months later (Haslam et al., 2016). As the present study did not test mechanism, we are not in a position to conclude whether multiple group membership was an agent of change. We are also not in a position to state whether other possible mechanisms were involved — whether derived from the social identity approach to health (in which mechanisms such as self-esteem and perceived control are theorized to enhance outcomes; see Haslam et al., 2018) or cognitive behaviour theory (in which improvement is theorized to occur through the modification of maladaptive cognitions). This would require measurement of these mechanisms over time to capture change processes; something that was not done in this study. Additionally, to be confident about the basis for therapeutic change, there are numerous requirements in addition to showing strong association, including demonstration of the specificity of the mechanism, replicability and dose-response relationships over time (Kazdin, 2007). Accordingly, there is a need for future research to invest in such demonstrations, in order to provide a more precise understanding of the ways in which G4H improves outcomes.

A third factor that warrants attention in future research is program integrity. While the present study captured facilitator responses to program content and consistency, there is

clearly much more that can be done to assess this rigorously. In particular, future studies could audio- and video-tape sessions (with participant permission) to assess therapist competence (not just adherence), as well as the extent to which therapists included activities and approaches that were specific to G4H (vs. similar to those used in psychological TAU). It will also be important to collect data from participants themselves concerning their perceptions of program integrity and expectations of treatment outcome as these can be associated with treatment adherence and thus influence treatment outcomes (e.g., Uebelacker, Weinstock, Battle, Abrantes, & Miller, 2018).

Finally, there are measurement limitations, related to the brevity of some scales used (notably, the RULS and mini-SPIN), the failure to include objective diagnosis, and to the fact that the additional data included in the supplementary days since baseline analysis was collected at different timepoints across conditions. As a consequence, the missing data from the latter were not missing at random, which limits the conclusions that can be drawn from this particular analysis. Missing data at follow-up were handled using a full information likelihood method for the primary analysis, and using multiple imputation in the MANCOVA analysis. Although these strategies went some way towards addressing the bias associated with participants lost to follow-up (Larsen, 2011; Jacobsen, J.C., Glud, C., Wetterslev, J., & Winkel, P, 2017), future trials should prioritise retention. These are recognized challenges in any clinical trial, yet attention to these issues is necessary to gain the comprehensive understanding of treatment effectiveness required for psychological intervention.

Conclusion

“All the lonely people, where do they all belong?”

Eleanor Rigby, Lennon-McCartney

This Beatles song’s poignant riff on the solitary lives of Eleanor Rigby and Father McKenzie speaks to a core question at the heart of loneliness: where and how might people

who are socially and psychologically isolated be helped to feel a sense of belonging? G4H provides a novel answer to this question through a focus on building people's sense of connection with social groups that they perceive to be meaningful and self-relevant, and in ways that serve to build a sense of shared social identity with others. Speaking to the efficacy of this solution, findings of the trial we have presented here provide evidence of G4H's capacity to reduce loneliness, and thereby lessen its damaging mental health consequences.

More work is clearly needed to strengthen this case, notably in the form of research that compares the efficacy of G4H to cognitive behavioural approaches, and large-scale multicentre studies. It would appear that much is to be gained by following this path, not least in helping determine the distinctive contributions that social identification, cognitive biases, and their theoretical underpinnings make to understanding and managing the health and social costs of loneliness. Beyond this too, there are additional benefits of G4H related to the ease with which it can be facilitated, its non-pharmacological nature, its capacity to build connectedness to community, and its transdiagnostic potential. As these benefits and the present findings suggest, G4H has the capacity to be a useful tool in the arsenal of those seeking practical ways of addressing this pressing social issue.

References

- Antony, M. M., Bieling, P. J., Cox, B., J., Enns, M. W., & Swinson, R. P. (1998). Psychometric Properties of the 42-Item and 21-Item Versions of the Depression Anxiety Stress Scales in Clinical Groups and a Community Sample. *Psychological Assessment, 10*, 176-181. doi: 10.1037/1040-3590.10.2.176
- Bates, D., Mächler, M., Bolker, B., & Walker, S. (2015). Fitting Linear Mixed-Effects Models using lme4. *Journal of Statistical Software, 67*(1). doi: 10.18637/jss.v067.i01
- Bentley, S.V., Greenaway, K., Haslam, S. A., Cruwys, T., Steffens, N.K., Haslam, C., & Cull, B. *Online social identity mapping*. Manuscript under review.
- Cacioppo, J. T., Cacioppo, S., & Boomsma, D. I. (2014). Evolutionary mechanisms for loneliness. *Cognition and Emotion, 28*, 3-21. doi: 10.1080/02699931.2013.837379
- Blackwell, & McDermott (2014). Test Review: Patient Health Questionnaire–9 (PHQ-9). *Rehabilitation Counseling Bulletin, 57*, 246–248. doi: 10.1177/0034355213515305
rcb.sagepub.com
- Cacioppo, S., Grippo, A.J., London, S., Goossens, L., & Cacioppo, J. T. (2015). Loneliness: Clinical import and interventions. *Perspectives on Psychological Science, 10*, 238-249. doi:10.1177/1745691615570616.
- Cacioppo, J. T., & Hawkely, L. C. (2009). Perceived social isolation and cognition. *Trends in Cognitive Sciences, 13*, 447-454. doi: 10.1016/j.tics.2009.06.005.
- Cacioppo, J.T., Hawkley, L. C., Crawford, E., Ernst, J.M., Burleson, M.H., Kowalewski, R. B.,.... Bernston, G. G. (2002). Loneliness and health: Potential mechanisms. *Psychosomatic Medicine, 64*, 407-417.
- Cacioppo, J.T., Hughes, M. E., Waite, L. J., Hawkley, L. C., & Thisted, R. A. (2006). Loneliness as a specific risk factor for depressive symptoms: Cross-sectional and

longitudinal analyses. *Psychology and Aging*, 21, 140-151. doi: 10.1037/0882-7974.21.1.140

Cattan, M., White, M., Bond, J., & Learmouth, A. (2005). Preventing social isolation and loneliness among older people: A systematic review of health promotion interventions. *Ageing & Society*, 25,41–67. doi: 10.1017/S0144686X04002594

Connor, K. M., Kobak, K. L., Churchill, L. E., Katzelnick, D., & Davidson, J. R. (2001). Mini-SPIN: A brief screening assessment for generalized social anxiety disorder. *Depression and Anxiety*, 14, 137-140.

Crawford, J. R., & Henry, J. D. (2003). The Depression Anxiety Stress Scales (DASS): Normative data and latent structure in a large non-clinical sample. *British Journal of Clinical Psychology*, 42, 111–131. doi: 10.1348/014466503321903544

Cruwys, T., Steffens, N. K., Haslam, S. A., Haslam, C., Jetten, J., & Dingle, G. A. (2016). Social Identity Mapping: A procedure for visual representation and assessment of subjective multiple group memberships. *British Journal of Social Psychology*, 55, 613-642. doi: 10.1111/bjso.12155

Cruwys, T., Wakefield, J. R. H., Sani, F., Dingle, G. A., & Jetten, J. (2018). Social Isolation Predicts Frequent Attendance in Primary Care. *Annals of Behavioral Medicine*, 52, 817-829. doi: 10.1093/abm/kax054

Donohue, M. C., & Aisen, P. S. (2012). Mixed model of repeated measures versus slope models in Alzheimer's disease clinical trials. *Journal of Nutrition, Health & Aging*, 16, 360–364.

Drury, J., Cocking, C., & Reicher, S. D. (2009). The nature of collective resilience: Survivor reactions to the 2005 London bombings. *International Journal of Mass Emergencies and Disasters*, 27, 66-95.

- Fogliati, V. J., Terides, M. D., Gandy, M., Staples, L. G., Johnston, L., Karin, E....., Dear, B. F. (2016). Psychometric properties of the mini-social phobia inventory (Mini-SPIN) in a large online treatment-seeking sample. *Cognitive Behavior Therapy, 45*, 236-257. doi: 10.1080/16506073.2016.1158206
- Goossens, L., Klimstra, T., Luyckx, K., Vanhalst, J. and Teppers, E., 2014. Reliability and Validity of the Roberts UCLA Loneliness Scale (RULS-8) With Dutch-Speaking Adolescents in Belgium. *Psychologica Belgica, 54*, 5–18. doi: 10.5334/pb.ae
- Griffin, J. (2010). *The Lonely Society?* London, Mental Health Foundation. Retrieved from: https://www.mentalhealth.org.uk/sites/default/files/the_lonely_society_report.pdf
- Haslam, C. (2018). Scaffolding a stronger society. *The Psychologist, 31*, 44-47.
- Haslam, C., Cruwys, T., Haslam, S.A., Bentley, S., Dingle G., & Jetten, J. (2015a). *GROUPS 4 HEALTH Facilitator's Manual* (version 2.0). University of Queensland, Australia: Social Identity and Groups Network.
- Haslam, C., Cruwys, T., Haslam, S.A., Bentley, S., Dingle G., & Jetten, J. (2015b). *GROUPS 4 HEALTH Workbook* (version 2.0). University of Queensland, Australia: Social Identity and Groups Network.
- Haslam, C., Cruwys, T., Haslam, S.A., Dingle, G.A., & Chang, M.X-L. (2016). Groups 4 Health: Evidence that a social-identity intervention that builds and strengthens social group membership improves health. *Journal of Affective Disorders, 194*, 188-195. doi: 10.1016/j.jad.2016.01.010
- Haslam, C., Holme, A., Haslam, S.A., Iyer, A., Jetten, J., & Williams, W.H. (2008). Maintaining group membership: Identity continuity and well-being after stroke *Neuropsychological Rehabilitation, 18*, 671-691. doi: 10.1080/09602010701643449.
- Haslam, C., Jetten, J., Cruwys, T., Dingle, G. A., & Haslam, S. A. (2018). *The new psychology of health: Unlocking the social cure*. London and New York: Routledge.

- Haslam, S. A., Jetten, J., Postmes, T., & Haslam, C. (2009). Social identity, health and well-being: An emerging agenda for applied psychology. *Applied Psychology: An International Review*, *58*, 1-23. doi:10.1111/j.1464-0597.2008.00379.x
- Hayati Rezvan, P., Lee, K. J., & Simpson, J. A. (2015). The rise of multiple imputation: A review of the reporting and implementation of the method in medical research Data collection, quality, and reporting. *BMC Medical Research Methodology*, *15*, 1–14. <http://doi.org/10.1186/s12874-015-0022-1>
- Hawkley, L. C., & Cacioppo, J. T. (2010). Loneliness matters: A theoretical and empirical review of consequences and mechanisms. *Annals of Behavioral Medicine*, *40*, 218-227. doi: 10.1007/s12160-010-9210-8
- Holt-Lunstad, J., Smith, T. B., & Layton, J. B. (2010). Social relationships and mortality risk: A meta-analytic review. *PLoS Medicine*, *7*, e1000316. doi:10.1371/ journal.pmed.1000316
- Iyer, A., Jetten, J., Tsivrikos, D., Postmes, T., & Haslam, S. A. (2009). The more (and the more compatible) the merrier: Multiple group memberships and identity compatibility as predictors of adjustment after life transitions. *British Journal of Social Psychology*, *48*, 707-733. doi: 10.1348/014466608X397628
- Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology*, *59*, 12–19.
- Jakobsen, J. C., Gluud, C., Wetterslev, J., & Winkel, P. (2017). When and how should multiple imputation be used for handling missing data in randomised clinical trials — a practical guide with flowcharts. *BMC Research Methodology*, *17*, 162. doi: 10.1186/s12874-017-0442-1
- Jetten, J., Branscombe, N. R., Haslam, S. A., Haslam, C., Cruwys, T., Jones, J. M., . . . Zhang, A. (2015). Having a lot of a good thing: Multiple important group memberships as

- a source of self-esteem. *PLoS ONE*, 10(6), e0131035. doi: 10.1371/journal.pone.0124609
- Jetten, J., Haslam, C., & Haslam S. A. (Eds.) (2012). *The social cure: Identity, health and well-being*. Hove, UK: Psychology Press.
- Kazdin, A.E. (2007). Mediators and mechanisms of change in psychotherapy research. *Annual Review of Clinical Psychology*, 3, 1-27. doi: 10.1146/annurev.clinpsy.3.022806.091432
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine*, 16, 606-613.
- Kupferberg, A., Bicks, L., & Hasler, G. (2016). Social functioning in major depressive disorder. *Neuroscience and Biobehavioral Reviews*, 69, 313-332. doi: 10.1016/j.neubiorev.2016.07.002
- Larsen, R. (2011). Missing data imputation versus full information maximum likelihood with second-level dependencies. *Structural Equation Modeling*, 18, 649–662. <http://doi.org/10.1080/10705511.2011.607721>
- Lenth, R., Singmann, H., Love, J., Buerkner, P. & Herve, M. (2019). Estimated Marginal Means, aka Least-Squares Means. Version 1.3.2. Retrieved from <https://cran.r-project.org/web/packages/emmeans/emmeans.pdf>
- Lifeline. (2016). *8 out of 10 Australians say loneliness is increasing: New survey* [Press release]. Retrieved from <https://www.lifeline.org.au/about-lifeline/media-centre/media-releases/2016-articles/8-out-of-10-australians-say-loneliness-is-increasing>.
- Lim, M. H., Rodebaugh, T. L., Zyphur, M. J., & Gleeson, J. F.M. (2016). Loneliness over time: The crucial role of anxiety. *Journal of Abnormal Psychology*, 125, 620-630. doi: 10.1037/abn0000162
- Mallinckrodt, C. H., Clark, W. S., & David, S. R. (2001). Accounting for dropout bias using mixed-effects models. *Journal of Biopharmaceutical Statistics*, 11, 9–21. doi: 10.1081/BIP-100104194

- Manea, L., Gilbody, S., & McMillan, D. (2012). Optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9): a meta-analysis. *Canadian Medical Association Journal*, *21*, 184, E191-196. doi:10.1503/cmaj.110829
- Mann, F., Bone, J. F., Lloyd-Evans, B., Frerichs, J., Pinfold, V., Ma, R., Wang, J., & Johnson, S. (2017). A life less lonely: The state of the art in interventions to reduce loneliness in people with mental health problems. *Social Psychiatry and Psychiatric Epidemiology*, *52*, 627-638. doi: 10.1007/s00127-017-1392-y
- Masi, C. M., Chen, H-Y., Hawkely, L. C., & Cacioppo, J. T. (2011). A meta-analysis of interventions to reduce loneliness. *Personality and Social Psychology Review*, *15*, 219-66. doi:10.1177/1088868310377394
- McCorkle, B. H, Dunn, E. C, Yu Mui, W., & Gagne, C. (2009). Compeer friends: a qualitative study of a volunteer friendship programme for people with serious mental illness. *International Journal of Social Psychiatry*, *55*, 291–305. doi: 10.1177/0020764008097090.
- Molenberghs, G., Thijs, H., Jansen, I. V. Y., Beunckens, C., Mallinckrodt, C., & Carroll, R. J. (2004). Analyzing incomplete longitudinal clinical trial data. *Biostatistics*, *5*(3), 445–464. Doi: 10.1093/biostatistics/kxh001
- Muldoon, O. T., & Downes, C. (2007). Social identification and post-traumatic stress symptoms in post-conflict Northern Ireland. *The British Journal of Psychiatry*, *191*, 146-149. doi: 10.1192/bjp.bp.106.022038
- Nolen-Hoeksema, S., & Ahrens, C. (2002). Age differences and similarities in the correlates of depressive symptoms. *Psychology and Aging*, *17*, 116–124.
- Pocock, S. J., McMurray, J. J.V., Collier, T. J. (2015). Making sense of statistics in clinical trial reports: Part 1 of a 4-part series on statistics for clinical trials. *Journal of the American College of Cardiology*, *66*, 2536-2549. Doi: 10.1016/j.jacc.2015.10.014

- Roberts, R. E., Lewinsohn, P. M., & Seeley, J. R. (1993). A brief measure of loneliness suitable for use with adolescents. *Psychological Reports, 72*, 1379-1391. doi: 10.2466/pr0.1993.72.3c.1379
- Tajfel, H., & Turner, J. C. (1979). An integrative theory of intergroup conflict. In W. G. Austin & S. Worchel (Eds.), *The social psychology of intergroup relations* (pp. 33-47). Monterey, CA: Brooks/Cole.
- Teo, A. R., Lerrigo, R., & Rogers, M. A. (2013). The role of social isolation in social anxiety disorder: A systematic review and meta analysis. *Journal of Anxiety Disorders, 27*, 353–364. doi: 10.1016/j.janxdis.2013.03.010
- Turner, J. C. (1982). Towards a redefinition of the social group. In H. Tajfel (Ed.), *Social Identity and Intergroup Relations* (pp.15-40). Cambridge: Cambridge University Press.
- Turner, J. C., Hogg, M. A., Oakes, P. J., Reicher, S. D., & Wetherell, M. S. (1987). *Rediscovering the social group: A self-categorization theory*. Oxford, UK: Blackwell.
- Twentyman, C. T., & Zimering, R. T. (1979). Behavioral training of social skills: A critical review. *Progress in Behavior Modification, 7*, 319-400. doi:10.1016/B978-0-12-535607.50012-8
- Uebelacker, L. A., Weinstock, L. M., Battle, C. L., Abrantes, A. M., & Miller, I. W. (2018). Treatment credibility, expectancy and preference: Prediction of treatment engagement and outcome in a randomized clinical trial of hatha yoga vs. health education as adjunct treatments for depression. *Journal of Affective Disorders, 238*, 111-117. doi: 10.1016/j.jad.2018.05.009
- Vedsted, P., & Christensen, M. B. (2005). Frequent attenders in general practice care: A literature review with special reference to methodological considerations. *Public Health, 119*, 118–137. doi: 10.1016/j.puhe.2004.03.007

Walter, Z. C., Jetten, J., Dingle, G. A., Parsell, C., & Johnstone, M. (2015). Two pathways through adversity: Predicting well-being and housing outcomes among homeless service users. *British Journal of Social Psychology, 55*, 357-374. doi: 10.1111/bjso.12127

Wilson, C., & Moulton, B. (2010). *Loneliness among older adults: A national survey of Adults 45+*. Prepared by Knowledge Networks and Insight Policy Research. Washington, DC: AARP.

Table 1

Descriptive statistics at baseline in each condition

	Treatment as Usual (TAU) Condition <i>N</i> = 54			Groups 4 Health (G4H) Condition <i>N</i> = 66		
Gender	66.7% female 33.3% male			62.1% female 37.9% male		
Education	0% Year 10 or less 35.2% High school certificate 3.7% Certificate or diploma 50.0% Bachelor degree 11.1% Postgraduate degree			4.5% Year 10 or less 34.8% High school certificate 21.2% Certificate or diploma 19.7% Bachelor degree 19.7% Postgraduate degree		
Nationality	69.2% Australia 9.6% China 5.8% Dual including Aus 15.4% others			68.8% Australia 3.1% China 6.3% Dual including Aus 21.9% others		
Ethnicity	71.2% Caucasian 17.3% Asian 11.5% others			76.6% Caucasian 17.2% Asian 6.13 others		
Diagnosis ^a	38.3% None 42.6% Major Depression 35.2% Anxiety Disorder (GAD, Panic, SAD, or unspecified) 9.3% PTSD 11.1% others			43.1% None 40.9% Major Depression 39.4% Anxiety Disorder (GAD, Panic, SAD, or unspecified) 6.1% PTSD 13.6% others		
Receiving adjunct psychopharmacological treatment	Yes 31.5% No 68.5%			Yes 51.5% No 48.5%		
Receiving adjunct psychological treatment	Yes 45.3% No 54.7%			Yes 45.5% No 54.5%		
	<i>M</i>	<i>SD</i>	Range	<i>M</i>	<i>SD</i>	Range
Age	30.00	11.64	18-69	31.91	13.69	17-68
<i>Primary outcome:</i>						
Loneliness	25.00	2.78	16-31	25.13	3.11	10-30
<i>Secondary outcomes:</i>						
Depression	19.70	9.40	0-40	20.82	9.96	2-40
Social anxiety	3.53	1.05	1.00-5.00	3.39	1.11	1.00-5.00
General Practitioner visits	0.78	0.97	0-4	1.41	1.65	0-6
Multiple group memberships	1.84	0.84	1.00-3.75	1.75	0.86	1.00-4.00

Note. *N* = 120.

- a. Note that many participants had multiple diagnoses and so these percentages do not sum to 100%.
SAD = Social anxiety disorder; GAD = Generalized Anxiety Disorder; PTSD = Post traumatic stress disorder.

Table 2

Mixed effects models

	<i>Predictor</i>	β	<i>SE</i>	<i>df</i>	<i>p</i>	<i>Intraclass correlation coefficient (Level 2 - participant)</i>	<i>Intraclass correlation coefficient (Level 3 - Group)</i>
Loneliness						.253	.054
	Time	-.350	.157	90.76	.028*		
	Condition	.140	.189	40.75	.459		
	Time * Condition	-.743	.218	93.58	<.001*		
Depression						.369	.084
	Time	-.393	.148	91.67	.009*		
	Condition	.061	.204	54.46	.762		
	Time * Condition	-.334	.206	93.98	.108		
Social anxiety						.663	.034
	Time	.030	.151	83.03	.803		
	Condition	-.164	.198	36.33	.413		
	Time * Condition	-.525	.169	84.34	.003*		
General Practitioner visits						.145	.081
	Time	.362	.184	91.34	.053		
	Condition	.432	.207	70.35	.041*		
	Time * Condition	-.752	.255	94.75	.004*		
Multiple group membership						.415	.056
	Time	.375	.142	91.12	.010*		
	Condition	-.090	.195	47.41	.647		
	Time * Condition	.523	.197	93.25	.009*		

Note. This table presents the outcome of three-level mixed effects models in which Level 1 (time) was a fixed effect, Level 2 (participant) was a random intercept and Level 3 (therapy group) was a random intercept. TAU participants were categorized as being in the same group for the purposes of this analysis. The full sample (N=120) was used, to honor the Intention-to-Treat Principle.

Table 3
Multivariate analysis of covariance

	F (1,113)	<i>p</i>	Partial η^2	Estimated marginal means at follow-up			
				G4H		TAU	
				<i>M</i>	<i>SE</i>	<i>M</i>	<i>SE</i>
Loneliness	23.68	<.001*	.18	20.40	.42	23.51	.47
Depression	1.40	.238	.01	17.66	1.19	19.80	.1.33
Social anxiety	20.36	<.001*	.15	3.02	.08	3.57	.09
General Practitioner visits	.101	.752	.00	2.19	.27	2.32	.31
Multiple group memberships	10.07	.002*	.08	2.65	.10	2.17	.11

Note. $N = 119$. Baseline measures of all five outcome variables were included as covariates, and missing data at follow-up was imputed using multiple imputation, with pooled estimates reported here. The omnibus effect of condition was significant, $F(5,108)=8.04$, $p < .001$. A per-protocol MANCOVA that analysed only completers ($N=82$) found comparable results with significant omnibus and condition effects for loneliness, social anxiety, and multiple group memberships.

Table 4

Mixed effects model with a continuous measure of timepoint (days since baseline)

<i>Predictor</i>	β	<i>SE</i>	<i>df</i>	<i>p</i>	<i>Intraclass correlation coefficient (Level 2 - participant)</i>	<i>Intraclass correlation coefficient (Level 3 - Group)</i>
Loneliness					.298	.075
Days Since Baseline	-.31	.074	148.77	<.001		
Condition	-.276	.179	34.50	.132		
Days Since Baseline * Condition	-.339	.112	151.35	.003*		
					.397	.061
Depression						
Days Since Baseline	-.268	.072	140.81	<.001*		
Condition	.171	.183	36.09	.355		
Days Since Baseline * Condition	-.169	.109	143.05	.125		
					.611	.006
Social anxiety						
Days Since Baseline	-.046	.067	129.43	.494		
Condition	-.415	.174	25.82	.025*		
Days Since Baseline * Condition	-.214	.102	130.80	.037*		
					.157	.058
General Practitioner visits						
Days Since Baseline	.072	.092	156.89	.434		
Condition	.103	.173	38.07	.555		
Days Since Baseline * Condition	-.319	.138	158.63	.022*		
					.374	.058
Multiple group membership						
Days Since Baseline	.316	.072	145.71	<.001*		
Condition	.274	.179	37.00	.133		
Days Since Baseline * Condition	.250	.108	148.00	.022*		

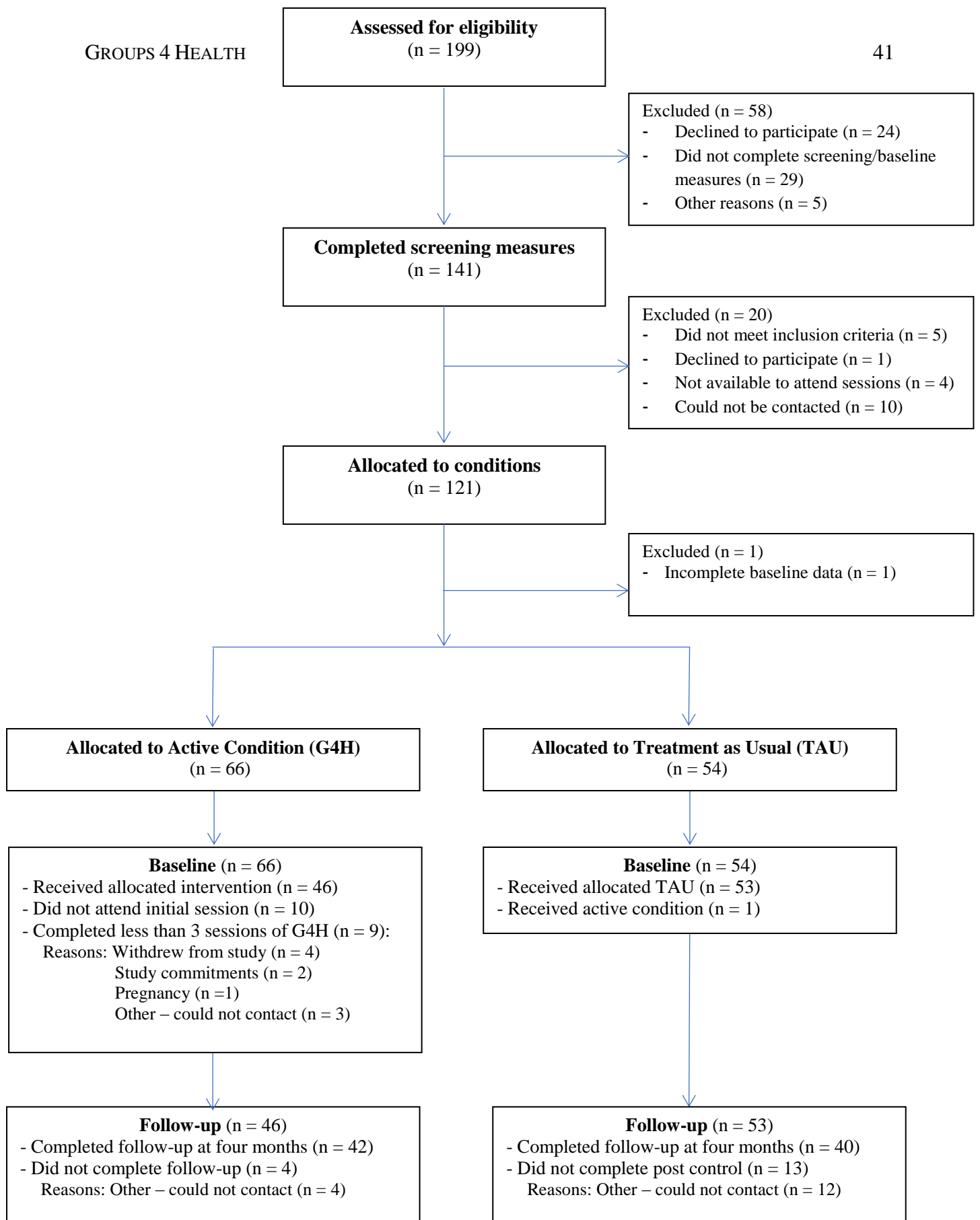


Figure 1. RCT CONSORT diagram

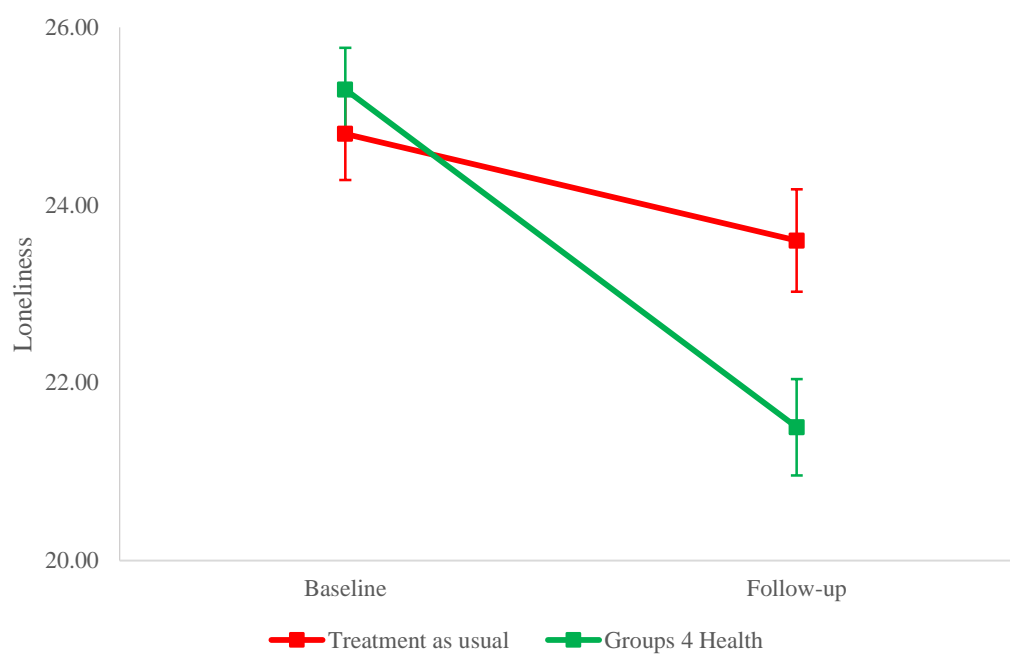


Figure 2. Intention to treat analysis on loneliness.

Note. Error bars represent standard errors. $N = 120$.

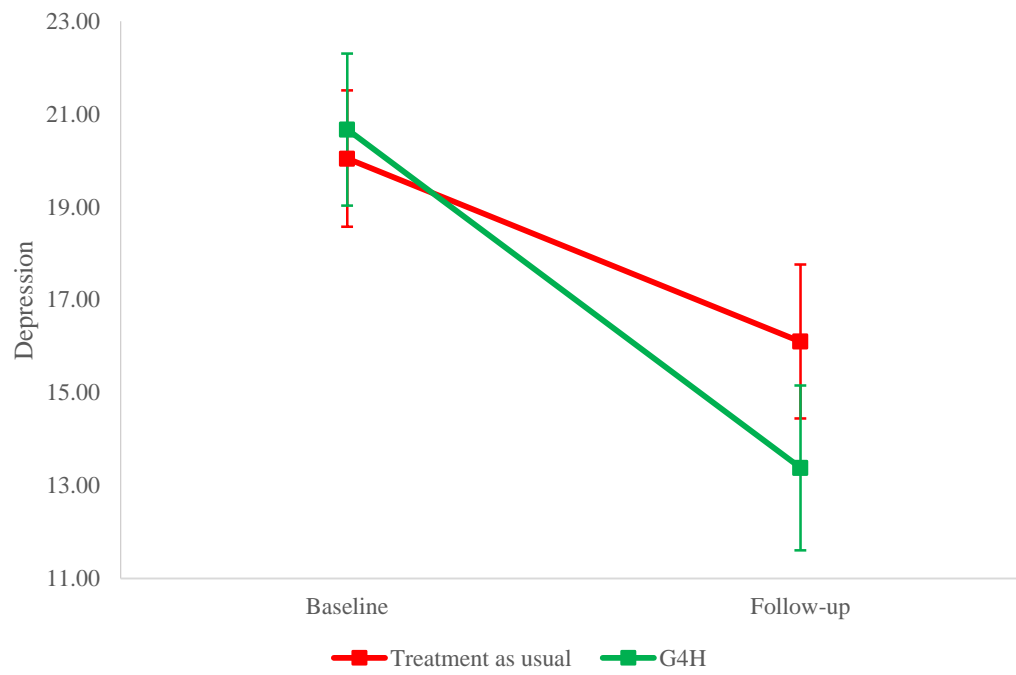


Figure 3. Intention to treat analysis on depression.

Note. Error bars represent standard errors. $N = 120$.

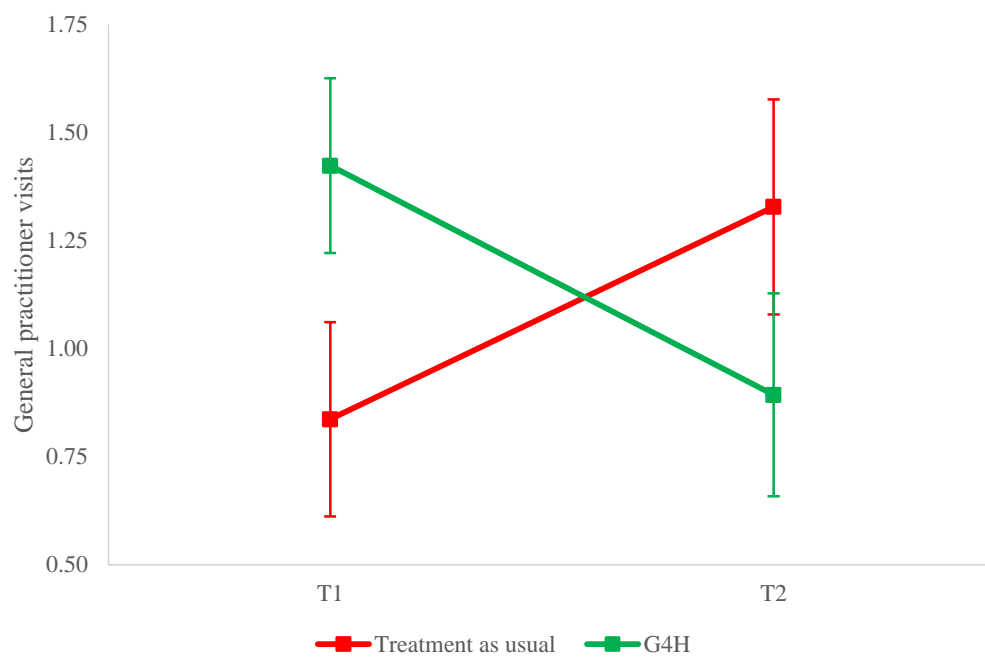


Figure 4. Intention to treat analysis on health service utilisation.

Note. Error bars represent standard errors. $N = 120$.

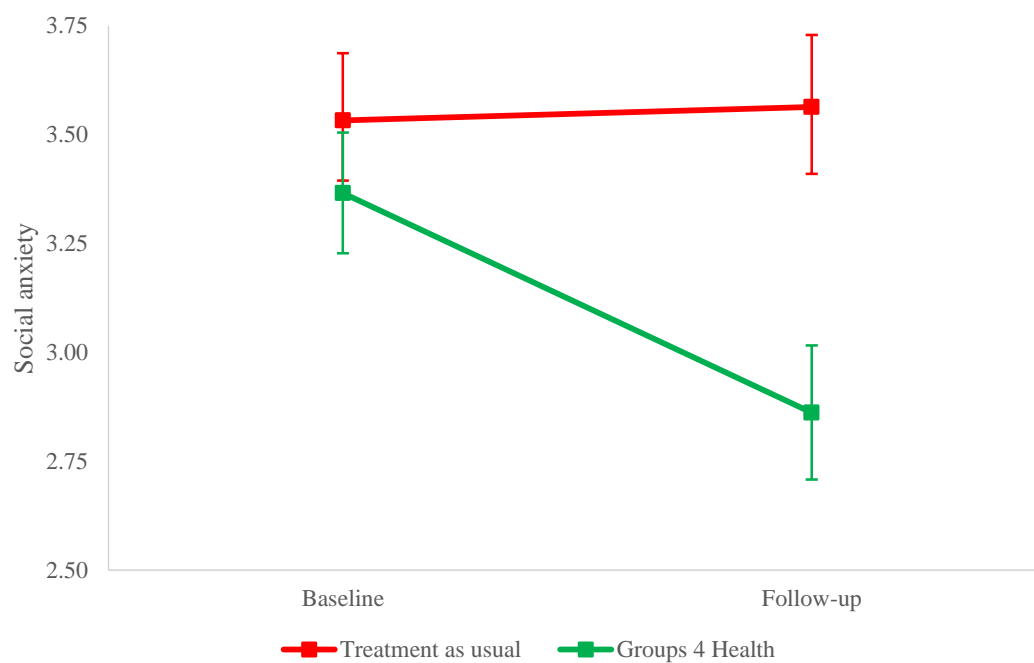


Figure 5. Intention to treat analysis on social anxiety.

Note. Error bars represent standard errors. $N = 120$.

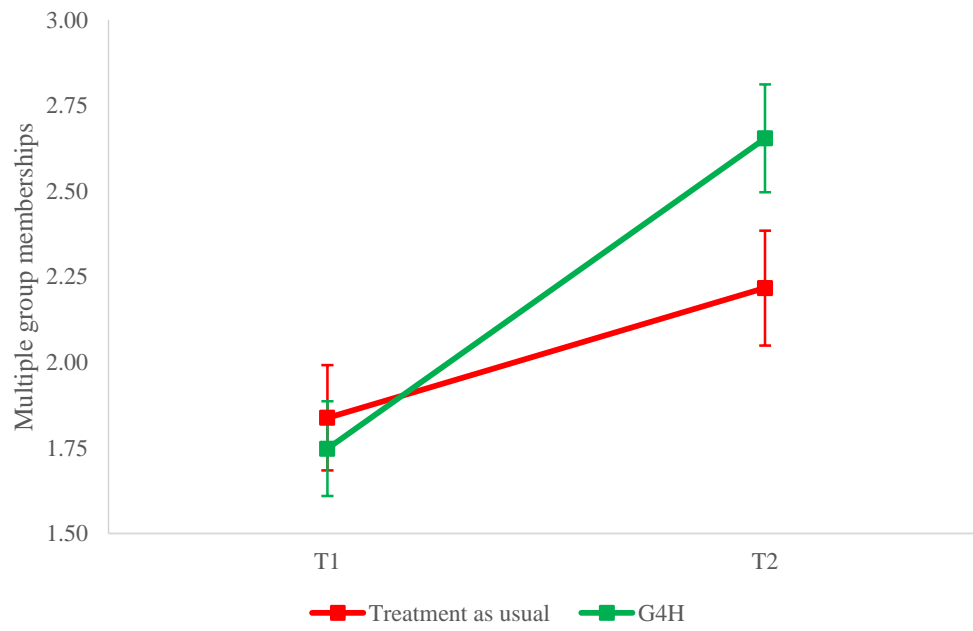


Figure 6. Intention to treat analysis on multiple group memberships.

Note. Error bars represent standard errors. $N = 120$.

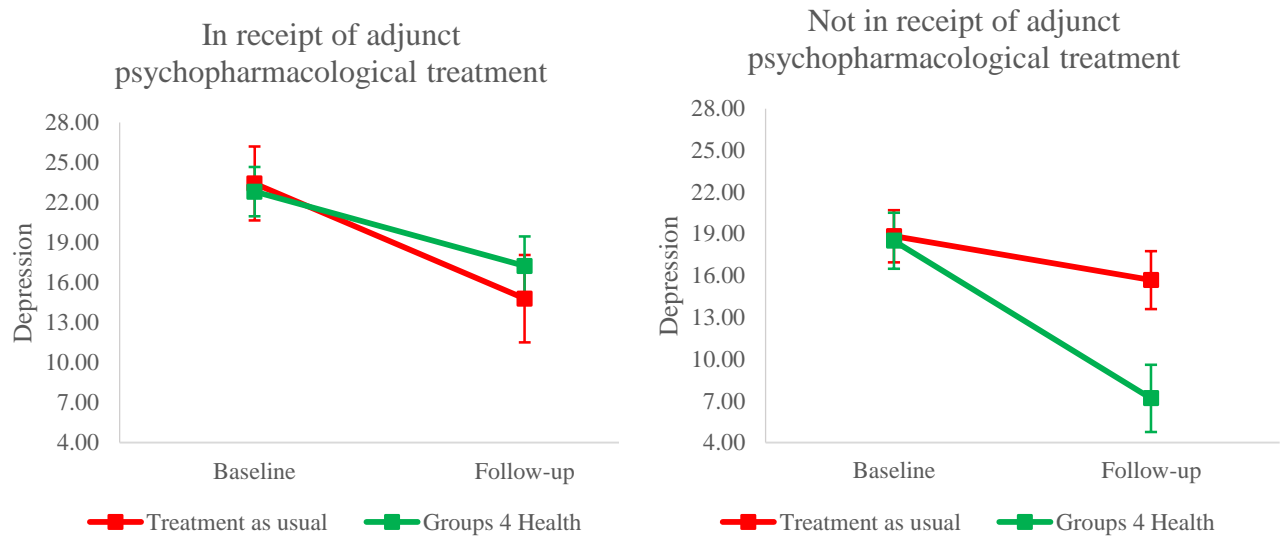


Figure 7. Three-way interaction between time, condition, and adjunct pharmacological treatment predicts depression.

Note. Error bars represent standard errors. $N = 105$; 15 people whose adjunct treatment status changed are excluded from this analysis.