Non-traditional support workers delivering a brief psychosocial intervention for older people with anxiety and depression: the NOTEPAD feasibility study

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Scientific summary

The NOTEPAD feasibility study

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Scientific summary

Background

Anxiety and depression often coexist in older people, and isolation, loneliness and loss may be important contributors. These disorders may be underdiagnosed and undertreated, and are associated with increased use of health and social care services, and raised mortality. Barriers to diagnosis include the reluctance of older people to present to their general practitioner (GP) with depression or anxiety symptoms because of stigma, and because the treatments offered are not acceptable to them.

Third (or voluntary) sector services may have the potential to offer non-stigmatising interventions to support the management of older people with anxiety and depression.

Aims and objectives

To refine a community-based psychosocial intervention for older people with anxiety and/or depression so that it can be delivered by non-traditional providers, such as support workers (SWs), in the third sector.

To determine whether or not SWs can be trained to deliver this intervention to older people with anxiety and/or depression.

To test procedures and determine if it is feasible to recruit and randomise patients, and to conduct a process evaluation to provide data to inform a future randomised trial.

Design

Three phases, each informed by a patient and public involvement and engagement (PPIE) group.

Setting

Third-sector community groups in North Staffordshire for phase 1 of the study.

General practices in Stoke-on-Trent and North Staffordshire.

Support workers employed by Age UK North Staffordshire.

Methods

Phase 1: qualitative study – interviews with older adults attending community groups, and third-sector workers. Analysis informed refinement of the intervention.

Phase 2: refinement of the intervention at an expert consensus group. Development of training, training materials and manual for SWs; development of materials for study participants (older adults). Recruitment and training of SWs employed by Age UK North Staffordshire.

Phase 3: feasibility study to assess whether or not –

- sufficient general practices can be recruited to participate in a study to evaluate the feasibility of this approach
- we can recruit and retain participants in a randomised study, including the completion of follow-up questionnaires
- the SWs can deliver a psychosocial intervention to older people with anxiety and/or depression
- this intervention can be implemented in routine NHS services.

Process evaluation to explore:

- whether or not older people find working with a SW and joining groups acceptable
- the perspectives of the SWs about training, support to deliver the intervention, and their experience of working with older people in a more structured way
- whether or not the manuals developed to support training and delivery of the psychosocial intervention are acceptable and useful
- what participating GPs understood about the study and the impact it had on their work.

Outcomes for phases 1 and 2

The intervention, based on the team's previous research, was refined in the light of the phase 1 data analysis and the consensus group. The psychosocial intervention comprised one-to-one contact between older people with anxiety and/or depression, based on the principles of behavioural activation (BA), with encouragement to attend and participate in a group activity.

We developed training materials, a SW manual and a patient participant manual. We recruited six SWs from Age UK North Staffordshire and trained them to deliver the intervention.

Sample size for feasibility study

A formal power calculation was not conducted. To assess feasibility, we aimed to recruit 30–40 participants in each arm to reliably estimate recruitment, retention and attrition rates to inform a fully powered randomised controlled trial (RCT). We anticipated that the total combined loss to follow-up would not exceed 20% at 4 months and, therefore, aimed to recruit 50 participants to each arm.

Participants

Practices using EMIS Web (EMIS Health, Leeds, UK) were identified by the Clinical Research Network West Midlands. Practice lists were searched by clinical research network (CRN) research facilitators for people aged $\geq$ 65 years. GPs screened the lists and removed people who met the exclusion criteria. Potentially eligible older adults were sent an information pack and screening questionnaires, including Patient Health Questionnaire-9 items (PHQ-9) and Generalised Anxiety Disorder-7 items (GAD-7). Those who returned completed questionnaires, consented to further contact and scored $\geq$ 10 on either PHQ-9 and/or GAD-7 were contacted by telephone by a CRN research nurse (RN). Those who continued to score $\geq$ 10 on PHQ-9 and/or GAD-7 at the telephone assessment were offered a visit by the RN for further discussion about the study, consent and completion of baseline questionnaires. Eligible people were randomised to either the intervention arm or the usual-care arm.

Intervention and comparison

The intervention was informed by the literature, the team's previous research and the qualitative work in phase 1. The intervention was a person-centred, one-to-one psychosocial intervention based on the principles of BA; a structured programme of reducing the frequency of negatively reinforced avoidant behaviours in parallel with increasing the frequency of positively reinforcing behaviours to improve functioning and mood. The intervention included signposting to local agencies and activities, when acceptable to the study participants, and the SWs were encouraged to accompany the study participants to a first visit to a group. The intervention was delivered by SWs recruited from Age UK North Staffordshire.

The intervention was compared with usual care; participating GPs were not given any additional information or advice about the management of older adults with anxiety and depression.

Outcome measures

The primary outcome measure was Clinical Interview Schedule-Revised (CIS-R); secondary outcome measures included PHQ-9; GAD-7; self-efficacy; EuroQol-5 Dimensions, five-level version (EQ-5D-5L); Control, Autonomy, Self-realisation and Pleasure-12 items (CASP-12); De Jong Gierveld Loneliness Scale; Social Participation Scale; and Adult Attitude to Loneliness scale. Participant burden for completion of the questionnaires was noted in free text by the RN.

Analysis

Analysis followed a detailed statistical analysis plan formally agreed with the study steering committee prior to analysis. The analysis focused on (1) describing the key process measures to decide if a main trial would be feasible, (2) baseline description of the study sample, (3) exploratory analysis of clinical outcomes, (4) reports of adverse events in any of the treatment arms, (5) descriptive summaries of the contacts made with the SW (in relation to adherence to intervention) and satisfaction with care, and (6) the extent of missing data and data accuracy.

Feasibility outcomes were estimated using descriptive statistics [with 95% confidence intervals (CI), when appropriate]. The assessment of key process measures included determining the engagement of GP practices, the recruitment, training and retention of SWs, response rate to the screening questionnaire, recruitment uptake and attrition.

Process evaluation

To assess the acceptability of the intervention to participants, we conducted semistructured interviews with participants in the intervention group shortly after follow-up at 4 months, and aimed to interview any study participants who dropped out of the intervention. Participants were interviewed to determine their perspectives on the intervention with emphasis on how acceptable and useful they found the sessions with the SW, whether or not participants attended any groups and how useful they found them. We also explored barriers to and facilitators of engagement with the SW or with groups and determined whether or not participant engagement in a group has continued. In addition, we aimed to speak to those people who were potentially eligible for the study but who declined to participate.

The perspectives of GPs in participating practices were explored in semistructured interviews; this included their contact with patients who had experienced the intervention, and whether or not it had affected their management of older people with anxiety and/or depression. We explored GPs' views on the roles and

contributions of the third sector in supporting this population, including barriers to, and facilitators of, working with this sector.

We interviewed the six SWs who participated in the training and delivered the intervention. We explored their views and experiences of working with older people with depression and/or anxiety and whether or not they believed that the intervention had helped. We asked about their experiences of training and supervision, and any liaison with primary care.

Semistructured interviews were transcribed verbatim, with the transcripts forming the data for analysis. Data were analysed thematically using the constant comparison method.

The narrative in the free-text participant burden question in the baseline and follow-up questionnaires was collated.

A sample of the first and second SW–study participant consultations were digitally audio-recorded with SW and participant consent. These audio-recordings focused on the fidelity of the intervention delivery; for example, which elements of this intervention the SWs used and whether or not there were any gaps in intervention delivery.

Patient and public involvement and engagement

The study design and processes were informed by a PPIE group. Group participants at the meetings held prior to submission of the funding application endorsed the concept of a 'non-medicalised' approach to the management of depression and anxiety in older people, and welcomed partnering with third-sector groups such as Age UK. PPIE members supported the idea of a one-to-one intervention delivered by a worker from Age UK. Members of the group felt that most older people would be happy to talk to the SW and supported the idea of tailoring activities to the older person's interests. Many felt that older people might need some encouragement and reassurance to take part and felt that barriers to participation, such as transport and lack of confidence, would need to be addressed, of which we took note in refining the intervention.

In subsequent meetings, the PPIE group provided input on the patient information sheets, letters and participant resources for phases 1 and 3. The group contributed to the NOTEPAD (NOn-Traditional providers to support the management of Elderly People with Anxiety and Depression) logo and suggested the strapline 'Supporting Mental Strength', which was adopted by the research team. The PPIE group reflected on the recruitment difficulties and the results of the process evaluation.

Results of feasibility study

Six general practices were recruited to the study, each agreeing to recruit older people to the study. Recruitment of participants during a 9-month period had been planned, but, owing to delays in ethics and Health Research Authority approvals, this was reduced to a 5-month recruitment period. There were 3762 initial mailings, with 1267 returned questionnaires. This was a response rate of 33%, against a predicted response rate of 40%.

A total of 773 people consented to further contact. Out of these, 113 were potentially eligible for the study (scoring ≥ 10 on PHQ-9 and/or GAD-7). A total of 49 baseline visits were conducted by CRN RNs, with 38 participants randomised.

The consent rate among potentially eligible people was slightly higher than anticipated [38 out of 113 (34%) against 30% estimated in the protocol].

Overall follow-up response rate was 86% (95% CI 72% to 96%) against an anticipated follow-up of 75% at 4 months.

The completion rate of items on the questionnaires was very good. All questions had missing data rates of < 10%, with the exception of:

- question A4 at baseline (current employment status – missing data rate 16%)
- question B7 at baseline (the way in each illness limits activity – missing data rate 11%).

Five out of the six SWs who were trained to deliver the intervention were allocated study participants and four SWs worked with participants in the intervention arm. Two of the SWs withdrew from the study owing to changes in their personal circumstances and employment status with Age UK.

Baseline characteristics

All participants were white British, with a median age of 71 years. Most were retired, over half were married and one-third lived alone. Nearly half reported taking medication for 'low mood' or 'stress' and nearly all disclosed long-standing illness or disability.

The PHQ-9 and/or GAD-7 scores of randomised participants were higher than potentially eligible participants.

Outcomes

The study was not powered to demonstrate differences in outcomes.

Process evaluation

Potentially eligible people who declined to be further assessed by the RN, or declined consent to randomisation, suggested that they did not have anxiety or depression, or did not feel that the study was relevant to them. Some people stated that they were 'too busy' with caring responsibilities or managing physical health problems.

Analysis of the digital recordings of SW–study participant sessions (fidelity checking) suggested that the SWs delivered the intervention as intended.

The training was acceptable to the SWs and they valued the SW manual. The number of sessions and contact times between SWs and study participants varied between three and six sessions, each lasting between 15 minutes and 4 hours. Requirements for supervision for each SW varied, with one-to-one supervision time varying between 60 and 280 minutes per SW.

Older people recruited to the study disclosed long-standing mental health problems. Some admitted to loneliness, which was not linked with a lack of close relationships. The intervention was acceptable to older people participating in the study, particularly the opportunity to talk to the SW. The resources were valued, particularly the diary and information about staying well. Not all participants felt that attending groups would be helpful.

Analysis of the process evaluation data will enable us to further refine the intervention.

Although GPs recognised that older people are a vulnerable group, they suggested that they had little time to offer pastoral support to older people, and that there were limited referral options. GPs suggested that they had little understanding of the NOTEPAD study, which they felt had not affected their routine work, although some GPs expressed irritation about instances when the suicide ideation protocol resulted in a telephone call to the practice. GPs were not aware of the work done by SWs with their patients.

The study was not powered, and data not collected, to assess cost-effectiveness.

Conclusions

Although recruitment was lower than anticipated, it was feasible to recruit and randomise patients and to test procedures, but further development of recruitment strategies is needed before this intervention can be tested in a fully powered RCT.

Workers in third-sector services have the potential to deliver non-stigmatising interventions to support and manage older people with anxiety and depression, which is potentially useful within a resource-poor NHS.

Implications for health and social care

- Support workers, recruited from Age UK North Staffordshire, were capable of working with older adults with anxiety and depression and delivering the psychosocial intervention as intended.
- The NOTEPAD intervention was acceptable to older adults, the personal qualities of the SWs were valued and the intervention was perceived to be less stigmatising than statutory services.
- Signposting to group activities was not acceptable to all older adults; older males did not want to be passive recipients of services and may prefer a more reciprocal relationship.
- It is important that the expertise of third-sector service workers is recognised and utilised within primary care.

Research recommendations

- Before a fully powered RCT to evaluate the clinical effectiveness and cost-effectiveness of a psychosocial intervention delivered by third-sector workers can be considered, further work is needed to refine procedures and intervention, focusing on older adults with physical long-term conditions who are already on antidepressants and living alone.
- The intervention might need to include a structured liaison with primary care/co-location of SWs within practices.
- Future work should explore partnership with a range of third-sector providers across more geographical sites.
- A longitudinal study using ethnographic methods is needed to assess the contribution and long-term sustainability of third-sector organisations in the management of older people with anxiety and depression.

Trial registration

This trial is registered as ISRCTN16318986.

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