A psychological intervention by community pharmacies to prevent depression in adults with subthreshold depression and long-term conditions: the CHEMIST pilot RCT

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Declared competing interests of authors: Jan Badenhorst reports being the Superintendent Pharmacist for Whitworth Chemists Ltd (Newcastle upon Tyne, UK), of which some pharmacies took part in the Community Pharmacy Mood Intervention Study (CHEMIST), and is chairperson of Tees Local Pharmaceutical Committee representing community pharmacies in Teesside, where some pharmacies involved in CHEMIST were based. Adam Todd is currently a member of the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Prioritisation Committee A (2020–present). This committee aims to develop funding calls in the areas of primary and social care. Catherine Hewitt reports being a member of the NIHR HTA Commissioning Sub Board (2016–17) and NIHR HTA Commissioning Committee (2015–20). Simon Gilbody has been a member of several NIHR Committees (2008–20). David Ekers was a member of the National Institute for Health and Care Excellence Depression Guideline development group and is a member of the NIHR HTA programme funding committee. Carolyn Chew-Graham reports personal fees from West Midlands National Institute for Health Research Applied Research Collaboration during the conduct of the study.

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The CHEMIST pilot RCT

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Scientific summary

Background

Approximately 30% of the UK population have a long-term physical health condition. People with long-term conditions are two to three times more likely to experience depression. Comorbid depression and long-term conditions can result in poorer health outcomes, such as lower quality of life, reduced ability to self-manage and increased health-care costs.

Subthreshold depression (mild depressive symptoms) is a major risk factor for progression to major depression, with prevalence estimates of up to 20% in those with long-term conditions. Although psychological interventions are effective at reducing depression symptoms in this population, mental health services struggle to meet the demands of major depression and over 80% of people with 'below threshold' depression remain untreated. A public health approach to the management of comorbid subthreshold depression and long-term conditions may be to offer health-care interventions in innovative and accessible settings.

Community pharmacies in England are an accessible and available health-care provider, with 89% of the population living within a 20-minute walk of a local pharmacy, especially within areas of high social deprivation. The Healthy Living Pharmacy programme aims to improve the health and well-being of the local population by extending the roles of pharmacy teams to include delivery of health promotion programmes, such as smoking cessation and weight management. Such health interventions share similarities with the content of behaviour change/management approaches to subthreshold depression. Community pharmacies are, therefore, potentially well placed to offer opportunistic enhanced support to people with a range of health problems, including subthreshold depression, alongside existing health promotion services.

Existing interventions involving a psychological approach (behavioural activation) have been shown to be effective at reducing symptoms of subthreshold depression, even when delivered by non-mental health specialists. The community pharmacy may provide a suitable setting in which to offer such health interventions, but insufficient evidence exists to support implementation. The Community Pharmacies Mood Intervention Study (CHEMIST) is a feasibility study and pilot randomised controlled trial to evaluate a bespoke enhanced support intervention for use within a community pharmacy setting for adults experiencing comorbid subthreshold depression and long-term conditions.

Objectives

Feasibility study

- To refine a bespoke enhanced support intervention for implementation by community pharmacy staff for people with subthreshold depression and long-term conditions.
- To develop and refine study procedures for testing in an external pilot randomised controlled trial.

External pilot randomised controlled trial

- To quantify the flow of participants (eligibility, recruitment and retention rates).
- To evaluate proposed recruitment, assessment and outcome measure collection.
- To examine the delivery of the enhanced support intervention in a community pharmacy setting.
- To conduct a process evaluation to explore the acceptability of the enhanced support intervention within the community pharmacy setting, elements of the enhanced support intervention that might be considered useful (or not) and the appropriateness of study procedures.

Methods

Design

A feasibility intervention study with nested qualitative evaluation and an external pilot, two-arm, 1 : 1 individually randomised controlled trial, with nested qualitative process evaluation and economic evaluation.

Setting

Community pharmacies in the north of England.

Participants

To be eligible for the study, participants needed to be aged ≥ 18 years, have subthreshold depression and have at least one long-term health condition.

Potentially eligible participants were provided with study information via community pharmacies and following general practitioner database searches if they were identified as being aged ≥ 18 years with at least one long-term condition. The presence or absence of subthreshold depression symptoms was assessed by the study team using a structured diagnostic interview (Mini International Neuropsychiatric Interview).

Intervention

The bespoke enhanced support intervention (behavioural activation within a collaborative care framework) involved up to six sessions delivered face to face in the community pharmacy or over the telephone by trained community pharmacy staff (enhanced support intervention facilitators). Intervention participants were provided with a self-help workbook. Enhanced support intervention facilitators completed a bespoke 2-day intervention training workshop and passed a competency assessment.

All participants in the feasibility study were offered the enhanced support intervention. Participants in the pilot randomised controlled trial were randomised 1 : 1 to either the enhanced support intervention or usual care (usual primary care management of subthreshold depression and other local community provision).

Outcomes

The main outcomes included recruitment and retention rates, data completeness of outcome measures and engagement with the enhanced support intervention.

Participants completed a range of study questionnaires at baseline and at the 4-month follow-up. These included self-reported depression severity as the intended primary outcome (assessed with the Patient Health Questionnaire-9), and anxiety (General Anxiety Disorder-7), physical/somatic health problems (Patient Health Questionnaire-15), health-related quality of life (Short Form-12 items), health utility (EuroQol-5 Dimensions, three-level version) and resource use (bespoke questionnaire) as intended secondary outcome measures.

Results

Feasibility study

Twenty-four participants were recruited between April and December 2017 from seven community pharmacies and one general practice. Participants were aged between 51 and 83 years (mean age 66 years), six participants were male and all participants identified as being of white ethnicity. The most common health problem reported was high blood pressure ($n = 16$). Data completeness of outcome measures was 100% at baseline, and between 95% and 100% at the 4-month follow-up. Participant retention at 4 months was 83%. One participant withdrew from the study. A slight reduction in

depression symptoms at the 4-month follow-up (mean reduction of 3.5 points on the Patient Health Questionnaire-9) was observed, although the sample size is small and randomisation was not employed.

Seventeen community pharmacy staff were trained to deliver the enhanced support intervention and nine went on to support a minimum of one participant. Seventeen participants commenced the enhanced support intervention sessions (71%) and, of these, all completed two or more sessions and 10 completed all six sessions. Analysis of interview data suggested that participants and enhanced support intervention facilitators viewed the community pharmacy as an appropriate place to offer a mental health intervention, and that the intervention made sense and was acceptable. Participants engaged with the self-help workbook and valued the contact with enhanced support intervention facilitators. Although enhanced support intervention facilitators reported initial concerns in delivering the intervention, their confidence in delivering this increased with experience. The practical challenges of identifying potential participants for the study and the increased work burden, especially during busy periods, were highlighted by enhanced support intervention facilitators.

The economic analysis reported a 100% questionnaire completion rate, with low levels of missing items and no out-of-range responses, indicating the feasibility of collecting quality-of-life and resource use data. Visits to the general practitioner were the most common type of resource use reported.

The feasibility study facilitated important learning that led to refinements to the study materials (including the enhanced support intervention and training materials) and study processes for the pilot randomised controlled trial.

Pilot randomised controlled trial

Between March 2018 and April 2019, 44 participants (target of 100 participants) were recruited from 12 community pharmacies and five general practices. Twenty-four participants were randomised to the enhanced support intervention and 20 participants were randomised to usual care. Participants were aged between 20 and 89 years (mean age 67 years) and 52% ($n = 23$) were female. The most common health problems reported were arthritis ($n = 30$), followed by cardiovascular ($n = 24$) and respiratory ($n = 19$) conditions.

Data completeness of outcome measures at baseline and at the 4-month follow-up was 100%. Participant retention rate at 4 months was 93% and two participants withdrew from the study. There was a slight reduction in depression symptoms at the 4-month follow-up in both treatment arms, with a slightly larger reduction in the usual-care arm than the intervention arm (mean reduction of 2.1 and 1.1 points on the Patient Health Questionnaire-9, respectively); however, the sample size ($n = 41$ at follow-up) is too small to draw any conclusions, and the findings should be interpreted with caution.

An additional 17 community pharmacy staff were trained to deliver the enhanced support intervention. Eleven enhanced support intervention facilitators (five of whom were trained in the feasibility study and six of whom were trained in the pilot randomised controlled trial) delivered the intervention to at least one intervention participant. Of the 24 participants randomised to the enhanced support intervention, 18 (75%) commenced the intervention sessions. Sixteen (89%) of these completed at least two sessions and nine participants competed all six sessions. Difficulties were experienced in assessing fidelity to the enhanced support intervention.

The process evaluation used normalisation process theory as a framework in which to understand the key factors that enabled or constrained the implementation of the enhanced support intervention. Findings indicated that the enhanced support intervention made sense to participants, and this increased with experience of the intervention. Concerns over confidentiality and privacy within a pharmacy setting were reported to be a potential barrier by some participants. Observing the positive intervention effects was seen as facilitating engagement among enhanced support intervention facilitators. However, a key barrier to implementation was the work needed to embed recruitment

processes and intervention delivery structures into existing routine pharmacy practice, and the impact of intervention delivery on the availability of key pharmacy facilities.

The economic analysis revealed that health service use was within the expected range, with the most common resource use being visits to the general practitioner, nurse and pharmacy. In both the enhanced support intervention and the usual-care arms, there was little change in quality of life and health service use between baseline and follow-up. There was some indication that the intervention might reduce the use of primary care and community services and hence costs, although the sample size was insufficient to draw any statistical conclusions. The estimated cost of the enhanced support intervention was £51.40 per participant for an average of four enhanced support intervention sessions.

Conclusions

The community pharmacy represents a relatively new setting in which to deliver a depression prevention intervention. CHEMIST demonstrates that community pharmacies are interested in mental health research and are keen to participate, recognising the potential role that they could play. Community pharmacy staff can be successfully trained to deliver a psychological intervention (behavioural activation) to people with comorbid subthreshold depression and long-term conditions.

Recruitment was a challenge throughout the study, and this has implications for conducting a large-scale definitive randomised controlled trial. Community pharmacies were limited in their ability to promote the study to large numbers of pharmacy customers, and pharmacy staff reported difficulties in finding the time to effectively embed study processes, including recruitment and intervention delivery, into busy routine pharmacy practice. Concerns regarding confidentiality may have also affected recruitment to the study. Despite this, the study demonstrated good levels of engagement with the enhanced support intervention and excellent retention rates at follow-up, suggesting that people are willing to engage in mental health research delivered in the community pharmacy. The process evaluation suggests that the enhanced support intervention was acceptable to those receiving and delivering the intervention, and identified key learning for future studies, particularly with respect to recruitment and implementation.

The community pharmacy would appear to be ideally placed to provide support to people with mental–physical multimorbidity. The CHEMIST findings suggest that the community pharmacy represents an acceptable setting in which to offer depression prevention support to at-risk groups. Importantly, the study has provided important learning on how to embed research and study processes in this busy public health setting, and highlighted the organisational and operational barriers to consider for successful implementation; such findings will be useful in the design and delivery of future studies in the community pharmacy.

Recommendations for further research

Further research is required to inform the design and delivery of a definitive randomised controlled trial to test the clinical effectiveness and cost-effectiveness of depression prevention interventions within the community pharmacy setting. Such research should seek to explore and address important barriers to recruitment, intervention delivery and implementation of psychological interventions in this setting. Consideration needs to be given to study and intervention design and the impact of intervention structures on existing routine activities within the community pharmacy. Important factors to explore in future research include confidentiality and disclosure of mental health problems within this setting. Further research should seek to enhance accessibility and inclusion of diverse patient groups.

Trial registration

This trial is registered as ISRCTN11290592.

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