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Mental health nurse-delivered interventions - RCTs

Randomised controlled trials of mental health nurse-delivered interventions: A systematic review

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Author contributions

GLD conceived of the study. GLD, MAM, NB, TT designed and conducted the literature search strategy. All authors contributed to study quality appraisal and risk of bias review. GLD, MAM performed data extraction and prepared Tables and Figures. GLD prepared the first draft of the manuscript. All authors were involved in the revision of the draft manuscript and have agreed to the final content.

Randomised controlled trials of mental health nurse-delivered interventions: A systematic review

ABSTRACT

Introduction: Nurses are the largest professional disciplinary group working in mental health services and have been involved in numerous trials of nursing-specific and multidisciplinary interventions. Systematic appraisal of relevant research findings is rare.

Aim: To review trials from the core Anglosphere (UK, US, Canada, Ireland, Australia, New Zealand) published from 2005-2020.

Method: A systematic review reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses. Comprehensive electronic database searches were conducted. Eligible studies were randomised controlled trials of mental health nurse-delivered interventions conducted in relevant countries. Risk of bias was independently assessed. Synthesis involved integration of descriptive statistics of standardised metrics and study bias.

Results: Outcomes from 348 between-group comparisons were extracted from $K=51$ studies ($N=11,266$ participants), Standardised effect sizes for 68 (39 very small/small, 29 moderate/large) statistically significant outcomes from 30 studies were calculable. All moderate/large effect sizes were at risk of bias.

Discussion: Trial evidence of effective mental health nurse-delivered interventions is limited. Many studies produced few or no measurable benefits; none demonstrated improvements related to personal recovery.

Implications for practice: Mental health nurses should look beyond gold standard RCT evidence, and to evidence-based interventions that have not been trialled with mental health nurse delivery.

200 Words

Keywords: Systematic review, Randomized Controlled Trial, Mental Health Nursing, Evidence-Based Practice

Relevance statement

Good mental health nursing practice relies upon a constantly evolving evidence base. The highest level of primary evidence, the randomised controlled trial, has been increasingly used to support mental health nursing but there have been few attempts to comprehensively review this research. This systematic review provides an overview and synthesis of randomised controlled trials of mental health nurse-delivered interventions conducted in major English-language speaking nations since 2005. It highlights where best evidence lies and, crucially, shows where there is urgent need for further development of trial evidence.

Accepted Article

Accessible Summary

What is known on the subject

- Well conducted randomised controlled trials provide the highest level of evidence of effectiveness of healthcare interventions, including those delivered by mental health nurses.
- Trials have been conducted over the years but there has not been a comprehensive review since 2005, and never one including studies conducted outside the UK.

What the paper adds to existing knowledge

- The paper provides a comprehensive overview of results from randomised controlled trials of mental health nurse-delivered interventions conducted in the UK, Ireland, US, Australia, New Zealand, or Canada and reported 2005 to 2020.
- It highlights that the trial evidence is limited and offers only partial evidence for interventions that are central to mental health nursing practice.

What are the implications for practice

- Much mental health nursing practice is not supported by the highest level trial evidence. Mental health nurses need to carefully select evidence on which to base their practice both from the mental health nursing literature and beyond.
- Mental health nurses and other stakeholders should demand greater investment in trials to strengthen the evidence base.

185 Words

1. INTRODUCTION

A robust and dynamic evidence base for practice is a key indicator of the health of any professional discipline (Australian Council of Professions, 2018). For the mental health nursing profession, Curran and Brookers' (2007) systematic review surveyed the state of evidence for the effectiveness of mental health nursing-delivered interventions conducted in the United Kingdom based on completed randomised controlled trials. Fifty-two studies published between 1980 and 2005 were identified and the authors concluded that "in the UK, mental health nurses are involved in the delivery of a wide range of interventions in a variety of clinical health settings, with broadly positive results" (p.479). Additional optimism was warranted given a gathering momentum: all but four trials were published post-1990. UK-based mental health nursing was by 2005 riding a wave of knowledge advancement with three new published trials per year on average compared with one per 3-year period in the 1980s. Since then there has been no similar review of trial research undertaken in the UK. Here we address that issue, but also extend the scope of interest to encompass work conducted outside of the UK in order to provide an international dimension. We have therefore conducted a review of trials of mental health nurse-delivered interventions conducted in the core Anglosphere (Bennett, 2012) and published from 2005 to 2020.

The randomised controlled trial, together with the agglomeration of trials in a systematic review and meta-analysis, sits at the pinnacle of medically defined hierarchies of evidence (National Clinical Guideline Centre, 2010; Oxford Centre for Evidence-based Medicine, 2009). Standards for initial and continued registration and practice as a mental health nurse in English-language speaking countries are underpinned by an obligation to ensure one's actions lie within the scope of appropriate and contemporary evidence including in the UK (Nursing and Midwifery Council, 2018), US (American Nurses Association, 2015),

Australia (Neville et al., 2010), New Zealand (New Zealand College of Mental Health Nurses, 2012), Canada (Registered Psychiatric Nurse Regulators of Canada, 2014), and Ireland (Office of the Nursing & Midwifery Services Director, 2012). There are some indications that the value and importance of evidence in mental health nursing is growing; for example, the impact factor of two leading scholarly mental health nursing journals (International Journal of Mental Health Nursing and Journal of Psychiatric and Mental Health Nursing) are both currently at a 10-year high, suggesting that published research in the field is being cited more frequently (Clarivate, 2019). The importance placed upon the evidence base for practice in undergraduate nursing curricula provides further support about the growing role of research findings for practice (e.g., Australian College of Nursing, 2013).

Mental health nursing service provision is highly dependent on resource allocation and it remains important to demonstrate that mental health nurses are delivering interventions that are effective in terms of appropriately selected outcome measures including personal recovery, safety, financial cost, or clinical efficacy. In this respect, the identification of well-conducted trials as the pinnacle of effectiveness evidence is in our view axiomatic; however, the selection of interventions which are acceptable to and represent the priorities of likely recipients is also key to the notion of evidence-based practice as a judicious amalgam of research evidence, clinical know-how, and patient preference (Dawes et al., 2005).

2. AIMS

In the above context we aimed to review evidence about mental health nursing interventions derived from RCTs conducted in six English language nations (the 'core Anglosphere') and published since the last major review in order to: i) identify the quantity, quality, and focus of relevant trial research conducted over the last 16 years; ii) examine the magnitude of change achieved across outcomes from the included studies in order to provide better

understanding of the value of mental health nurse-delivered interventions; iii) determine whether any potentially homogeneous subgroupings of interventions exist that might be subjected to meta-analysis. The review is therefore both temporally and geographically limited and we do not claim to provide definitive information about the efficacy of specific interventions based on the *totality* of trial evidence. However, we do view the study as a systematic review because it meets a number of important criteria in terms of its aims which are: i) to uncover the international evidence; ii) to confirm current practice and identify new practices; iii) to identify and inform areas for future research; iv) to investigate conflicting results; and v) to inform decision-making about future reviews and primary research. Further, the study used explicit and systematic methods to identify, appraise, and synthesise information (Munn et al., 2018). Additionally, the study extends a previous systematic review in three ways. First, it draws on a wider, international geographical range than Curran and Brooker (2007) by including trials conducted in any of the countries of the core Anglosphere. Second, we have extracted study effect sizes to provide important information about intervention effectiveness. Finally, we have synthesised study findings in line with Synthesis Without Meta-analysis (SWiM) guidelines to maximise transparency about our conclusions (Sterne et al., 2020).

3. METHODS

3.1 Design

We did not register a review protocol. To address objective i) a comprehensive identification and review of trials conducted in specific culturally comparable countries and published between 2005 and 2020 was conducted using principles outlined in the PRISMA 2020 statement (Page et al., 2021). To address objective ii) we calculated effect sizes and reported summary measures of their distribution following Synthesis Without Meta-analysis (SWiM) guidelines (Campbell et al., 2020). To address objective iii) we conducted descriptive

analyses of the body of research identified to determine where groups of studies with common interventions or population groups might exist in sufficient numbers to make a future systematic review and meta-analysis feasible; we also examined differences between the effect sizes achieved between groups of studies as an indicator of study homogeneity.

3.2 Search strategy

3.2.1 Data sources

The search was conducted in multiple electronic databases (Scopus, PsycArticles, CINAHL, MEDLINE, Cochrane Library, NIH U.S. National Library of Medicine ClinicalTrials.gov, Australian New Zealand Clinical Trials Registry, Dissertation Abstracts). Supplementary searches were conducted in Google Scholar. Date of publication was limited to 1st January 2005 to 31st December 2020. Each source was last consulted in the week commencing April 19th 2021. Additional searches were made in the tables of contents (to year end 2020) of selected specialist mental health nursing journals (International Journal of Mental Health Nursing, Journal of Psychiatric and Mental Health Nursing, Archives of Psychiatric Nursing, Issues in Mental Health Nursing, Journal of the American Psychiatric Nurses Association, Journal of Psychosocial Nursing and Mental Health Services, Perspectives in Psychiatric Care, British Journal of Mental Health Nursing). References lists from included studies were also hand searched.

3.2.2 Search terms

A population concept context (PCC) structure informed the review. The population of interest was any group or individuals (no limits applied) receiving an intervention that was, wholly or partly, delivered by one or more mental health nurses; the concept of interest was the mental health nurse-delivered intervention; the context was studies conducted at least partly in any of six English-speaking nations using a randomised controlled design.

Outcomes of interest were any directly relating to the population group including inter alia health, wellbeing, experience, and functioning (all searches available in Supplementary Tables S4 and S5).

3.2.3 Eligibility criteria

Included studies were conducted at least partly in one or more of the countries of interest and published between 2005 and 2020. Studies in which participants were randomised at either individual or cluster level to one of two or more conditions were eligible. At least one study condition must have met our definition of a mental health nurse-delivered intervention: either i) delivered by one or more individuals including one or more who is explicitly identified as a mental health nurse from the study text and irrespective of the setting; or ii) delivered by one or more individuals including one or more who is a registered nurse employed in mental health services and not explicitly identified as a non-mental health nurse. This definition was agreed after consideration a) of the need to include trials where an intervention is delivered outside of the normal context of mental health service care e.g., by specially trained mental health nurses employed for the purpose of a trial of depression care delivered in a general medical setting to people with coronary heart disease; b) that in some countries, notably Australia, mental health nursing is not a specialist field of practice at pre-registration level and, unlike the UK, registered nurses working in mental health settings comprise varying proportions of individuals with a specialist mental health nursing qualification (Gray et al., 2016). Thus our definition of a mental health nurse-delivered intervention is pragmatic and maximised sensitivity of the search strategy. We defined interventions as any activity delivered directly or indirectly (e.g., training mental health nurses to deliver a specific intervention) to a clinical population in the context of a trial and not limited to existing mental health service users. Service user-related outcome data must

have been collected and therefore indirect interventions such as staff education without any follow-up on outcomes for service users were not eligible.

All reports identified from literature searching were exported to EndNote where de-duplication was conducted. Three authors (xx,xx,xx) conducted independent application of eligibility criteria to the first 100 reports at title/ abstract level in order to establish a shared understanding. Once established that criteria were being applied consistently the authors conducted screening of the remaining references individually. Full text versions of all studies identified as potentially includable were obtained and each reviewed independently by two of the team for inclusion in the final review with any discrepancies being discussed until consensus was achieved.

3.3 Data extraction

3.3.1 Study information

Information about population/sample, publication year, country, design, methods, trial registration, randomisation procedure and allocation concealment, follow-up schedule, the nature and type of experimental and control interventions and related involvement of mental health nurses including any associated training, details of any a priori power calculation, analysis, and patient-related outcomes were extracted using a standard pro forma. Type of intervention was classified according to the Omaha system (Martin, 2005), a standardized taxonomy designed to describe nursing care. All data extraction was conducted independently by xx plus one of the other authors.

3.3.2 Study outcomes

To maximise cross-study comparability where studies had multiple follow-up points we extracted all service user or carer-related outcomes data (P values or other tests indicative of statistical significance and descriptive data including means and standard deviations for

control and experimental groups) from the period closest to 12 months. Few studies explicitly stated which was their primary outcome and we therefore extracted all presented outcomes. Subgroup analyses were not considered.

3.4 Study quality and risk of bias assessment

Study quality was assessed against criteria from critical appraisal tools (BMJ Publishing Group 2019; Centre for Evidence Based Medicine, 2020). Risk of bias for specific outcomes was conducted using the Cochrane Risk of Bias 2 assessment tool (Sterne et al., 2019) for every statistically significant result (overall rating of low risk of bias, high risk of bias, or some concerns). Each quality and risk of bias assessment was conducted independently by two authors with discrepancies referred to a third to achieve consensus (see Supplementary Tables S1 and S2).

3.5 Data synthesis and analysis

We planned to do meta-analysis of study results only in the event that subsets of trials with broadly homogeneous interventions, participants, and outcomes were identified. In the event this was not the case and we followed the 9-item synthesis without meta-analysis (SWiM) reporting guidelines (Campbell et al., 2020) to describe and explain our analytical decisions. Studies were sorted into categories by participant population: i) those with diagnoses of severe mental illness (SMI) including schizophrenia spectrum disorders, bipolar disorder, major depressive disorder (Public Health England, 2018); ii) those with common mental disorders such as anxiety or depression (National Collaborating Centre for Mental Health, 2011); iii) groups with mixed or other diagnoses excluding dementia; and iv) groups of older adults and their carers. This was similar to the reporting structure described by Curran and Brooker (2007). Extracted results were converted to standardised mean differences (d) with 95% Confidence Intervals using an online conversion tool (Wilson, n.d.). In addition, results

from all experimental study arms, and from all control arms where mental health nurses were involved in intervention delivery, were converted to within-group standardised mean differences (see Appendix 1). Descriptive statistics, specifically frequencies of significant P values and of standardised mean differences at cut-offs of 0.19 (very small), 0.49 (small), 0.79 (moderate), and 0.8+ (large), supported a summary of direction of change and magnitude of effect (Campbell et al., 2020). Synthesis of study findings was conducted at the level of population type and was informed by consideration of whether interventions produced statistically significant positive outcomes, the effect size achieved, and the risk of bias. Heterogeneity was investigated by examining whether significant results were more common among particular population or intervention types. To test this we conducted chi square analyses and examined standardised residuals to identify post hoc significant between category differences. This was not a pre-specified analysis.

4. RESULTS

4.1 Characteristics of included papers

After application of inclusion and exclusion criteria 63 papers or reports originating from 51 studies were included in the full review (see PRISMA flow diagram Figure 1 and Table 1). Studies were conducted in the UK ($k=27$; 52.9%), US ($k=17$, 33.3%); Australia ($k=5$, 9.8%), Canada and New Zealand (both $k=1$, 1.9%).

>>*Insert Table 1 about here*<<

4.1.1 Samples included

Across 48 studies $N=11,266$ people were enrolled and randomized into intervention ($n=4,992$) or control/comparator ($n=5,078$) arms. Studies by Bowers et al. (2015) and Lanza et al. (2016), where the randomisation unit was hospital ward, and reported outcomes were per shift rather than per individual, did not report on the number of individuals enrolled.

Happell et al (2014) did not report the number of participants in their trial. Two further studies (Beebe et al., 2016, 2017; White & Winstanley, 2010) did not report n allocated per study arm, therefore intervention plus control n do not equal total N .

4.1.3 Follow up and retention

The mean ([SD], range) follow-up period from each study closest to one-year was 42.4 weeks ([39.8], 1 to 260); the commonest period was 52-weeks ($k=23$ studies). Of individuals randomised, $N=8,589$ (76.2%) were retained to the selected endpoint (SD 13.9%, range 31.1% to 100.0%). Retention in comparison or control arms was slightly higher than in intervention groups (76.6% vs 72.2%).

4.1.4 Study quality

Study quality was generally good evidenced by a median quality score of 13 (range 6 to 17) from a possible 17 (Mean=13.3, $SD=2.8$). Four studies received an overall rating less than 10 (Beebe et al., 2016, 2017; Happell et al., 2014; Thompson et al., 2012; White & Winstanley, 2010). There was evidence of protocol registration for $k=16$ studies (see Appendix 1). Risk of bias is discussed in relation to individual study outcomes (see 4.3 to 4.6).

4.2 Mental health nurse involvement in intervention and control arms

In 49 studies mental health nurses were involved in delivery of interventions in study experimental arms. The two exceptions were Rohricht and Priebe (2006), where usual care by a team including mental health nurses was the nominal control arm in a study testing body-oriented psychotherapy delivered by a dance therapist; and Happell et al. (2014), where usual care by a team including mental health nurses was the control in a trial of a specialist cardiometabolic health nurse role. To ensure consistency with the aims of the review the comparator/control and intervention arms of these studies were transposed so that

when we talk about 'mental health nurse-delivered intervention arms' we refer to the 49 intervention arms involving mental health nurse-delivered interventions and the two control arms just described.

4.3 Study outcomes

Of 11,266 participants, 7,970 (63.6%) were enrolled in one of the 30 (58.8%) studies for which there was at least one significant between group measured gain in any outcome.

Details by participant group are presented in sections 4.3.1 to 4.3.4 and in Table 2.

>> *Insert Table 2 about here*<<

4.3.1 RCTs with participants diagnosed with severe mental illness

Twenty seven studies recruited $N=5,959$ (Mean [SD] $n=220.7$ [258.3]) individuals into experimental ($n=3,216$) and control ($n=2,559$) trial arms. Studies were conducted in the UK ($k=14$), US ($k=11$), Australia, and New Zealand ($k=1$ each). Interventions comprised case management ($k=6$), surveillance ($k=1$), teaching, guidance, and counselling ($k=14$) and treatments and procedures ($k=6$) and were delivered entirely by nurses in $k=18$ studies and by professionals including nurses in $k=9$. In $k=18$ studies the nurses involved were described as experienced or advanced. Participants were drawn from community ($k=13$), inpatient ($k=2$), and both ($k=12$) settings and the follow-up point closest to 12-months was 1 to 3 months ($k=5$), between 3 and 6 months ($k=4$), 6 to 12 months ($k=2$), 12 months ($k=14$) and greater than 12 months ($k=2$).

A total of 212 between group intervention – outcome tests of significance were extracted from 25 studies. Of these, 43 (21.4%) from $k=15$ different studies (range 1 to 9 per study) indicated statistically significant positive change for participants in the intervention group relative to a control group. A further five outcomes, from two single studies, revealed a significant negative change for participants in the intervention arm. Four of these outcomes

were in the study in which mental health nurses were involved in delivery of the nominal control intervention whose results were transposed for the purposes of the current review (Rohricht & Priebe, 2006).

Of the 43 significant positive results standardised mean differences were calculable for 38 from 15 studies (see Supplementary Table S3). Srihari et al.'s (2015) examination of a US first episode psychosis service accounted for five of the moderate and large effect sizes including improvements on measures of vocational engagement, employment, unemployment (all large effect size), and on positive psychiatric symptoms and non-hospitalisation (moderate effect sizes). This study's outcomes were judged as having 'some concerns' in relation to overall risk of bias. The only other studies achieving large effect sizes were England (2007, 2008) for psychotic symptoms and psychotic symptom severity and Blank et al. (2011) for viral load in people with severe mental illness and HIV+ status. Other studies producing moderate effect sizes were collaborative care for weeks in any manic episode (Bauer et al., 2006ab), a CBT intervention for self-esteem (England et al., 2007, 2008), an integrated risk reduction intervention for reduced BMI (Frank et al., 2015), a psychopharmacology-related educational intervention for mental health nurses for treatment alliance (Harris et al., 2009), and a CBT intervention for negative symptoms of schizophrenia (Turkington et al., 2008). Of these, England's study was judged 'some concerns' in relation to risk of overall bias. Studies by Bauer et al (2006ab), and Turkington et al. (2008) were found to be at risk of bias only in relation to blinding of allocation. Studies by Bauer et al (2006ab), Harris et al (2009), Srihari et al (2015), and Turkington et al. (2008) produced one or more small effect sizes in addition to other moderate and/or large effects already mentioned. Studies by Gilbody et al. (2017), Graham et al (2016), Lee et al (2014), Holt et al (2018, 2019), Simon et al. (2005), and Turkington et al. (2006) all

produced from one to three very small or small effect sizes each, and no moderate or large differences.

Studies producing no significant between group effects at all related to an oral hygiene educational intervention (Adams et al., 2018), a telephone/ text message based support intervention for outcomes including psychiatric symptoms and medication adherence (Beebe et al., 2014); a specialist supportive intervention to enhance the therapeutic relationship with outcomes related to symptoms of mania and depression and to self-efficacy (Crowe et al., 2012); a cognitive-behavioural based medication adherence therapy intervention (Gray et al., 2006); a mental health practitioner-delivered transitional care model intervention for relapse prevention (Hanrahan et al., 2014); two lifestyle management interventions for weight loss (Holt et al., 2018, 2019; Usher et al., 2012); cognitive analytic therapy-based consultancy for nurses with relevant patient reported outcomes including psychological distress (Kellett et al., 2014); Rohricht and Priebe's (2006) trial of body-oriented therapy in which mental health nursing was the control arm but treated here as the intervention arm; a whole team behavioural and interpersonal intervention for improving personal recovery-related outcomes (Slade et al., 2015); and use of an improvement protocol checklist by nurses to improve physical health (White et al., 2018). In only eight instances did intervention arm only analyses suggest that a lack of between group significant effects was due to improvement in both the intervention and control arms, namely: a text / telephone supportive intervention for psychiatric symptoms (Beebe et al., 2016, 2017); a smoking cessation programme's effect on smoking status and nicotine dependence (Gilbody et al., 2015); adherence therapy for psychiatric symptoms (Gray et al., 2016); Harris et al's (2001, 2009) trial of medication management training for community mental health nurses for patient related outcomes (drug attitudes and psychopharmacological treatment alliance); and Turkington et al's (2008) cognitive behavioural therapy intervention for symptoms of

schizophrenia, and depression. On just three occasions analysis of control arm results – in which the control arm intervention met the study definition of mental health nurses-delivered – suggested significant positive gain: Gray et al's (2016) health education control condition for psychiatric symptoms, and outcomes related to negative and total symptoms of schizophrenia in Turkington et al's (2008) trial of cognitive behavioural therapy.

4.3.2 RCTs with participants non-severe mental illness diagnoses

Eleven studies recruited a total of $N=2,085$ individuals into experimental ($n=1,090$) and control ($n=995$) arms (Mean [SD] N per study 189.6 [186.7]). Studies were conducted in the UK ($k=6$), the US ($k=4$), and Australia ($k=1$). Interventions classified according to Omaha system (Martin, 2005) comprised case management ($k=5$) and treatments and procedures ($k=6$). Interventions in $k=7$ studies were delivered entirely by mental health nurses and in $k=4$ studies by professionals including mental health nurses. Nurses involved in intervention delivery were described as experienced ($k=9$), simply as nurses/registered nurses ($k=1$) or comprised both these categories ($k=1$). Participants were drawn from community ($k=10$), or both community and inpatient settings ($k=1$). Outcomes measures related to mental health symptomatology ($k=10$) and self-harm ($k=1$). Outcomes were measured over periods up to 3 months ($k=2$), between 3 and 6 months ($k=4$), one year ($k=5$). Mean [SD] follow-up period was 34.5 [17.5] weeks.

A total of 74 between group intervention – outcome results were extracted from 11 studies. Of these, 25 (33.8%) from $k=9$ studies (range 1 to 5 per study) indicated a statistically significant positive change for participants in the intervention group relative to a control group on at least one outcome. Two studies, accounting for 16 intervention-outcome pairings, reported no significant between group positive outcomes at all (Barley et al., 2014; Hazell et al., 2009). All 25 significant results were converted to standardised mean differences which were small ($n=11$), moderate ($n=5$) and large ($n=9$). Three of the five

moderate standardised mean differences were accounted for by studies also producing large changes, namely those by Ekers et al (2011ab), Beebe et al. (2010), and Fortney et al. (2015). The remaining two were both related to improvements in depression ratings in Chew Graham et al.'s (2013) trial of a collaborative care approach for that condition. All of the 14 moderate and large study outcomes were judged to be of some concern in relation to study bias. Seven of the studies produced statistically significant results for at least one outcome in the intervention and mental health nurse-delivered control arm where the between group analysis had indicated no significant difference. Thus, while for some outcomes between group analyses suggested no difference, within group analyses suggested this was due to improvements for individuals in both arms.

4.3.3 RCTs with participants with mixed or no mental illness diagnoses

Five studies recruited a total of $N=1274$ individuals into experimental ($n=590$) and control ($n=500$) trial arms (Mean [SD] N per study 212.3 [178.3]). White & Winstanley (2010) reported recruitment of $N=170$ patient participants but did not disclose numbers in each study arm. Happell et al (2014) did not include full details and is not included in this figure.

A further two studies (Bowers et al., 2015; Forchuk et al., 2005) were conducted on inpatient mental health units but the outcomes data was reported at unit or shift level and numbers of participants cannot therefore be determined. Studies were conducted in the UK ($k=3$), the US ($k=1$), Australia ($k=3$), and Canada ($k=1$). Interventions comprised teaching, guidance, and counselling ($k=5$), case management ($k=1$), and surveillance ($k=1$).

Interventions in $k=5$ studies were delivered entirely by mental health nurses and in $k=3$ studies by professionals including mental health nurses. Nurses involved in intervention delivery were described as experienced ($k=1$), or simply as nurses/registered nurses ($k=7$). Participants were drawn from inpatient ($k=4$), community ($k=3$), or both community and inpatient settings ($k=1$). Outcomes were measured over periods up to 3 months ($k=2$),

between 3 and 6 months ($k=3$), and one year ($k=3$). Mean [SD] follow-up period was 28.7 [21.9] weeks.

Across nine studies 22 intervention – outcome results pairings suggested statistically significant improvement in five outcomes from four studies. One standardised mean difference indicated a moderate improvement in polypharmacy prescribing in Thompson et al.'s (2008) study. A small improvement was present in one quality of life related subscale, but not in overall scores or on seven other subscales, in Forchuk et al.'s (2005) supported discharge trial; and very small effect sizes for conflict and containment reduction were calculated for Bowers et al.'s (2015) Safewards trial. We discuss the interpretation of effect sizes in the Discussion. Outcomes from studies producing significant improvements were rated as at low (Bowers et al., 2015), 'some concerns' (Thompson et al., 2008; Thompson et al., 2012), and high (Forchuk et al., 2005) risk of bias. Effect sizes were not calculable in three studies (Happell et al., 2014; Lanza et al., 2016; White & Winstanley, 2010). Lanza et al.'s (2016) study of a violence prevention community meeting for reduction of inpatient aggression actually produced results suggesting small but significant increases violence in the intervention group. In one study (Happell et al., 2009) there was a significant improvement in the staff-rated global outcome in the mental health nurse-delivered experimental study arm but, due to equal improvement in the control study arm, there was no significant between group improvement.

4.3.4 RCTs with older aged adults with dementia diagnoses and their carers

Four studies recruited a total of $N=1598$ individuals or dyads into experimental ($n=782$) and control ($n=816$) trial arms (Mean [SD] N per study 399.5 [195.1]). Average age of non-carer participants was more than 70 years. All studies were conducted in the UK. Interventions classified according to Omaha system (Martin, 2005) comprised teaching, guidance, and counselling ($k=3$) and treatments and procedures ($k=1$). Interventions in $k=1$ study were

delivered entirely by mental health nurses and in $k=3$ studies by professionals including mental health nurses. Nurses involved in intervention delivery were described as experienced ($k=1$), or simply as nurses/registered nurses ($k=3$). Participants were drawn from inpatient ($k=1$) and community ($k=3$) settings. Selected follow-up was 1 to 3 months ($k=1$), 6 to 9 months ($k=1$), and 12 months ($k=2$). Mean [SD] follow-up period was 40.3 [18.6] weeks.

Across the four studies 48 intervention – outcome results pairings indicated statistically significant improvement in five outcomes from two studies. Standardised mean differences were calculated from all five with resulting figures showing moderate satisfaction-related outcome among relatives in Hill et al.'s (2019) trial of mental health nurse delivered problem solving therapy. All other standardised mean differences were small, all related to satisfaction and found in Goldberg et al.'s (2013) trial of a specialist medical and mental health unit compared to standard care. These five outcomes were all judged to be of some concern in relation to study bias. No analysis demonstrated that lack of significant differences was due to improvements in both study arms.

4.4 Heterogeneity of study outcomes

Table 2 shows that larger proportions of statistically significant positive change were found in studies of populations with non severe mental illness diagnoses and fewest in those with older age adults and their carers. Also that significant positive change was most prevalent in studies where interventions were classified as case management approaches or as treatments and procedures.

5. DISCUSSION

The present study has updated and expanded work by Curran and Brooker (2007) which surveyed the UK mental health nursing trial research landscape in the period 1980 to 2005.

Enhancements to that groups' methodology in the current study comprise a wider casting of the net for includable studies across the Anglosphere, more fine-grained analysis of study outcomes by calculation of standardised mean differences, independent assessments of study bias, and transparent synthesis of findings according to SWiM guidelines (Sterne et al., 2020). The result is that we can confidently repeat Curran and Brooker's (2007) assertion that mental health nurses have been involved in a range of interventional research with diverse groups and in different capacities. What we are less confident about repeating is their statement that these interventions produced 'broadly positive results'.

The current review had three objectives. First, we aimed to describe the characteristics, focus, quantity, and quality of research. More than half of all trials were conducted in the UK: a high ranking would be expected given the relative populations of countries included in the study. It may be surprising, however, that the US was proportionately under-represented in second place with 34.0% of all trials. This may reflect that, along with Australia and New Zealand, the US operates a generic pre-registration training for nurses from which the student emerges as a registered nurse as opposed to a registered mental health nurse (see e.g., National Organization of Nurse Practitioner Faculties, 2003). The UK, Ireland, and Canada run specialist mental health focused programmes whose graduates are titled 'mental health nurses' (e.g., Nursing & Midwifery Council, n.d). This could potentially have led to us failing to identify relevant studies in the US, Australia, and New Zealand as being about 'mental health nurse-delivered' interventions. To mitigate against this, we applied an inclusion criteria for all studies such that interventions delivered by nurses working routinely in mental health services – irrespective of country of location – were classified as mental health nurse-delivered unless explicitly indicated otherwise. A corollary of this is that any future systematic review and meta-analysis of mental health nurse-delivered interventions will need to investigate heterogeneity across studies based on

the axis of pre-registration specialist – non specialist status. At present, the UK sets the benchmark for the volume of research into mental health nurse-delivered interventions. However, it was notable that, despite country limiters being applied during our search, our strategy still identified 47 randomised controlled trials conducted in a range of nations with Iran, Turkey, and China being most voluminous. There is an urgent need for global mental health nursing RCT evidence to be synthesised and a need for research about the transferability of interventions from other nations to the Anglosphere. Results of the current review suggested that candidate studies for systematic review and meta-analysis could be drawn on the basis of intervention type (case management or formal treatment procedures) or study population (those with severe or non severe mental illness diagnoses) since these are the only studies with sufficient volume of studies.

The quality of research was generally good overall, although risk of bias – determined using the Cochrane Risk of Bias 2 method of examining by individual outcome – was of some concern for all moderate and large effect sizes. To a large extent this was due to the lack of participant or deliverer masking, an acknowledged problem in nursing research (Polit et al., 2011). This finding reduces the certainty with which we can recommend any intervention trialled in these 51 studies, and amplifies the urgent need for future trials of mental health nurse-delivered interventions to improve in terms of rigour.

Half of the included studies ($k=25$ involving 55.8% of all participants recruited) were conducted with participants with SMI while $k=10$ (20%; involving 21.4% of all participants) recruited people with common mental disorders or who self harmed. Compared with Curran and Brooker (2007), who reported that 34.6% of studies fell into the latter category, this suggests a decrease in the proportion of trials in which mental health nurses deliver interventions to people with non-SMI diagnoses. This probably reflects that mental health nursing is by and large associated with providing services for those with the most complex

needs, especially given the growth of programmes such as Improving Access to Psychological Therapies (IAPT) in the UK where, from 2008, more than 10,000 new psychological therapists – not mental health nurses - were trained to deliver evidence-based treatment for anxiety and depression (Clark, 2018). This is, of course, a welcome development but it does accentuate the need for mental health nurses to develop effective interventions for their core client group that reflect those user's priorities. This could be a challenge given that significant findings were most likely to be identified in studies with people with non severe mental illness.

With one exception the trials included in this review were not initiated with the express intent of investigating the effectiveness of mental health nurses compared with another group. In that exception, Kendrick et al. (2005, 2006) directly compared generic and specialist mental health nurse-delivered problem-solving interventions for people with anxiety and depression with those provided by GPs finding that symptom-related change in each study arm was positive though with no superiority for any group over another. Significant benefits from both mental health nurse-provided intervention conditions relative to GPs occurred in relation to satisfaction only and were considerably more burdensome financially. Elsewhere, Holt et al.'s (2018, 2019) trial of a structured lifestyle self-management program in which mental health nurses had considerable involvement, and a control condition comprising printed advice only, had statistically significant but clinically dubious effect on weight loss among people diagnosed with schizophrenia spectrum disorders. In the US, a similar picture emerged from Simon et al.'s (2005) nurse-provided co-ordinated care package for people diagnosed with bipolar disorder with results revealing a statistically significant positive result for time spent with mania symptoms but with only modest effect size and no significant change for time spent with depression. While it is in the nature of investigative trials that positive benefits cannot be guaranteed, it may seem

disappointing that significant relative measured benefit only accrued to participants in some outcomes from only two thirds of studies and in just over one fifth of all measured outcomes. This suggests that mental health intervention researchers need to consider ways to increase the potency of the interventions they test and/or to sharpen or more carefully choose the outcomes they measure. However, there is also a need to consider what magnitude of effect we should reasonably expect and how the achieved magnitude compares with those in other fields. However, like the statistical significance statistic p , effect size is essentially arbitrary. What is deemed a 'visible' outcome will vary across fields, and effect sizes themselves vary across study designs, comparators, and intervention types (Schäfer and Schwarz, 2019). In the current study we calculated the effect size of Bowers et al.'s (2015) Safewards intervention to be 'very small' but, taken at face value, reductions of 15% to 25% in rates of conflict and containment seem substantial so caution is warranted before dismissing such findings as trivial based on this criterion alone.

Despite the ongoing paradigm-shift in the mental health nursing profession to consumer and recovery -oriented models this has, on the current evidence, yet to have filtered through to the level of trial evidence with the sole exception of Slade et al.'s (2015) REFOCUS project. Here, a measure of personally meaningful recovery was adopted as the primary outcome but anticipated gains were not made from participant self-report. This demonstrates that shifting from outcomes which focus on service priorities to those more aligned with user requirements will be challenging. Some might argue that the endeavour to measure is inherently problematic but, in our view, the need to develop properly resourced, consumer-focused mental health services is a serious, professional objective which requires serious professional approaches to establishing an evidence base about what works and for who. But, to reiterate, 'what works' is a term that must be understood to align with the users' priorities.

The current collation of trial evidence facilitates some focus on questions about the ongoing development of the mental health nursing evidence base over the past 16 years. Outside of the UK, trial research was - with the exception of the US - a rare occurrence. Given the lack of previous collation of non-UK research the current study provides a baseline only and we wait to see how trial research develops overseas. For the UK, Curran and Brooker's (2007) review of studies 1980 to 2005 using similar inclusion and exclusion criteria to our own identified 52 studies (2 per year) compared with our identification of 27 studies from 2005 to 2020 (1.7 per year). Considering that most studies identified by Curran and Brooker (2007) were published in the period 1990 to 2005, at a rate of 2.6 per year, the drop off rate is even more alarming. So, while the UK appears to lead the world in terms of volume of mental health nursing-related trial conduct, the trajectory is downwards. This is not entirely reflected in the total number of participants enrolled into trials in the periods covered by the two reviews: UK trials published 2005 to 2020 comprised studies which randomised a total of 7580 individuals (mean [SD] 291.5 [280.4] per trial discounting Bowers et al. 2015 where individual service user participants were not enumerated). Curran and Brooker's (2007) work describes trials which randomised 6352 people (122.2 per trial). Thus, in recent years in the UK, trials have become fewer in number but have recruited in greater numbers. One question requiring clarification is, therefore, what is preventing mental health nursing academics from conducting trials? Clearly, when conducted well and based on clearly articulated mental health nursing theory, interventions like Safewards (Bowers et al., 2015) show important treatment effects. Nurse-led pilot trials have also shown potential (MacInnes et al., 2016) and further reinforce the need for academe to strengthen their resolve and efforts in developing and implementing trials with user-focused outcomes.

The nature and level of mental health nursing involvement in the interventions studied in our review was, like those in Curran and Brookers (2007) original review, heterogeneous. Thus,

largely nurse-delivered interventions such as Safewards (Bowers et al., 2015) sit alongside other large studies where nursing involvement is fractional and more incidental to their profession (e.g., Woods et al., 2012; Slade et al, 2015) and studies conceived by nurses sit alongside those conceived by medics or others.

5.1 Limitations

We acknowledge a number of limitations related to the current review. The work covers only the last 16 years; however, the period from 1980 to 2005 in the UK has been previously comprehensively reviewed. Only work conducted in the core Anglosphere were included. While this is an expansion on Curran and Brookers (2007) review of UK-only studies we acknowledge this as a limitation in that trials from outside of this select group of countries may also provide good evidence. Our decision was based on a need to limit the scope of the review to a manageable size while retaining integrity in terms of the coherence of the rationale for doing so. We could conceive of no stronger candidate than language as an appropriate indicator of cultural similarity. Future reviews should consider whether to broaden inclusion scope on the basis of e.g., geographical proximity, economic level, or service similarity. Even with language as an indicator of similarity problems may still be considered present: for example, nurse-preparation in Australia is generic such that most of those nurses working in mainstream mental health service would not have a verifiable professional claim to 'mental health nurse' status as would be the case, for example, in the UK. We adopted Curran & Brooker's (2007) approach of including studies where interventions were delivered by nurses routinely working in a mental health service. On a country-by-country basis it could be argued, therefore, that some studies were included which did not merit that status. However, we made a decision that to be over-inclusive by accepting that the common understanding of a mental health nurse as it might be understood in each individual country was preferable to excluding relevant studies. We also

acknowledge as a limitation that the review was not registered in advance. At the time of the original conception of the review (2015) fewer than 10% of systematic review protocols were registered (Rombey et al., 2020).

6. CONCLUSION

Trial research remains the pinnacle of the hierarchy of clinical evidence. There are glimmers of hope that mental health nursing interventions will continue to be developed and evidenced but we should not ignore worrying signs of a decline in this field. At least in the UK a smaller number of trials was conducted in recent years compared with an apparently more vigorous field in the 1990s and early 2000s. Of concern is the small number of mental health nurse-involved trials which have measured outcomes that are explicitly identified as important to service users. Where this has happened (e.g., Slade et al., 2015) the anticipated recovery-related benefits were not demonstrated. It is important for mental health nurse academics to develop interventions with user-focused outcomes which sit within well-articulated and well-tested mental health nursing theoretical frameworks. Our analysis suggests that the effects achieved by mental health nurse-delivered interventions are equivalent to those in fields such as psychology and this is a promising finding to build on.

7. RELEVANCE TO CLINICAL PRACTICE

Mental health nurses have access to some interventions that have been trialled in well-designed contemporary studies with positive results, but the range is limited. This poses a potential threat to mental health nursing as a distinct and evolving profession. Currently, nurses working in mental health settings who strive towards evidence-based practice will need to look beyond gold standard RCT evidence, or to evidence for interventions that have not necessarily been delivered by mental health nurses. Mental health nurses need to be honest and realistic about the volume and strength of evidence that supports their practice, to

adopt good evidence into practice where it does exist, and clearly articulate the gaps in order to inform debate about research priorities.

Accepted Article

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Mental health nurse-delivered interventions - RCTs

Table 1: RCTs involving mental health nurse delivered interventions

Study	Design	Population/ Sample randomised	Interventions and MHN involvement	End-point weeks
a. People diagnosed with severe mental illness				
Adams et al (2018) UK	Pragmatic, open cluster RCT	N= 1248 patients from early intervention psychosis teams.	Oral health care checklist delivered by experienced clinicians ('mostly nurses') Vs. Treatment As Usual (TAU) by clinical team (including nurses)	52
Bauer et al (2006ab) US	Randomised effectiveness trial	N=330 patients hospitalised for bipolar disorder randomised at discharge	'Collaborative care intervention clinic': specialty team comprising psychiatrist and nurse care coordinator. No afterhours care, all manualised care, psychoeducation, clinical guidelines Vs. Usual care	156
Beebe et al (2011) US	RCT	N=97 outpatients with schizophrenia spectrum disorders (SSD)	<u>W</u> alk, <u>A</u> ddress sensations, <u>L</u> earn about exercise, <u>C</u> ue exercise behaviour for <u>S</u> SDs (WALC-S) MHN-delivered motivational group intervention to increase exercise behaviour + 16-week walking group. Vs. Time and attention health behaviour group + 16 -week walking group	13
Beebe et al (2014) US	RCT	N=30 patients with SSD allocated equally to 3 conditions	Daily MHN-delivered text message reminders (TXT) Vs. Weekly telephone intervention problem solving for SSD (TIPS) (manualised protocol and delivery by MHNs) Vs. TXT + TIPS	13
Beebe et al (2016, 2017) US	RCT	Outpatients with SSD. N=185.	TIPS see Beebe et al. (2014) Vs. TAU (medication-related follow-up appointments with psychiatrist and case manager. No evidence of MHN involvement)	26
Blank et al. (2011) Hanrahan et al. (2011) US	Longitudinal RCT	N=238 people with Severe Mental Illness and HIV+	52-week nursing intervention (weekly meetings, assessment, care-planning, co-ordination). Delivered by Masters level advanced practice MHNs (M=16.5 years experience) Vs. TAU (No evidence of MHN involvement)	52
Crowe et al. (2012) New Zealand	Pragmatic RCT	N=78 adults with bipolar disorder receiving Community Mental Health Team support	Specialist supportive care to develop adherence-promoting therapeutic relationship. Delivered by 2x Community Mental Health Nurses supervised by experienced therapist +TAU Vs. TAU ('Usual psychiatric and nursing care')	39
England (2007, 2008) US	RCT	N=65 individuals with schizophrenia/schizo-affective disorder	Cognitive nursing intervention 12 sessions delivered by experienced graduate MHN + TAU ('Healthcare providers routine use of communication strategies while providing psychiatric or primary care services including medication') Vs. TAU	54
Foster & Jumnoodoo (2008) UK	Longitudinal randomised design	N=20 attendees with a history of relapse to SMI at one day hospital	8-week relapse prevention group delivered by author (MHN) Vs. TAU (monitoring and supervision in a community-based mental health day hospital (including nurses).	52
Frank et al (2015) US	Randomised trial	N=122 people diagnosed with bipolar disorder	Integrated risk reduction i) treatment by study psychiatrist; ii) assessment, referral, monitoring and co-ordination by nurse practitioner OR psychiatric research nurse (PRN) iii) Healthy lifestyle program. Nurses were graduate/postgraduate MHNs with bipolar expertise in bipolar. Vs. Psychiatric Care with Medical Monitoring (i) psychiatric treatment by a study psychiatrist; (ii) assessment and referral for primary care medical treatment+ TAU (No MHN involvement)	26
Gilbody et al (2015) UK	Pilot pragmatic two-arm parallel group RCT	N=97 smokers 18+ with SMI and interest in cutting down.	MHN-delivered bespoke smoking cessation + TAU Vs. TAU (advice on accessing NHS smoking cessation services including NHS Quitline telephone service, usual GP and mental health team care)	52
Gilbody et al (2019) UK	Pragmatic randomised controlled trial	N=526 smokers 18+ with SMI and interest in cutting down.	MHN-delivered bespoke smoking cessation + TAU Vs. TAU (advice on accessing NHS smoking cessation services including NHS Quitline telephone service, usual GP and mental health team care)	52
Graham et al (2016) UK	Pilot random-ised trial	Adults with diagnoses of schizophrenia spectrum, bipolar or recurrent depressive disorder, newly admitted and with history of substance/alcohol misuse (N=59)	Brief Integrated Motivational Intervention: manualised cognitive therapy delivered by inpatient unit staff including nurses + TAU Vs. TAU (nursing and medical staff)	13
Gray et al (2006) UK	Single blind RCT	N=409 people with SSD on antipsychotic medication for 12 months and clinical instability.	8-session Adherence Therapy a brief individual cognitive-behavioural approach aimed at joint decision making. Vs. 8-session health education control condition. Both delivered by same team (2 MHNs, 4 psychologists, 3 Psychiatrists).	52

Mental health nurse-delivered interventions - RCTs

Study	Design	Population/ Sample randomised	Interventions and MHN involvement	End-point weeks
Hanrahan et al. (2014) US	RCT	N=40 acute mental health inpatients with SMI and a major medical condition (diabetes, cancer, asthma).	Specialist MHN Practitioner delivered 12-week transitional care model-intervention. Nurse available 24/7 and has prescribing powers. Helps manage physical symptoms by accompanying person to appointments, promotes adherence. Mean 48 contacts per person Vs TAU (No specific MHN involvement)	13
Harris et al., (2001, 2009) UK	Cluster RCT	People with schizophrenia diagnosis (N=169). Drawn from caseloads of N=56 CMHPs	10-day medication management training programme for CMHPs who subsequently had contact with service users + monthly individual supervision Vs. Training waiting list, usual CMHP care	39
Holt et al. (2018, 2019) UK	Two-arm, analyst-blind, parallel-group RCT	People with first episode psychosis, schizophrenia, or schizoaffective disorder (N=412).	Four weekly group-based, structured lifestyle self-management education sessions, fortnightly support contacts, three booster sessions (Of 220 sessions 162 (71%) included a MHN + TAU Vs. TAU (Printed advice on lifestyle and the risks associated with weight gain.)	52
Kellett et al (2014) UK	Randomised controlled design	Assertive outpatient team (AOT) patients with schizophrenia diagnosis N=20 .	Intervention: Cognitive analytic therapy (CAT) consultancy (training team in CAT, consultancy sessions with individual team members, team supervision) [Training delivered by non-MHNs to the AOT which comprised MHNs, social workers, medics, and support staff] Vs. TAU (No consultancy sessions)	52
Lee et al. (2014) US	Randomised experimental design	Individuals with SMI and receiving psychotropic medicine N=22	Intervention: Education on brisk walking for 30-min daily plus weekly phone call, pedometers. Delivered by MHN PI (MHN) Vs. Written information about physical activity.	8
Rohricht & Priebe (2006) UK	RCT	Outpatients with SSD (N=45).	MHN-delivered Supportive Counselling + TAU. Vs. Body-oriented psychological therapy delivered by dance therapist + TAU. Both groups 20 x 60-90 min sessions over 10-weeks.	16
Simon et al. (2005) US	Random-ised trial	N=441 people diagnosed with bipolar disorder.	Assessment, care planning, telephone monitoring, feedback to treatment team, structured group psychoeducation. Provided by trained nurse care managers with minimum 5-yr experience) Vs. TAU	52
Slade et al (2015) UK	Cluster RCT	27 mental health teams and N=403 patients with primary diagnosis of psychosis	REFOCUS 1-yr whole team intervention comprising behavioural and interpersonal components. All teams multidisciplinary including MHNs (13/139 REFOCUS and 16/127 TAU patients had used an MHNs services in 6-months prior to baseline) Vs. TAU	52
Srihari et al (2015) US	Pragmatic Randomized Controlled Trial	Individuals aged 16 to 45 years within 5-years of onset of a psychotic illness (N=120).	STEP. Patients chose from a menu of options: psychotropic prescription, family education, CBT, case management for employment and educational support. Delivered by a team including nurses. Vs. TAU. (unclear MHN involvement)	52
Turkington et al (2006) UK	RCT	Adults (N=343) with schizophrenia diagnosis from inpatient/ outpatient settings.	Insight into schizophrenia program using Cognitive Behaviour Therapy (CBT) and psychoeducation (6-sessions per patient). Delivered by MHNs (only one with a higher qualification in CBT) Vs. TAU (normal care plan as organised by community keyworker)	52
Turkington et al. (2008) UK	RCT	Patients (N=90) with diagnosis of schizophrenia with persistent symptoms	CBT Vs Befriending. Both 20 sessions and delivered by one of two experienced MHNs trained in CBT	260
Usher et al (2012) Australia	RCT	N=101 people with serious mental illnesses for which second generation antipsychotics are usually prescribed	'Passport 4 Life': Education and discussion intervention. 12 weekly x 1-h sessions focused on healthy eating, exercise, motivation plus 30-min exercise activity. Sessions conducted by experienced mental health nurses. Vs. TAU (Unclear MHN involvement)	12
White et al (2018) UK	Single-blind, cluster-RCT	Patients of MHNs working in CMHTs with SMI. Intervention (N=170).	Health Improvement Profile: CMHN-delivered following 3-h training; manualised approach to enhancing general medical wellbeing of patients with SMI through 27-item health check. 27 addressing common problems + TAU Vs. TAU (Includes psychiatric assessment and review, case management, psychotropic medication, and nursing care	52

Mental health nurse-delivered interventions - RCTs

Study	Design	Population/ sample randomised	Interventions and MHN involvement	End-point weeks
b. People diagnosed with non severe mental disorder				
Barley et al. (2014) UK	Randomised Controlled Pilot Study	Adults with symptomatic Coronary Heart Disease (e.g. chest pain) and depression <i>N</i> =81.	Intervention: Provided by one of two case managers (one was an adult nurse and health psychologist and one an adult and mental health nurse). Personalised Care case manager conducts face-to-face assessment, patients identify important issues contributing to depression and care manager provides information, signposting to services and uses behaviour change techniques. Follow up telephone calls + TAU Vs. TAU: Care from GP and practice nurse.	52
Beeber et al. (2010) US	Randomised test [of] efficacy	Newly immigrant Latina mothers of infants and toddlers in Early Head Start services <i>N</i> =80.	In-home, culturally-tailored Interpersonal psychotherapy delivered by English-speaking trained MHNs with Master's degrees with an interpreter Vs. Closely monitored TAU condition. Unclear MHN input. Both duration: 22-weeks plus 4-weeks follow up.	26
Beeber et al. (2013) US	Randomised, two-group, repeated measures design	Mothers (<i>N</i> =226) with depressive symptoms and their infants enrolled in Head Start programs.	Brief, personalised IPT modules written in vernacular. Ten face-to-face in-home assessments and 1-month booster telephone calls Vs. Attention Control (sessions of same duration) + TAU. Unclear MHN input.	26
Chew-Graham et al. (2007) UK	RCT	People >60 years old, depressed in primary care <i>N</i> =105.	Collaborative care approach for depression management with regular access to old age psychiatrist every 4 weeks. Community Psychiatric Nurse acting as care co-ordinator delivered intervention Vs. TAU (No MHN involvement)	16
Cullum et al. (2007) UK	Pragmatic RCT	Acute medical admissions (<i>N</i> =121) age 65+ in medical hospital 3-6 days with possible depression	TAU+ Liaison Psychiatric Nurse assessed patients, formulated care plan and liaised with medical team, primary care and social services. Monitored mood, mental state and treatment response for 12-weeks Vs. TAU (No MHN involvement). Usual medical care including referral if depression recognised	12
Ekers et al. (2011ab) UK	Pragmatic RCT	<i>N</i> =47 adult users of GP or primary care mental health services with depression diagnosis.	Behavioural activation over 12 x 1-hour sessions delivered by two MHNs with no previous formal therapy training Vs. TAU. Unclear MHN involvement. Followed up by GP or primary care mental health worker	13
Fortney et al (2015) US	Pragmatic randomised effective-ness trial	US army veterans with PTSD diagnosis (no psychosis or substance use comorbidity) and receiving care at veterans' health clinic <i>N</i> =265.	Telemedicine-based Outreach for PTSD . PTSD care teams based in veterans' medical centres supporting small community-based outpatient clinics: i) primary care providers; ii) PTSD telephone-nurse care managers; iii) telephone clinical pharmacists; iv) interactive video psychologists; v) interactive video psychiatrists Vs. Usual Care (unclear MHN involvement)	52
Gilbody et al (2017) UK	RCT	Older adults (65+) from primary care practices reporting sub-threshold depression <i>N</i> =705.	Program of collaborative care delivered (by a case manager with a background in mental health nursing or a graduate psychologist) in 8 weekly sessions (1 face-to-face then telephone). Telephone support, symptom monitoring, brief psychological intervention of behavioural activation Vs. TAU (Usual primary care)	52
Hazell et al (2009) Australia	Randomised Trial	Individuals 12-16 year old referred to CAMHS with at least two episodes of self-harm in past 12-mos. <i>N</i> =72.	CBT-informed group intervention with social skills and psychotherapy elements 6 x 1-h sessions and option for attendance at longer term group. Delivered by clinicians from participating sites who were qualified psychologists, clinical psychologists, social workers or nurses Vs. Routine CAMHS care	52
Kendrick et al (2005, 2006) UK	Pragmatic three-arm RCT	People with common mental disorders (<i>N</i> =247)	Generic MHN care (up to 6-sessions comprising their application of clinical judgement) Vs. Care from MHNs specialist trained in problem solving treatment (up to 6-sessions) Vs. GP care (TAU no MHN involvement)	26
Peden et al. (2005) US	Randomised Controlled Prevention Trial	Low-income single mothers with depressive symptoms/negative thoughts (<i>N</i> =136)	4-week Group intervention for negative thought reduction. CBT-informed. Delivered by psychiatric nurses with experience in leading groups Vs. Usual care (unclear MHN involvement)	52

Mental health nurse-delivered interventions - RCTs

Study	Design	Population/ sample randomised	Interventions and MHN involvement	End-point weeks
c. Mixed groups of patients and those with no psychiatric diagnosis				
Bowers et al. (2015) UK	Pragmatic cluster RCT	Patient/ staff conflict and containment events on acute psychiatric wards (k=31)	Safewards :10 theory-based nursing interventions. Ward nurses trained in interventions by research team. Vs. Nurse-delivered healthy lifestyle intervention	24
Forchuk et al (2005) Canada	Cluster randomised trial	Patients in wards in 4 hospitals. N=390.	Transitional discharge model to facilitate relationship between ward and community care provider plus peer support for 1-y. All staff given 12-h training Vs. TAU with usual nursing input	52
Happell et al (2009) Australia	Random assignment	Clients(N=103) of a mental health crisis assessment and treatment team.	Nurse practitioner candidate (employee in a mental health team) initiated planning and treatment. Intervention for experimental group 7-days then transfer to TAU. Vs. TAU (No MHN involvement)	1
Happell et al. (2014) Australia	RCT	Adults attending a community mental health service N=11	TAU by mental health team Vs. Consultations with cardiometabolic health nurse (not MHN)	26
Lanza et al. (2016) US	Cluster random-ised trial	Patients in wards in 7 units.	Violence prevention community meeting by ward nursing staff 3x-daily for 21-weeks Vs. TAU by ward team including nurses	21
MacInnes et al (2016) UK	Pilot cluster RCT	N=112 patients from 6 forensic units.	6-mo structured communication approach DIALOG. Monthly patient-nurse meetings involving computer-mediated approach and nondirective counselling. Delivered by ward nurses trained in DIALOG technique Vs. TAU Usual care involving nurses	52
Thompson et al (2008) UK	Pragmatic cluster random-ised controlled trial	Patients on acute psychiatric unit N=555.	Multi-faceted intervention to change prescribing behaviours of clinical staff (academic detailing with doctors, educational and CBT-informed workbook for ward doctors (N=88) and nurses (N=218), medication chart reminder system and evidence-based polypharmacy guideline Vs. Evidence based polypharmacy guideline only for 168 nurses and 81 doctors	22
Thompson et al (2012) US	Randomised control pilot study	N=19 adults (18 to 66 years) with a diagnosis of non-epileptic seizure.	'Reframing' approach (40 –90-min interview) to diagnosis of non-epileptic seizure to help them understand and accept (MHN delivered). Vs. Unclear	8
White & Winstanley (2009, 2010) Australia	Cluster RCT	Patients of nurses working in 17 adult MH facilities in 9 locations (N=170).	4-day Clinical supervision training for nurses on experimental wards. Those trained in clinical supervision provided supervision to nurses in their workplaces Vs. TAU by ward team	52
d. Older aged adults and their carers				
Goldberg et al (2013); Tanajewski et al (2015) UK	RCT	Older adults (65+) in acute medical care and identified as 'confused' by physicians. N=600.	Medical and mental health unit. 28-bed specialist unit employing specialist mental health staff including three nurses, occupational therapist and sessional psychiatrist. Staff trained in management of delirium and dementia. Environment appropriate to confusion. Vs Standard care (geriatric or general medical wards. Unclear MHN involvement.	13
Hill et al (2019) UK	RCT	Patients (N=300) admitted to medical wards with first or recurrent stroke. Median age 72 years.	Problem solving manualised therapy from a psychiatric nurse (6-sessions + homework) Vs. Non-specific support by volunteers. Vs. TAU.	52
Moniz-Cook et al. (2008) UK	Exploratory pragmatic RCT	N=113 dyads (informal carer and patient) dementia patients with an informal carer not urgently referred for inpatient care. Mean age 77.2 years.	Psychosocial intervention for carers. Four consecutive weekly in-home visits plus clinical judgment about future contact. CMHN-delivered involving 9 nurses who received training (selected by management) Vs. 20 CMHNs providing usual care and not selected for training	52
Woods et al. (2016) UK	Pragmatic Multi-Centre Randomised Trial	N=488 dyads (informal carer and patient) community dwelling people with mild to moderate dementia and a relative or carer in regular contact. Mean age 77.4 years.	Joint reminiscence groups of up to 12 dyads weekly for 12-w and monthly for 7-mos held in community centres. Two facilitators led each session each from a variety of professional backgrounds, and included occupational therapists, mental health nurses, clinical psychologists, arts workers and community support workers. Vs. TAU (access to any other usual services. MHN involvement unclear)	44

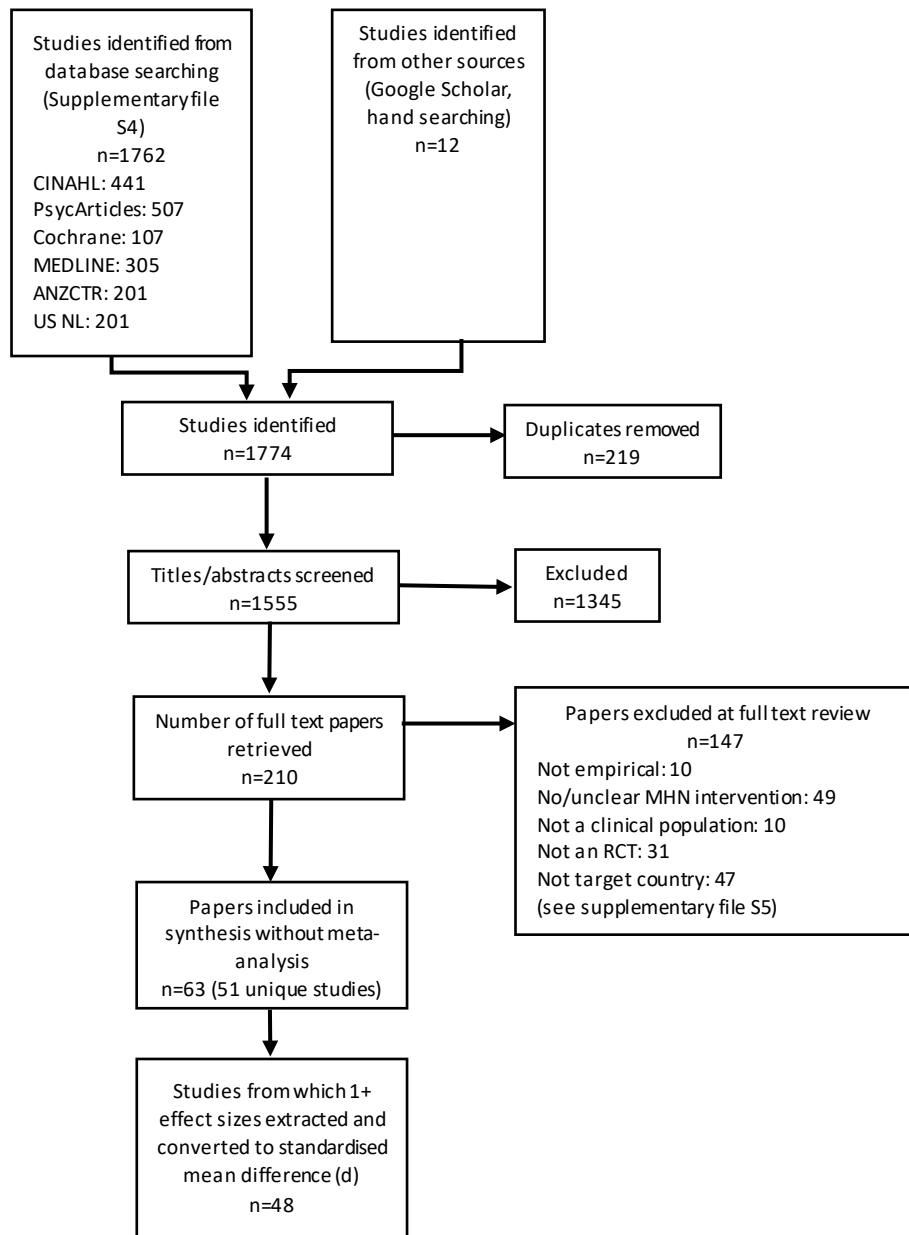
Mental health nurse-delivered interventions - RCTs

Table 2: Summary of significance and effect sizes by study population and intervention type

Population	n outcomes significant/ Noutcomes	Significance and effect size																											
		Case management						Surveillance						Teaching, guidance & counselling						Treatments & procedures									
		Not significant	Very small	Small	Moderate	Large	Significant only	Significant decline	Not significant	Very small	Small	Moderate	Large	Significant only	Significant decline	Not significant	Very small	Small	Moderate	Large	Significant only	Significant decline	Not significant	Very small	Small	Moderate	Large	Significant only	Significant decline
Severe mental illness	43/212 (20.3)	32	2	12	4	4	0	1	5	0	0	0	0	0	0	106	2	2	0	0	4	4	21	2	5	3	2	1	0
Non severe mental illness	25/73 * (34.2)	25	0	6	3	3	0	0	-	-	-	-	-	-	-	-	-	-	-	-	-	23	0	5	2	6	0	0	
Mixed/ none	4/24 (16.7)	1	0	0	0	0	0	0	4	0	0	0	0	0	0	15	2	1	1	0	0	0	-	-	-	-	-	-	
Older age and carers	1/39 * (2.6)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	31	0	0	1	0	0	0	7	0	0	0	0	0	
Totals	73/348 (21.0)	58	2	18	7	7	0	1	9	0	0	0	0	0	0	152	4	3	2	0	4	4	51	2	10	5	8	1	0
		34/93 (36.6)**						0/9 (0.0)						9/169 (5.3)**						26/77 (33.8)**									

*P<.01 **P<0.0001 N.B. Significant only = result indicating statistically significant result but outcome effect size non calculable. All categories refer to positive significant change except not significant and significant decline.

Figure 1: PRISMA flow diagram



Where studies comprised three groups the two compared groups are indicated in parentheses. Except where indicated * outcomes measures were continuous.