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Effectiveness of a peer mediated educational intervention in improving general practitioner diagnostic assessment and management of dementia: a cluster randomised controlled trial

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9 **Effectiveness of a peer mediated educational intervention in improving general**
10 **practitioner diagnostic assessment and management of dementia: a cluster**
11 **randomised controlled trial**
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ABSTRACT

Objective To test the effectiveness of an educational intervention for general practitioners in improving detection and management of dementia, and quality of life outcomes for patients and carers.

Design Double blind, cluster randomised controlled trial.

Setting General practices in Australia between 2007 and 2010.

Participants General practices were randomly allocated to the waitlist (n=37) or intervention (n=66) group, in a ratio of 1:2. A total of 2,030 (1478 intervention; 552 waitlist) community dwelling participants aged 75 years or older were recruited via 168 GPs (113 intervention; 55 waitlist).

Interventions A practice-based medical detailing intervention led by a peer medical or nurse educator that included (i) training in use of the General Practitioner assessment of Cognition (GPCOG) dementia screening instrument, (ii) training in diagnosis and management based on Royal Australian College of General Practitioners (RACGP) Dementia Guidelines, using a case based approach (iii) identifying and addressing general practitioners' (GPs') perceived barriers to dementia diagnosis, and (iv) a business case outlining a cost effective dementia assessment approach for the practice.

Main Outcome Measures Compared with a baseline pre-intervention audit (i) Sensitivity and specificity of GP identification of dementia, (ii) referral to appropriate services and/or medical specialists for memory problems (iii) patient and carer quality of life, depression and satisfaction with care (specifically communication and enablement).

Results At one year, the educational intervention had improved the sensitivity of GP judgment of dementia ($p=0.002$; odds ratio 6.0, 95% CI: 1.92-18.73), satisfaction with GP communication for all patients ($p=0.024$; odds ratio 2.1, 95% CI: 0.27-3.93) and for patients with CAMCOG-R dementia ($p=0.007$; odds ratio 7.44, 95% CI: 2.02-12.86) and enablement of carers ($p=0.0185$; odds ratio 24.77, 95% CI: 4.15-45.40). The intervention had no significant effect on diagnostic specificity, management of dementia, or patient and carer quality of life.

Conclusion Practice based medical detailing improved detection of dementia in primary care, patient satisfaction with GP communication and enablement of carers.

Trial Registration ACTRN12607000117415

Strength and Limitations

- Individual and contemporaneous home assessments were completed for each participant, rather than relying on administrative data such as GP records.
- The educational intervention was specifically designed to address a number of identified barriers to GP identification and management of dementia and was also personalised to each GP.
- Evaluation measures included not only detection and management of dementia, but also patient and carer outcomes, thus capturing the last (and essential) translational output from the intervention.
- Findings relating to carers must be interpreted with caution due their relatively high (and differential) loss to follow-up.
- GP learning was not directly measured, and the adherence to dementia guidelines was assessed by self-reporting of dementia related tests and referrals by GPs.

INTRODUCTION

Dementia is a complex and variable condition which affects cognition, behaviour and the person's ability to perform everyday tasks. The number of people living with dementia worldwide is currently estimated at 46.8 million. This number is expected to double by 2030 and almost triple by 2050, due to the increasing longevity of the world population [1].

Timely diagnosis and management of dementia is desired by many patients with dementia and their carers [2-4], to improve their access to interventions and support at the most appropriate time [5]. Diagnostic disclosure of memory problems is associated with better physical and environmental quality of life (QoL) in people with dementia [6], and is not associated with poorer health-related QoL [7]. A timely diagnosis may help people with dementia, and their carers, understand and cope with the challenging symptoms of dementia, fulfil short-term goals and facilitate planning for the future while they are still competent to do so [8, 9]. Referral can be made for social support services and specialist treatments, including anti-dementia medications that may slow the course of cognitive decline. Studies have shown that general practitioners fail to identify about 50% of mild dementia cases in the community [10-12] and demonstrate gaps in recorded diagnostic processes against guidelines[13].

There are a number of barriers to diagnosis of dementia that can be attributed to the patient or carer, the general practitioner (GP) or systemic factors [14, 15]. The gradual decline in functional ability in the early stages of dementia can be attributed to 'normal' aging, not only by the person with the condition or those close to them, but also by their GP [16-18]. The stigma associated with dementia may delay help seeking [19]. Only one in five people who mention memory problems to their GP have dementia [12], so the GP may choose to observe such a patient, rather than proceeding early to an expensive and alarming diagnostic assessment. Other GP-related barriers to early diagnosis include lack of knowledge [9] and/or confidence [16, 17, 20-23], the reality that dementia diagnosis is difficult due to slow and fluctuating onset and overlap of symptoms with other diseases, lack of a definitive diagnostic test[22], and the

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3 perception of dementia diagnosis as a specialist domain [24]. No medication exists which will
4 effectively reverse or halt the progress of these disorders, and GPs may not conceptualise social
5 and system support for ongoing cognitive decline as therapeutic; nihilism may also hinder
6 diagnosis and management [25].
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11 An intervention aimed at overcoming patient barriers to dementia diagnosis resulted in more
12 patients presenting to their GP with memory problems, but no increase in diagnoses [26].
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15 GPs' detection and management of dementia have been addressed in several educational
16 interventions with varying success [15, 27-31]. Large seminar-based interventions have limited
17 effectiveness [25], however educational interventions that incorporated active small-group
18 learning tasks, resulted in improved detection of dementia [30, 31]. The most effective
19 educational strategies appear to be those delivered in the context of a coordinated dementia
20 case management setting[28], and designed to target the specifically determined barriers for
21 individual practitioners [15, 32].
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31 The objective of this study was to determine the effectiveness of an educational intervention
32 that included a peer outreach detailing visit to each practice, using model cases to illustrate case
33 identification and management, and designed to address individual GP needs. The barriers to GP
34 diagnosis and management of dementia addressed were: the limited time available for
35 consultation, lack of relevant knowledge and attitudinal factors. Further discussion with the GP
36 elicited and addressed any additional barriers. Primary outcomes were patient focussed (QoL
37 and depression scores); secondary outcome measures included GP and carer factors.
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METHODS

Study Design

This study (the AGP trial) was a cluster randomised trial with a 12 month follow-up. A parallel design was employed. Practices with participating general practitioners (GPs) were randomly allocated in a ratio of 2:1 to either an intervention or waitlist group. Intervention practices (n=66) received a dementia related educational peer outreach visit, and completed two patient audits with feedback. Waitlist practices (n=37) completed two audits without feedback and were mailed the then-current Royal Australian College of General Practitioners (RACGP) Dementia Guidelines at 12 months [33]. The rationale and study design have been reported in detail previously [34].

Participants

Practices eligible for inclusion in the study were located within 30km of each urban study site headquarters (Sydney, Newcastle, Melbourne, Adelaide) or from the rural study site of Bendigo or its surrounding towns; had community dwelling patients aged ≥ 75 years; and used a computerised patient database. GPs that had been involved in development of the project were excluded. The cluster randomisation has been described elsewhere [34]. Briefly, a list of all eligible practices was compiled and sent to an independent party, the Centre for Epidemiology and Biostatistics at the University of Newcastle (CCEB), for randomisation. CCEB provided the approach order for the practices; a project nurse or GP visited each practice to explain the project and recruit GPs prior to allocation of the practice to intervention or waitlist. Practices were stratified by site, and by size of practice as either standard or large (>7 GPs working in the practice), and then allocated to intervention or waitlist in a ratio of 2:1 in randomly rotated blocks of 3 and 6. Of the 2,800 GPs approached, 168 (6%) entered the study. This sample was representative based on comparison with demographics of all active recognised GPs in Australia [35].

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3 GPs sent letters of invitation to all patients who met the inclusion criteria, inviting them to
4 participate in the study. Those who agreed to participate responded by returning a consent form
5 to the local study site. Patients eligible for inclusion in the study were aged ≥ 75 years, had
6 visited their GP within the last 24 months, and were able to speak and understand English. The
7 exclusion criteria were Parkinson's disease, multiple sclerosis, motor neuron disease, central
8 nervous system inflammation, psychotic symptoms prior to recruitment, developmental
9 disability, progressive malignancy or substance abuse, too sick to complete the study, or
10 resident of aged care facility at entry to the study.
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19 Carers of patients were eligible for the study if they had been identified as a carer or support
20 person by a patient scoring <80 on the revised Cambridge Cognitive Examination (CAMCOG-R)
21 [36], had prior consent from the patient with dementia for his/her carer to participate and were
22 able to speak and understand English.
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28 *Intervention*

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30 The intervention in this study consisted of an educational session conducted at each GP's
31 surgery by a trained peer medical or nurse educator. The session was conducted after
32 completion of the baseline audit of patients by the GP, and included (i) instruction in the use of
33 the General Practitioner assessment of Cognition (GPCOG) dementia screening instrument [37],
34 (ii) an interactive presentation on dementia diagnosis, diagnostic workup and management
35 based on the RACGP Dementia Guidelines[33], (iii) an exploration of the GP's perceived barriers
36 to dementia diagnosis, and (iv) a business case outlining the cost recovery potential of dementia
37 assessment in terms of the Australian government's Medicare Benefits Schedule. The systemic
38 issue of lack of time in the GP consultation was addressed by training the GPs in the use of a brief
39 screening instrument and by discussing potential methods of obtaining assistance from the
40 practice nurse. Case studies were used to illustrate appropriate management. A second audit
41 was held at 12 months, after which results of the nurse assessment were fed back to the GPs.
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3 mailed a written summary of their patient's home assessment and the RACGP Dementia
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5 Guidelines after completion of the 12 month audit.
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8 9 *Data Collection*

10 At baseline, waitlist and intervention GPs received a list of their participating patients to audit.
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12 This audit task required GPs to provide their clinical judgement in relation to each patient's
13
14 dementia status using one of four options: No Dementia, Possible Dementia, Probable Dementia,
15
16 Definite Dementia. GPs completed a supplementary audit for any patients with possible,
17
18 probable or definite dementia to gather data on memory related tests and investigations
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20 performed (i.e. paper and pencil test for cognition or depression; pathology; radiology) and
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22 referrals to services and specialists. Differential diagnosis and identification of reversible causes
23
24 were also requested. This audit was repeated at 12 months. Although GPs were aware that there
25
26 were intervention and waitlist groups, they were not aware of the nature of the intervention,
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28 and indeed both groups participated in the audit. We therefore consider that GPs were blinded
29
30 to the group allocation for the entirety of the study.
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34 Patient and carer assessments were conducted at their home by a research nurse at baseline and
35
36 12 months. Information was collected from patients and carers relating to their personal and
37
38 social circumstances including socioeconomic status using the Index of Relative Social
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40 Advantage and Disadvantage (IRSAD) [38], quality of life, depression and satisfaction with GP
41
42 care. The cognitive function of patients was assessed using the GPCOG and CAMCOG-R. All
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44 nurses were trained in administration of each instrument and adhered to a standardised
45
46 interview protocol to minimise interviewer bias. The specific patient characteristics collected
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48 and the instruments and criteria used have been described previously [6, 12]. If requested by the
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50 GP, the nurse also conducted a "75+ Health Assessment", an item that can be rebated under the
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52 Australian Medicare system. These data were not used by the study, but were returned to the GP
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54 for his or her use. Research nurses and patients were blinded to the group allocation for the
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56 entire study.
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3 At the completion of the baseline assessment, each patient received a letter prepared by the
4 project manager, directing them to obtain an appointment with his/her GP. Patients in the
5 waitlist group, were seen by their GP to review their 75+ Health Assessment only. For patients
6 in the intervention group, the GP followed up on the 75+ Health Assessment, re-administered
7 the GPCOG and provided care in the light of their recent education. Results of the GP-
8 administered GPCOG were forwarded to the local study site headquarters. GPs were not
9 informed of the outcome of the research nurse assessment until after the 12 month audit
10
11 Following their GP visit, patients and carers in the intervention group were asked to complete a
12 short satisfaction survey regarding the use of the GPCOG by their GP. The survey was returned
13 immediately to administrative staff at the GP surgery or to the study team via a reply-paid
14 envelope.

25 26 *Study Outcomes*

27 The outcome measures (collected at baseline and 12 months) used to examine the effect of the
28 educational intervention were:
29

30 31 *Primary Outcomes*

- 32 • World Health Organization Quality of Life Instrument (WHOQoL-BREF) scores for
33 patients [39] (higher score indicative of higher quality of life)
- 34 • Geriatric Depression Scale (GDS) [40] scores for patients (score greater than five
35 indicative of depression)

36 37 *Secondary Outcomes*

- 38 • sensitivity and specificity of the second GP audit (prior to feedback on the first audit) for
39 dementia compared with the revised Cambridge Cognitive Examination (CAMCOG-R), a
40 brief neuropsychological test battery from The Cambridge Examination for Mental
41 Disorders of the Elderly [36]. (score of <80 determined as indicating dementia for this
42 study)
- 43 • the number of GP reported test types (pathology, pencil-and-paper, imaging) and
44 referrals (specialist and support services) related to dementia,
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- WHOQoL-BREF scores for carers,
- Beck Depression Inventory (BDI) [41] scores for carers (higher total scores over 13 indicative of more severe depressive symptoms),
- General Practice Assessment Questionnaire Version 2 (GPAQ) [42] scores for patients and carers. The GPAQ domains utilised in this study were related to GP communication (8 questions) and patient enablement following consultation with their GP (3 questions). Mean domain scores were transformed into a percentage of the maximum possible score, with higher scores indicative higher satisfaction or enablement.
- GP identification of differential diagnoses
- GP identification of reversible causes of dementia
- acceptability of memory screening using the GPCOG

Due to the low reporting of differential diagnoses or treatment of reversible causes of dementia by GPs at baseline and 12 months, the effect of the intervention on these secondary outcome measures [34] could not be evaluated.

Sample Size

It was calculated that 45 patients with dementia in each group (waitlist and intervention) would give a power of 0.9 to detect a 7% difference between the change in pre and post scores on any of the four domain scales of the WHOQOL-BREF with a type 1 error of .05. Clustering within each GP was discounted, as each GP was not expected to have many patients in the study, but consideration was given to cluster correlations of patients within a GP practice. An intra-class correlation coefficient of 0.05 and an average cluster size of 5 patients with dementia in a practice, were used to calculate a design effect of 1.45 and a total sample size of 54 patients per group. Therefore in order to allow comparison of outcomes between the waitlist and intervention groups overall we aimed to recruit 168 participants with dementia (56 patients in the waitlist group; 112 in the intervention group). This sample size also allowed comparisons

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3 within the intervention group, related to the benefits and acceptability of a screening or a case
4 finding approach to dementia diagnosis (to be reported separately). We allowed for a 15% drop
5 out over a 12 month period in this elderly patient group. Thus, based on a dementia prevalence
6 of approximately 10% in over 75 year old Australians, we aimed to recruit a total of 2,000
7 participants.
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12 *Statistical Analyses*

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14 Sensitivity of the GP's diagnosis was calculated as the percentage of patients that the GP
15 correctly classified as having dementia. Specificity was calculated as the percentage of patients
16 that the GP correctly classified as not having dementia. The difference in sensitivity of GP
17 diagnosis of dementia between the waitlist and intervention groups was tested by fitting a GEE
18 model (specifically a Logistic Regression) to the population with CAMCOG < 80. The outcome in
19 the model was whether the GP's diagnosis at the 12 month audit agreed with the classification
20 given by the CAMCOG at 12 months. The predictor variable was group (Intervention or Waitlist)
21 and the clustering variable was GP practice. Site was included as a categorical covariate. A
22 similar model was used to test the difference in specificity between the groups by fitting a
23 Logistic Regression GEE to the population with CAMCOG ≥ 80 at baseline.
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35 For other all other outcome measures, the average score was compared between intervention
36 and waitlist groups using a Linear Regression GEE. The predictor variable of interest was group
37 and the clustering variable was GP practice. Site was included as a categorical covariate.
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42 Baseline scores were also included as a predictor.
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RESULTS

Characteristics of Participants

Two thousand and thirty community dwelling participants aged 75 years or older were recruited via 168 GPs (Table 1). General practices were randomly allocated to the waitlist or intervention group, in a ratio of 1:2. The baseline characteristics and outcome measures for GP, patient and carer participants are shown in Tables 1 and 2.

The 12 months assessment was completed by 97% of GPs (98% waitlist; 96% intervention), 79% of patients (75% waitlist; 80% intervention) and 63% of carers (71% waitlist; 61% intervention), who entered the study (Figure 1).

Outcome Measures for Patients

Outcome measures were examined for all patients, and separately for patients with CAMCOG-R dementia. In both populations, there was no significant difference in depression or quality of life domain scores for the waitlist and intervention groups at 12 months (Table 3). Satisfaction with GP communication was higher in the intervention group compared with control at 12 months for all patients ($p=0.024$; odds ratio 2.1, 95% confidence interval 0.27 to 3.93) and for patients with CAMCOG-R dementia ($p=0.007$; odds ratio 7.44, 95% confidence interval 2.02 to 12.86).

Of the 245 patients in the intervention group who returned their survey on acceptability of the GPCOG screening test administered by their GP, 68.4% liked the examination and a further 30.3% were neutral; 78.3% felt reassured that the GP had checked their memory and concentration, while less than 1% felt irritated or very irritated by the examination.

Detection of Dementia

The percentage of patients with CAMCOG-R dementia who were correctly identified by the GP (as having possible, probable or definite dementia) was similar in the waitlist (43%) and intervention (45%) groups at baseline (Table 4). At 12 months following a single educational visit in the intervention group and prior to feedback on the baseline audit, there was an increase (to 65%) in the percentage of patients who were correctly identified as having dementia in the

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3 intervention group but a decrease (to 29%) in the waitlist group (Table 4). We found that after
4
5 adjusting for baseline values, the sensitivity of GP judgment of dementia was significantly higher
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7 in the intervention than the waitlist group at 12 months ($p=0.002$; odds ratio 6.0, 95%
8
9 confidence interval 1.92 to 18.73). This means that GPs who had received training in the value of
10
11 diagnosing dementia and in the use of a screening instrument were more likely to detect
12
13 dementia than GPs who did not receive the training.

14
15 Approximately 90% of patients without CAMCOG-R dementia were correctly identified by
16
17 waitlist and intervention GPs at baseline and 12 months. That is, the specificity of GP judgment
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19 of dementia was approximately 90% at baseline and 88% at 12 months in both the waitlist and
20
21 intervention groups (Table 4). The lack of any significant difference in specificity between the
22
23 groups at 12 months ($p=0.530$), indicates that the higher sensitivity in the intervention group
24
25 was not at a significant cost to specificity.

26 27 28 *Evidence Based Care for Dementia*

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30 The number of diagnostic assessment test types (pencil-and-paper, pathology and radiology)
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32 and referrals (specialist and services) per patient was recorded at baseline (Table 2) and 12
33
34 months (Table 3) for those patients with a GP judgement of dementia. There was no difference
35
36 between the intervention and waitlist group in the number of tests or referrals per patient at
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38 baseline (tests, $p=0.05$; referrals, $p=0.53$) or 12 months (tests, $p=0.973$; referrals, $p=0.429$).

39 40 41 *Outcome Measures for Carers of Patients with CAMCOG-R Dementia*

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43 Carer outcomes measures at 12 months (adjusted for baseline and site) are presented in Table 3.
44
45 There was no significant difference in depression or quality of life domain scores for the waitlist
46
47 and intervention groups at 12 months (Table 3). Carers in the intervention group had a higher
48
49 GPAQ enablement score ($p=0.019$; odds ratio 24.77, 95% confidence interval 4.15 to 45.40) at
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51 12 months.

DISCUSSION

Principal Findings

This study examined the effects of a dementia-related educational intervention for GPs. Quality of life outcomes for patients and carers were not affected by the intervention. There was however, a significant improvement in the identification of patients with dementia by GPs in the intervention compared with the waitlist group. The higher sensitivity of GP clinical judgement of dementia in the intervention group was not at a significant cost to specificity, which remained similar in the two groups. Satisfaction with GP communication was higher at follow-up in the intervention group compared with the waitlist group for all patients, and specifically for those with dementia. Carer satisfaction with GP communication was not significantly different between the groups at 12 months, however carers of people with dementia in the intervention group reported higher enablement (that is, better ability to understand and cope with their situation). We found no difference in GP management of dementia between intervention and control groups, based on the number of tests and referrals. It may be that the intervention had a stronger emphasis on identification of dementia than on management, due to the time spent addressing attitudinal barriers to dementia identification.

Comparison with Other Studies

The improvement of dementia detection compared with waitlist by GPs following our practice-based educational intervention is consistent with previous studies using a small group workshop, decision support software or an interactive seminar approach [30, 31]. The GPCOG proved to be an effective element of the intervention [43]. Adherence to management guidelines was not improved by any of these interventions, but was improved in a study that combined the educational intervention with appointment of dementia care managers [44]. Despite the lack of any change in adherence to management guidelines in our study, in terms of test ordering and referrals, the improvement in satisfaction with GP communication and/or enablement in patients and carers in the intervention compared to the waitlist, suggest some other changes in GP management of dementia patients, not measured here.

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3 Satisfaction with GP communication encompasses a number of factors (including provision of
4 adequate time, exploring patients' needs, listening, explaining, giving information and sharing
5 decisions) and is a strong predictor of overall satisfaction with primary care [45]. Effective GP-
6 patient communication can potentially have a significant impact on patients' quality of life; it is
7 positively associated with psychological quality of life in people with dementia and with
8 physical, psychological, social and environmental quality of life in elderly patients without
9 dementia [6]. Despite the higher satisfaction with GP communication found in this study, there
10 was no concomitant difference in quality of life measures for patients or carers at 12 months as a
11 result of the intervention. Importantly, the improvement in the rate of dementia identification in
12 the intervention group compared to the waitlist, did not result in a decline in any of the quality
13 of life domains, a concern expressed previously by both carers and GPs [46-48].

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26 The improvement in enablement scores for carers of people with dementia in the intervention,
27 compared to the waitlist group, at 12 months indicates carers' increased capacity and confidence
28 with respect to treatment and self-management. Since enablement is related more to the
29 communication and empathy characteristics of the GP, than to the fulfilment of patient or carer
30 expectation regarding service outcomes [45, 49] there may have been some change in the GP
31 management of dementia patients that was not captured by monitoring rates of tests and
32 referrals. Unfortunately the improvement in enablement scores was not accompanied by any
33 difference in quality of life scores for carers. Carers of people with dementia have a reduced
34 quality of life compared to their contemporaries in the general population [50, 51]. There is little
35 evidence that support-based interventions for caregivers of people with dementia are uniformly
36 effective [52], although a manual based coping strategy programme reported reduced
37 depression and improvement in carer quality of life [53]. The improved carer enablement in the
38 intervention compared to the waitlist group, suggests that improved management of the person
39 with dementia, combined with a targeted coping strategy for carers may have the potential to
40 make significant improvements to carer quality of life.

Strengths and Limitations

This study is strengthened by the use of individual and contemporaneous home assessment of each participant, meaning that the project assessed current dementia status using a standardised instrument (CAMCOG-R) rather than relying on administrative data such as GP records, commonly used in GP research. The educational intervention used activities that had proved effective in previous research; was specifically designed to address a number of identified barriers to GP identification and management of dementia; and was personalised to each GP. An additional strength is that the effect of the intervention was assessed not only on detection and management of dementia, but also on patient and carer outcomes, thus capturing the last (and essential) translational output from the intervention.

While retention of GPs in the study was excellent, a limitation was the relatively high (and differential) loss to follow-up of carers. The results relating to carers must, therefore, be interpreted with caution. The observed improvement in GP identification of dementia in the intervention group compared with waitlist did not lead to differences in management. Since GP learning was not directly measured, and the adherence to dementia guidelines was assessed by self-reporting of dementia related tests and referrals by GPs, it is possible that some may have improved their practice but did not record it. There are also indications from the communication and enablement data that some positive changes in intervention GPs' interaction with the patients and carer occurred and were not reflected in the self-reported management data. A further limitation is the higher socio economic status of the intervention patients at baseline. Poorer socioeconomic status has been linked among other things with shorter GP consultations and poorer patient enablement [54]. However, this difference was not reflected in any baseline differences in outcome measures between intervention and waitlist.

The relatively short follow up period for this study is also a limitation. In the literature, an educational intervention combined with structured care management resulted in a reduction in

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3 the decline of health-related quality of life for dementia patients after 18 months, but not 12
4 months [44] suggesting that improvements to quality of life measures may manifest slowly.
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7 *Implications for Clinicians and Policymakers*

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9 This trial illustrates that a simple detailing intervention, though relatively costly compared with
10 large group teaching, can produce significant improvements in GP dementia identification, and
11 that these can translate into improved communication with consumers and enablement for
12 carers of people with dementia. Given the huge impact that dementia will have on health
13 services in the future, and the benefits to both the individual and the health system from timely
14 diagnosis and carer enablement, this is an important finding for both clinicians and policy
15 makers.
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24 *Future Research & Conclusion*

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26 This trial raises a number of questions for future research. One concerns the best way to
27 improve GP management of dementia according to guidelines. Dementia management is
28 complex and ranges from diagnostic assessment through to a primary care team approach to
29 those living with dementia in the community, and on to management in residential aged care.
30 Further research on how best to do this, and also how best to teach it, is urgently needed.
31
32 Another question, concerns the long term effects of better identification of dementia; further
33 longitudinal studies in primary care are needed for this. Funders should consider longitudinal
34 studies of dementia in primary care which capture the experience of consumers and carers from
35 prior to diagnosis, as in this study, and throughout their journey to explore the complex
36 interactions between personal, health system and broader community factors on the dementia
37 pathway.
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12
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16 and Nutricia, and been speakers sponsored by Pfizer, Novartis (HB only) and Janssen (HB only).
17 HB has been an investigator on projects funded by Pfizer, Novartis, Janssen, Lundbeck, Lilly and
18 Sanofi, and acted as a consultant for Merck and Baxter; (2) All other authors have no competing
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20
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23 conceived and developed this study, drafted the manuscript, had overall management of the
24 project and is guarantor. KM assisted in study design, data management and statistical analysis,
25 and drafted the manuscript. NS assisted in study design, and managed operations at the Adelaide
26 site. JG assisted in study design, and managed operations at the Melbourne site. JM assisted in
27 study design. PD assisted in study design, and managed operations at the Bendigo site. PM
28 assisted in study design and drafted the manuscript. NP developed the educational intervention,
29 assisted in study design. GH developed the educational intervention, assisted in study design. SG
30 assisted in study design, provided project management and drafted the manuscript. NW
31 performed the statistical analyses. HB assisted in study design and managed operations at the
32 Sydney site. All authors read and approved the final manuscript.

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3 **Ethical approval:** Ethics approval was sought and granted initially from the Newcastle
4 University Human Research Ethics Committee (Approval No. H-151-1205), and following this,
5 from the appropriate Ethics Committees at each site. All participants gave
6 written informed consent.
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10 **Data sharing:** no additional data available.
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Table 1| Characteristics of GPs, patients and carers in the Waitlist and Intervention groups at baseline.

Class or mean (SD)		Waitlist	Intervention	p-value
Patient characteristics		(n=552)	(n=1478)	
Gender	Male	259 (47%)	671 (45%)	0.5571
	Female	293 (53%)	805 (55%)	
Age (years)	Mean (SD)	81.2 (4.4)	81.3 (4.2)	0.5184
IRSAD ^a	Mean (SD)	6.7 (2.5)	7.1 (2.5)	0.0040
CAMCOG score	Mean (SD)	90.6 (7.8)	90.0 (8.2)	0.1522
CAMCOG diagnosis	Impaired	43 (7.8%)	124 (8.4%)	0.6871
	Not Impaired	505 (92%)	1352 (92%)	
Carer characteristics		(n=21)	(n=90)	
Gender	Male	6 (29%)	25 (28%)	0.9418
	Female	15 (71%)	65 (72%)	
Age (years)	Mean (SD)	70.3 (12.8)	73.0 (16.3)	0.4800
IRSAD	Mean (SD)	6.9 (2.2)	6.5 (2.5)	0.315
General Practitioner characteristics		(n=55)	(n=113)	
Gender	Male	28 (58%)	63 (58%)	0.9501
	Female	20 (42%)	46 (42%)	
Age (years)	Mean (SD)	51.5 (9.9)	50.4 (8.5)	0.4921
Practice Size	Solo	10 (22%)	17 (16%)	0.4700
	2-4 GPs	12 (27%)	38 (36%)	
	More than 5 GPs	23 (51%)	52 (49%)	
Number of patients in study	Mean (SD)	10.0 (6.6)	13.1 (11.6)	0.0707

^a Index of Relative Social Advantage and Disadvantage

Table 2| Baseline outcome measures of patients, dementia patients and their carers in the Waitlist and Intervention groups.

	Waitlist Mean (SD) (n=552)	Intervention Mean (SD) (n=1478)	p-value (GEE)
Patient measures			
Geriatric Depression Scale (GDS)	1.9 (1.9)	2.1 (2.1)	0.1616
WHOQoL – BREF:			
Physical	70.4 (15.3)	69.5 (15.0)	0.1472
Psychological	72.1 (12.9)	70.8 (12.6)	0.8118
Social	79.7 (13.6)	78.8 (13.2)	0.2848
Environmental	81.4 (10.8)	80.6 (11.4)	0.1529
GPAQ:			
Communication	81.4 (15.5)	80.5 (14.4)	0.3613
Enablement	67.7 (31.8)	66.0 (32.1)	0.8721
GP management of dementia patients^a	(n=63)	(n=192)	
Number of tests per patient (0–3)	0.79	1.13	0.0505
Number of referrals per patient (0–2)	0.24	0.31	0.5318
Dementia patient measures^b	(n=43)	(n=124)	
Accessed Memory Services (% yes)	6 (14%)	13 (12%)	0.4049
Geriatric Depression Scale (GDS)	3.5 (3.2)	3.3 (2.8)	0.4412
WHOQoL – BREF:			
Physical	66.45 (15.94)	63.80 (14.98)	0.3544
Psychological	67.44 (13.71)	64.80 (12.56)	0.4099
Social	73.58 (12.90)	76.65 (12.69)	0.1112
Environmental	76.04 (10.57)	74.60 (14.01)	0.6236
GPAQ:			
Communication	74.4 (14.2)	75.8 (15.1)	0.5928
Enablement	57.0 (33.7)	60.2 (34.6)	0.7961
Carer measures	(n=21)	(n=90)	
Beck Depression Inventory (BDI)	10.3 (8.6)	8.5 (6.3)	0.2874
WHOQoL – BREF:			
Physical	69.6 (16.7)	70.2 (13.8)	0.9966
Psychological	68.4 (14.4)	69.0 (10.9)	0.7595
Social	76.0 (19.2)	77.1 (12.2)	0.8294
Environmental	77.5 (12.5)	77.2 (11.6)	0.9529
GPAQ:			
Communication	67.9 (21.1)	78.4 (16.8)	0.0426
Enablement	50.0 (35.8)	61.2 (36.4)	0.1421

^a participants with GP audit of possible, probable or definite dementia

^b participants with CAMCOG < 80

Table 3| Twelve month outcome measures of patients, dementia patients and their carers in the Waitlist and Intervention groups

			Intervention vs. Waitlist	Adjusted p-value (GEE)
	Waitlist Mean (SD)	Intervention Mean (SD)	Difference at 12 months adjusted for baseline and site Mean (95% CI) or OR (95% CI)	
Patient measures	(n=416*)	(n=1188*)		
Geriatric Depression Scale (GDS)	2.1 (2.2)	2.1 (2.0)	-0.04 (-0.22 to 0.14)	0.6832
WHOQoL – BREF:				
Physical	68.7 (15.6)	68.8 (14.9)	0.45 (-0.83 to 1.73)	0.4880
Psychological	71.5 (12.9)	71.0 (12.3)	0.67 (-0.65 to 2)	0.3183
Social	77.7 (12.9)	77.1 (12.2)	-0.04 (-1.5 to 1.42)	0.9593
Environmental	81.1 (10.8)	79.9 (11.6)	-0.35 (-1.77 to 1.07)	0.6272
GPAQ:				
Communication	78.3 (16.4)	79.7 (15.0)	2.1 (0.27 to 3.93)	0.0242
Enablement	63.4 (34.9)	64.3 (32.5)	1.23 (-3.71 to 6.18)	0.6248
GP management of dementia patients^a	(n=44)	(n=166)		
Number of tests per patient (0–3)	0.64	0.55	OR: 1.01 (0.52 to 1.97)	0.9729
Number of referrals per patient (0–2)	0.16	0.18	OR: 1.50 (0.55 to 4.10)	0.4285
Dementia patient measures^b	(n=34)	(n=82)		
Accessed Memory Services (% yes)	3 (11%)	9 (13%)	OR: 2.15 (0.32 to 14.49)	0.4333
Geriatric Depression Scale (GDS)	3.1 (2.9)	2.7 (2.0)	-0.41 (-1.24 to 0.42)	0.3335
WHOQoL – BREF:				
Physical	65.4 (16.0)	66.0 (12.6)	2.55 (-1.23 to 6.34)	0.1864
Psychological	66.4 (15.0)	65.2 (12.6)	2.63 (-0.8 to 6.07)	0.1334
Social	73.6 (13.2)	75.0 (11.6)	0.79 (-3.7 to 5.29)	0.7297
Environmental	77.1 (13.6)	75.6 (12.2)	0.54 (-3.01 to 4.09)	0.7660
GPAQ:				
Communication	72.6 (18.6)	78.6 (15.3)	7.44 (2.02 to 12.86)	0.0072
Enablement	55.8 (36.1)	63.9 (33.3)	5.65 (-8.68 to 19.98)	0.4395
Carer measures	(n=15)	(n=55)		
Beck Depression Inventory (BDI)	8.2 (6.2)	7.3 (4.4)	-2.67 (-6.93 to 1.59)	0.2195
WHOQoL – BREF:				
Physical	76.3 (10.4)	69.8 (12.3)	-5.15 (-13.02 to 2.72)	0.1995
Psychological	71.4 (7.6)	69.0 (11.3)	1.58 (-2.56 to 5.71)	0.4556
Social	73.8 (16.0)	73.3 (13.5)	5.88 (-2.89 to 14.66)	0.1889
Environmental	81.0 (6.5)	77.6 (11.1)	-1.53 (-5.77 to 2.70)	0.4786
GPAQ:				
Communication	75.0 (13.2)	77.1 (19.0)	1.91 (-8.02 to 11.85)	0.7060
Enablement	42.9 (33.8)	64.1 (37.1)	24.77 (4.15 to 45.40)	0.0185

^a participants with GP audit of possible, probable or definite dementia at 12 months

^b participants with CAMCOG < 80 at 12 months

Table 4| Sensitivity and specificity of the GP Audit (compared to CAMCOG-R, a standardized instrument used to measure the extent of dementia) in the Waitlist and Intervention groups at baseline and 12 months

	Baseline		12 months		Intervention vs. Waitlist Difference at 12months ^a OR (95% CI)	Adjusted p-value (GEE)
	Waitlist (n=548)	Intervention (n=1476)	Waitlist (n=415)	Intervention (n=1187)		
Sensitivity ^b	18 (43%)	55 (45%)	7 (29%)	47 (65%)	6.00 (1.92 to 18.73)	0.0020
Specificity ^c	429 (91%)	1196 (90%)	272(88%)	844 (88%)	0.79 (0.38 to 1.65)	0.5298

^a adjusted for baseline and site

^b patients with CAMCOG-R score <80 that were judged by GP as having possible, probable or definite dementia

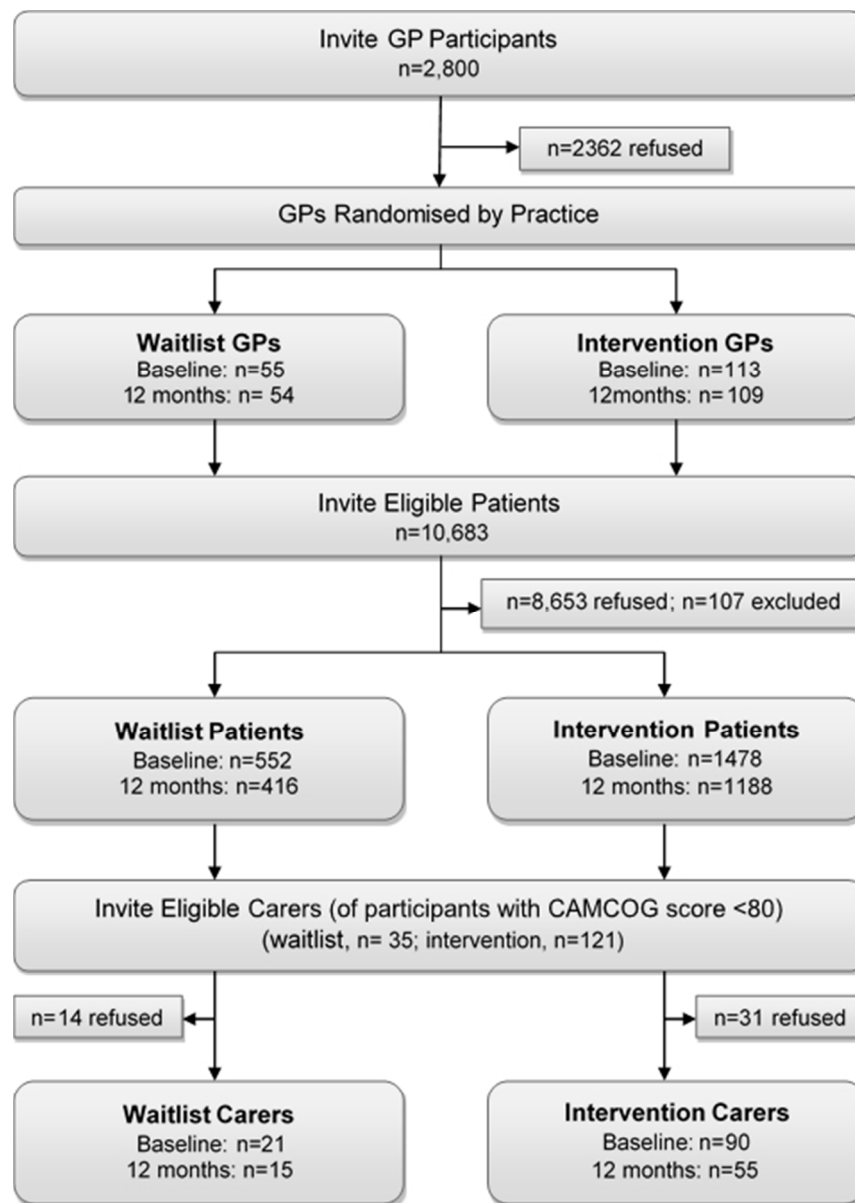
^c patients with CAMCOG-R score ≥80 that were judged not to have dementia by their GP

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FIGURE LEGEND

Figure 1 Flow of participants through the study. Baseline patient interviews were conducted May 2007 to November 2009; 12 month interviews were conducted August 2008 to December 2010.

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43x60mm (300 x 300 DPI)

Checklist of Items for Reporting Trials of Nonpharmacologic Treatments*

Section	Item	Standard CONSORT Description	Extension for Nonpharmacologic Trials	Reported on Page No.
Title and abstract†	1	How participants were allocated to interventions (e.g., “random allocation,” “randomized,” or “randomly assigned”)	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status	2
Introduction				
Background	2	Scientific background and explanation of rationale		4-5
Methods				
Participants†	3	Eligibility criteria for participants and the settings and locations where the data were collected	When applicable, eligibility criteria for centers and those performing the interventions	6
Interventions†	4	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental treatment and comparator	7
	4A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants	7 (and Pond et al 2012)
	4B		Details of how the interventions were standardized	7
	4C		Details of how adherence of care providers with the protocol was assessed or enhanced	7-8
Objectives	5	Specific objectives and hypotheses		5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)		9-10
Sample size†	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	When applicable, details of whether and how the clustering by care providers or centers was addressed	10

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5	Randomization– sequence generation†	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how care providers were allocated to each trial group	6 (and Pond et al 2014)
6	Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		6 (and Pond et al 2014)
7					
8	Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		6
9					
10	Blinding (masking)†	11A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co- interventions were blinded to group assignment	7-8
11					
12		11B		If blinded, method of blinding and description of the similarity of interventions†	7-8
13					
14	Statistical methods†	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	When applicable, details of whether and how the clustering by care providers or centers was addressed	10
15					
16	Results				
17	Participant flow†	13	Flow of participants through each stage (a diagram is strongly recommended)--- specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe deviations from study as planned, together with reasons	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	Fig 1
18					
19	Implementation of intervention†	New item		Details of the experimental treatment and comparator as they were implemented	11
20	Recruitment	14	Dates defining the periods of recruitment and follow-up		Fig 1
21					
22	Baseline data†	15	Baseline demographic and clinical characteristics of each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	12, Table 1
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Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by “intention-to-treat”; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)		Tables 1-4
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)		12-13 & Tables 1-4
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory		NA
Adverse events	19	All important adverse events or side effects in each intervention group		NA
Discussion				
Interpretation†	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	14
Generalizability†	21	Generalizability (external validity) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	15-16
Overall evidence	22	General interpretation of the results in the context of current evidence		14-17

*Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.
†This item was modified in the 2007 revised version of the CONSORT checklist.

BMJ Open

Effectiveness of a peer mediated educational intervention in improving general practitioner diagnostic assessment and management of dementia: a cluster randomised controlled trial

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Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Mental health, Geriatric medicine
Keywords:	GERIATRIC MEDICINE, MEDICAL EDUCATION & TRAINING, Dementia < NEUROLOGY, PRIMARY CARE

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3 *Prepared for BMJ Open*
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9 **Effectiveness of a peer mediated educational intervention in improving general**
10 **practitioner diagnostic assessment and management of dementia: a cluster**
11 **randomised controlled trial**
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ABSTRACT

Objective Test effectiveness of an educational intervention for general practitioners on quality of life and depression outcomes for patients.

Design Double blind, cluster randomised controlled trial.

Setting General practices in Australia between 2007 and 2010.

Participants General practices were randomly allocated to the waitlist (n=37) or intervention (n=66) group, in a ratio of 1:2. A total of 2,030 (1478 intervention; 552 waitlist) community dwelling participants aged 75 years or older were recruited via 168 GPs (113 intervention; 55 waitlist).

Interventions A practice-based academic detailing intervention led by a peer educator that included (i) training in use of the General Practitioner assessment of Cognition dementia screening instrument, (ii) training in diagnosis and management based on Royal Australian College of General Practitioners Dementia Guidelines (iii) addressing general practitioners' (GPs') barriers to dementia diagnosis, and (iv) a business case outlining a cost effective dementia assessment approach.

Outcome Measures Primary outcome measures were patient quality of life and depression; secondary outcome measures were (i) sensitivity and specificity of GP identification of dementia, (ii) referral to medical specialists and/or support services (iii) patient satisfaction with care, and (iv) carer quality of life, depression and satisfaction with care.

Results The educational intervention had no significant effect on patient quality of life or depression scores after 12 months. There were however improvements in secondary outcome measures including sensitivity of GP judgment of dementia ($p=0.002$; odds ratio 6.0, 95% CI: 1.92-18.73), satisfaction with GP communication for all patients ($p=0.024$; mean difference 2.1, 95% CI: 0.27-3.93) and for patients with dementia ($p=0.007$; mean difference 7.44, 95% CI: 2.02-12.86) and enablement of carers ($p=0.0185$; mean difference 24.77, 95% CI: 4.15-45.40).

Conclusion Practice based academic detailing did not improve patient quality of life or depression scores but did improve detection of dementia in primary care, patient satisfaction with GP communication.

Trial Registration ACTRN12607000117415

Strengths and Limitations

- Individual and contemporaneous home assessments were completed for each participant, rather than relying on administrative data such as GP records.
- The educational intervention was specifically designed to address a number of identified barriers to GP identification and management of dementia and was also personalised to each GP.
- Evaluation measures included not only detection and management of dementia, but also patient and carer outcomes, thus capturing the last (and essential) translational output from the intervention.
- Findings relating to carers must be interpreted with caution due their relatively high (and differential) loss to follow-up.
- GP learning was not directly measured, and the adherence to dementia guidelines was assessed by self-reporting of dementia related tests and referrals by GPs.

INTRODUCTION

Dementia is a complex and variable condition which affects cognition, behaviour and the person's ability to perform everyday tasks. The number of people living with dementia worldwide is currently estimated at 46.8 million. This number is expected to double by 2030 and almost triple by 2050, due to the increasing longevity of the world population [1]. As the number of people living with dementia increases, a shift from a specialist-led approach to a primary care based model would enable improved diagnosis and dementia care pathways to be implemented in an affordable manner [2]. Primary care is "more local, more holistic and personalised, and more comprehensive, integrated and continuous" than secondary care [2], and thus well placed to provide dementia identification and management and integration across primary health and social care services. This accords with the World Health Organization (WHO) identifying integrated care for the elderly at the centre of a new initiative [3]. Primary care physicians can attain similar outcomes to specialists when given responsibility for dementia care [4], with further improvements attainable given appropriate training, mentoring and resources.

Timely diagnosis and management of dementia is desired by many patients with dementia and their carers [5-7], to improve their access to interventions and support at the most appropriate time [8]. Diagnostic disclosure of memory problems is associated with better physical and environmental quality of life (QoL) in people with dementia [9], and is not associated with poorer health-related QoL [10]. A timely diagnosis may help people with dementia, and their carers, understand and cope with the challenging symptoms of dementia, fulfil short-term goals and facilitate planning for the future while they are still competent to do so [11, 12]. Referral can be made for social support services and specialist treatments, including anti-Alzheimer's medications that may slow the course of cognitive decline. [2, 4]

General practitioners fail to identify about 50% of mild dementia cases in the community [13-15] and demonstrate gaps in recorded diagnostic processes against guidelines [16]. A number of

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3 barriers to diagnosis of dementia can be attributed to patient, carer, general practitioner (GP)
4 and systemic factors [17, 18]. The gradual decline in functional ability in the early stages of
5 dementia can be attributed to 'normal' ageing, not only by persons with the condition or those
6 close to them, but also by their GPs [19-21]. The stigma associated with dementia may delay
7 help seeking [22]. Only one in five people who mention memory problems to their GP have
8 dementia [15], so the GP may choose to observe such a patient, rather than proceeding early to
9 what may be perceived as an expensive and alarming diagnostic assessment. Other GP-related
10 barriers to early diagnosis include lack of knowledge [12] and/or confidence [19, 20, 23-26], the
11 reality that dementia diagnosis is difficult due to slow and fluctuating onset and overlap of
12 symptoms with other diseases, lack of a definitive diagnostic test[25], and the perception of
13 dementia diagnosis as a specialist domain [27]. No medication exists which will effectively
14 reverse or halt the progress of these disorders, and GPs may not conceptualise social and system
15 support for ongoing cognitive decline as therapeutic and this nihilism may also hinder
16 management [28, 29].

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19 GPs' detection and management of dementia have been addressed in several educational
20 interventions with varying success [18, 30-34]. Large seminar-based interventions have limited
21 effectiveness [28], however educational interventions that incorporated active small-group
22 learning tasks have improved detection of dementia [32, 33]. The most effective educational
23 strategies in the general practice setting incorporate an academic detailing approach [35, 36]
24 that presents evidence based content in an engaging and clinically relevant manner, whilst
25 allowing flexibility to address the needs and concerns of individual practitioners [34] [37].

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28 The objective of this study was to determine the effectiveness of an educational intervention
29 that included an academic detailing visit to each practice, using model cases to illustrate case
30 identification and management and designed to address individual GP needs. The barriers to GP
31 diagnosis and management of dementia addressed were: the limited time available for
32 consultation, attitudinal factors, and lack of relevant knowledge. Further discussion with the GP

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3 elicited and addressed any additional barriers. Primary outcomes were patient focussed (QoL
4 and depression scores); secondary outcome measures included GP and carer factors.
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METHODS

Study Design

This study (the AGP trial) was a cluster randomised trial with a 12 month follow-up. A parallel design was employed. Practices with participating general practitioners (GPs) were randomly allocated in a ratio of 2:1 to either an intervention or waitlist group. Intervention practices (n=66) received a dementia related educational peer outreach visit, and completed two patient audits with feedback. Waitlist practices (n=37) completed two audits without feedback and were mailed the then-current Royal Australian College of General Practitioners (RACGP) Dementia Guidelines at 12 months [38]. The rationale and study design have been reported in detail previously [39].

Participants

Practices eligible for inclusion in the study were located within 30km of each urban study site headquarters (Sydney, Newcastle, Melbourne, Adelaide) or from the rural study site of Bendigo or its surrounding towns; had community dwelling patients aged ≥ 75 years; and used a computerised patient database. GPs that had been involved in development of the project were excluded. The cluster randomisation has been described elsewhere [39]. Briefly, a list of all eligible practices was compiled and sent to an independent party, the Centre for Epidemiology and Biostatistics at the University of Newcastle (CCEB), for randomisation. CCEB provided the approach order for the practices. A project nurse or GP visited each practice to explain the project and recruit GPs prior to allocation of the practice to intervention or waitlist. Practices were stratified by site, and by size of practice as either standard or large (>5 GPs working in the practice), and then allocated to intervention or waitlist in a ratio of 2:1 in randomly rotated blocks of 3 and 6. Of the 2,800 GPs approached, 168 (6%) entered the study. This sample was representative based on comparison with demographics of all active recognised GPs in Australia [40].

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3 GPs sent letters of invitation to all patients who met the inclusion criteria, inviting them to
4 participate in the study. Those who agreed to participate responded by returning a consent form
5 to the local study site. Patients eligible for inclusion in the study were aged ≥ 75 years, had
6 visited their GP within the last 24 months, and were able to speak and understand English. The
7 exclusion criteria were Parkinson's disease, multiple sclerosis, motor neuron disease, central
8 nervous system inflammation, psychotic symptoms prior to recruitment, developmental
9 disability, progressive malignancy or substance abuse, too sick to complete the study, or
10 resident of aged care facility at entry to the study.
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19 Carers of patients were eligible for the study if they had been identified as a carer or support
20 person by a patient scoring <80 on the revised Cambridge Cognitive Examination (CAMCOG-R)
21 [41], had prior consent from the patient with dementia for his/her carer to participate and were
22 able to speak and understand English. Eligible carers were provided with an information pack
23 and a letter of invitation. Those who agreed to participate responded by returning a consent
24 form to the local study site.
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32 ***Patient and public involvement***

34 Local reference groups at the Newcastle and Sydney sites included representatives of
35 Alzheimer's Australia (now Dementia Australia) to provide patients' and carers' perspectives in
36 best practice management of dementia. The reference groups (that also included members of
37 local divisions of general practice, geriatricians and practice nurses) provided stakeholder input
38 into the study protocol, requested wording changes to proposed information and consent forms,
39 considered the RACGP dementia guidelines and adapted them for local use e.g. developed a list
40 of local services for patients with dementia.
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48 Acceptability of the interview process, and dementia screening were measured. Participants
49 were asked to complete a short survey, which was returned to the local study site in a reply-paid
50 envelope to avoid bias due to the presence of the nurse or practice staff.
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3 Results of the interview process were provided to patients via their GP to ensure that they were
4 understood and discussed as appropriate.
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6 7 **Intervention**

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9 The intervention in this study consisted of an educational academic detailing session conducted
10 at each GP's surgery by a trained peer medical or nurse educator. GPs completed an audit of
11 their patients prior to the education, in order to obtain a baseline measure of their dementia
12 diagnosis rates and management practices. The educational session that followed included (i)
13 instruction in the use of the General Practitioner assessment of Cognition (GPCOG) dementia
14 screening instrument [42], (ii) an interactive presentation on dementia diagnosis, diagnostic
15 workup and management based on the RACGP Dementia Guidelines[38], (iii) an exploration of
16 the GP's perceived barriers to dementia diagnosis, and (iv) a business case outlining the cost
17 recovery potential of dementia assessment in terms of the Australian government's Medicare
18 Benefits Schedule. The systemic issue of lack of time in the GP consultation was addressed by
19 training the GPs in the use of a brief screening instrument and by discussing potential methods
20 of obtaining assistance from the practice nurse. Case studies were used to illustrate appropriate
21 management including behavioural, environmental and pharmacological strategies; when to
22 refer to support services (e.g Aged Care Assessment Team, Memory assessment unit,
23 Alzheimer's Australia, Meals on Wheels, respite care), solicitor or specialists; and carer health.
24 Intervention GPs were provided with a full copy of the RACGP Dementia Guidelines, as well as an
25 A4-sized summary poster at the conclusion of the academic detailing visit. A second audit was
26 held at 12 months in order to determine the effect of the educational intervention on outcome
27 measures while allowing sufficient time for the GP to have seen the patient several times.
28 Following the second audit, GPs were provided with the results of the comprehensive nurse
29 assessments conducted at baseline and 12 months, and offered an opportunity for self-reflection
30 and discussion with their academic detailer.
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3 Waitlist GPs completed two audits (baseline and 12 months) of their patients. Waitlist GPs were
4 mailed a written summary of their patient's home assessment and the RACGP Dementia
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6 Guidelines after completion of the 12 month audit.
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10 **Data Collection**

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12 At baseline, waitlist and intervention GPs received a list of their participating patients to audit.
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14 This audit task required GPs to provide their clinical judgement in relation to each patient's
15 dementia status using one of four options: No Dementia, Possible Dementia, Probable Dementia,
16
17 Definite Dementia. GPs completed a supplementary audit for any patients with possible,
18
19 probable or definite dementia to gather data on memory related tests and investigations
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21 performed (i.e. paper and pencil test for cognition or depression; pathology; radiology) and
22
23 referrals to services (including care services, memory assessment services and the Aged care
24
25 Assessment Team, and medical specialists). Differential diagnosis and identification of reversible
26
27 causes were also requested. This audit was repeated at 12 months. Although GPs were aware
28
29 that there were intervention and waitlist groups, they were not informed of their group
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31 allocation; both groups participated in the audit.
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36 Patient and carer assessments were conducted at their home by a research nurse at baseline and
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38 12 months. Information was collected from patients and carers relating to their personal and
39
40 social circumstances including socioeconomic status using the Index of Relative Social
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42 Advantage and Disadvantage (IRSAD) [43], quality of life, depression and satisfaction with GP
43
44 care. The cognitive function of patients was assessed using the GPCOG and CAMCOG-R. All
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46 nurses were trained in administration of each instrument and adhered to a standardised
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48 interview protocol to minimise interviewer bias. The specific patient characteristics collected
49
50 and the instruments and criteria used have been described previously [9, 15]. If requested by the
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52 GP, the nurse also conducted a "75+ Health Assessment", an item that can be rebated under the
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54 Australian Medicare system. These data were not used by the study, but were returned to the GP
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3 for his or her use. Research nurses and patients were blinded to the group allocation for the
4
5 entire study.
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8 At the completion of the baseline assessment, each patient received a letter prepared by the
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10 project manager, directing them to obtain an appointment with his/her GP. Patients in the
11
12 waitlist group, were seen by their GP to review their 75+ Health Assessment only. For patients
13
14 in the intervention group, the GP followed up on the 75+ Health Assessment, re-administered
15
16 the GPCOG and provided care in the light of their recent education. Results of the GP-
17
18 administered GPCOG were forwarded to the local study site headquarters. GPs were not
19
20 informed of the outcome of the research nurse assessment until after the 12 month audit, in
21
22 order to determine the effectiveness of the GP education process on GP diagnosis and
23
24 management of patients over the 12 month study period. Following their GP visit, patients and
25
26 carers in the intervention group were asked to complete a short satisfaction survey regarding
27
28 the use of the GPCOG by their GP. The survey was returned immediately to administrative staff
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30 at the GP surgery or to the study team via a reply-paid envelope.
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32 33 **Study Outcomes**

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35 The outcome measures (collected at baseline and 12 months) used to examine the effect of the
36
37 educational intervention were:

38 39 *Primary Outcomes*

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- 42 • World Health Organization Quality of Life Instrument (WHOQoL-BREF) scores for
43 patients [44] (higher score indicative of higher quality of life)
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 - 45 • Geriatric Depression Scale (GDS) [45] scores for patients (score greater than five
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47 indicative of depression)
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49 50 *Secondary Outcomes*

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- 52 • Sensitivity and specificity of GP identification of dementia compared with the revised
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54 Cambridge Cognitive Examination (CAMCOG-R), a brief neuropsychological test battery
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56 from The Cambridge Examination for Mental Disorders of the Elderly [41]. A cut point of
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3 79/80 differentiates between those having dementia and those not having dementia
4 with 93% sensitivity and 87% specificity [46]. For the purposes of this study a CAMCOG-
5 R score of less than 80 was used as an indicator of dementia.
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7

- 8 • the number of GP reported test types (pathology, pencil-and-paper, imaging) and
9 referrals (specialist and care support services) related to dementia,
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- 12 • WHOQoL-BREF scores for carers,
13
- 14 • Beck Depression Inventory (BDI) [47] scores for carers (higher total scores over 13
15 indicative of more severe depressive symptoms),
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17
- 18 • General Practice Assessment Questionnaire Version 2 (GPAQ) [48] scores for patients
19 and carers. The GPAQ domains utilised in this study were related to GP communication
20 (8 questions) and patient enablement following consultation with their GP (3 questions
21 related to patients' ability to understand and cope with their illness or problem). Mean
22 domain scores were transformed into a percentage of the maximum possible score, with
23 higher scores indicative higher satisfaction or enablement.
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25
- 26 • GP identification of differential diagnoses
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28
- 29 • GP identification of reversible causes of dementia (e.g. depression, vitamin B12
30 deficiency, hypothyroidism, adverse drug reaction)
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- 33 • acceptability of memory screening using the GPCOG
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- 36 • specialist and care services accessed
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41 Due to the low reporting of differential diagnoses or treatment of reversible causes of dementia
42 by GPs at baseline and 12 months, the effect of the intervention on these secondary outcome
43 measures [39] could not be evaluated. Likewise, the dementia management practices of GPs
44 during the study period, such as referral to specialists or care support services, and the services
45 actually accessed by participants were not effectively captured. The effect of the intervention on
46 these secondary outcomes related to management of dementia could therefore not be
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Sample Size

We calculated that a total sample size of 150 dementia patients would have 90% power to detect a mean difference of 7.0 between waitlist and intervention in the change in pre- and post- scores on any of the four domain scales of the WHOQOL-BREF with a Type I Error rate of 0.05. The standard deviation used was 18.5 and the overall correlation between pre- and post- scores was assumed to be 0.7. The study would also have 90% power to detect a mean difference of 0.9 on the 15-point GDS, assuming a standard deviation of 2.4 [42] and using the same set of assumptions for alpha and correlations.

The estimated sample size was adjusted for correlation due to clustering of patients within GP practices. Clustering within GP practices was discounted, as each GP was expected to have very few patients in the study. Assuming an intra-class correlation coefficient of 0.05 and an average cluster size of five patients per practice, the design effect is 1.2 and a total of 180 patients would be required.

An allocation of two patients in the intervention group for each patient in the control group also allowed comparisons within the intervention group related to the benefits and acceptability of a screening or case-finding approach to dementia diagnosis (to be reported separately). Therefore 68 patients in the waitlist control group and 135 patients in the intervention group were required.

We allowed for a 15% drop out over a 12 month in this elderly patient group. Thus, based on a dementia prevalence of approximately 10% in Australians aged over 75 years, we aimed to recruit a total of 2,400 participants.

Statistical Analyses

Sensitivity of the GP's diagnosis was calculated as the percentage of patients that the GP correctly classified as having dementia. Specificity was calculated as the percentage of patients that the GP correctly classified as not having dementia. The difference in sensitivity of GP diagnosis of dementia between the waitlist and intervention groups was tested by fitting a GEE

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3 model (specifically a Logistic Regression) to the population with CAMCOG<80. The outcome in
4 the model was whether the GP's diagnosis at the 12 month audit agreed with the classification
5 given by the CAMCOG at 12 months. The predictor variable was group (Intervention or Waitlist)
6 and the clustering variable was GP practice. Site was included as a categorical covariate. A
7 similar model was used to test the difference in specificity between the groups by fitting a
8 Logistic Regression GEE to the population with CAMCOG ≥ 80 at baseline.

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11 For all other outcome measures, the average score was compared between intervention and
12 waitlist groups using a Linear Regression GEE. The predictor variable of interest was group and
13 the clustering variable was GP practice. Site was included as a categorical covariate. Baseline
14 scores were also included as a predictor.
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30 RESULTS

31 *Characteristics of Participants*

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33 Of 2030 community dwelling participants aged 75 years or older recruited via 168 GPs (Table
34 1), 43 in the waitlist and 124 in the intervention group had dementia diagnosed as per the
35 CAMCOG. The baseline characteristics and outcome measures for GP, patient and carer
36 participants are shown in Tables 1 and 2.
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42 The 12 months assessment was completed by 97% of GPs (98% waitlist; 96% intervention),
43 79% of patients (75% waitlist; 80% intervention) and 63% of carers (71% waitlist; 61%
44 intervention), who entered the study (Figure 1).
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49 *Primary Outcome Measures*

50 Outcome measures were examined for all patients, and separately for patients with CAMCOG-R
51 dementia. In both populations, there was no significant difference in depression (all patients,
52 $p=0.683$; patients with dementia, $p=0.333$) or quality of life domain scores (all patients: $p=0.488$
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(physical), $p=0.318$ (psychological), $p=0.959$ (social), $p=0.627$ (environmental); patients with dementia: $p=0.186$ (physical), $p=0.133$ (psychological), $p=0.730$ (social), $p=0.766$ (environmental)) for the waitlist and intervention groups at 12 months (Table 3).

Secondary Outcome Measures

Detection of Dementia

The percentage of patients with CAMCOG-R dementia who were correctly identified by the GP (as having possible, probable or definite dementia) was similar in the waitlist (43%) and intervention (45%) groups at baseline (Table 4). At 12 months following a single educational visit in the intervention group and prior to feedback on the baseline audit, there was an increase (to 65%) in the percentage of patients who were correctly identified as having dementia in the intervention group but a decrease (to 29%) in the waitlist group (Table 4). After adjusting for baseline values, the sensitivity of GP judgment of dementia was significantly higher in the intervention than the waitlist group at 12 months ($p=0.002$; odds ratio 6.0, 95% confidence interval 1.92 to 18.73). This means that GPs who had received training in the value of diagnosing dementia and in the use of a screening instrument were more likely to detect dementia than GPs who did not receive the training.

Approximately 90% of patients without CAMCOG-R dementia were correctly identified by waitlist and intervention GPs at baseline and 12 months. That is, the specificity of GP judgment of dementia was approximately 90% at baseline and 88% at 12 months in both the waitlist and intervention groups (Table 4). The lack of any significant difference in specificity between the groups at 12 months ($p=0.530$), indicates that the higher sensitivity in the intervention group was not at a significant cost to specificity. The number of diagnostic assessment test types (pencil-and-paper, pathology and radiology) and referrals (specialist and services) per patient was recorded at baseline (Table 2) and 12 months (Table 3) for those patients with a GP judgement of dementia. There was no difference between the intervention and waitlist group in the number of tests or referrals per patient at baseline (tests, $p=0.05$; referrals, $p=0.53$) or 12 months (tests, $p=0.973$; referrals, $p=0.429$).

Satisfaction with Care

Satisfaction with GP communication was higher in the intervention group compared with control at 12 months for all patients ($p=0.024$; mean difference 2.1, 95% confidence interval 0.27 to 3.93) and for patients with CAMCOG-R dementia ($p=0.007$; mean difference 7.44, 95% confidence interval 2.02 to 12.86).

Of the 245 patients in the intervention group who returned their survey on acceptability of the GPCOG screening test administered by their GP, 68.4% liked the examination and a further 30.3% were neutral; 78.3% felt reassured that the GP had checked their memory and concentration, while less than 1% felt irritated or very irritated by the examination.

Secondary Outcome Measures for Carers of Patients with CAMCOG-R Dementia

Carer outcomes measures at 12 months (adjusted for baseline and site) are presented in Table 3. There was no significant difference in depression or quality of life domain scores for the waitlist and intervention groups at 12 months (Table 3). Carers in the intervention group had a higher GPAQ enablement score ($p=0.019$; mean difference 24.77, 95% confidence interval 4.15 to 45.40) at 12 months.

DISCUSSION

Principal Findings

This study examined the effects of a dementia-related educational intervention for GPs. The primary outcome measures related to quality of life and depression scores for patients and carers were not affected by the intervention. There were however, significant findings for several secondary outcome measures, including a significant improvement in the identification of patients with dementia by GPs in the intervention compared with the waitlist group. The higher sensitivity of GP clinical judgement of dementia in the intervention group was not at a significant cost to specificity, which remained similar in the two groups. Satisfaction with GP communication was higher at follow-up in the intervention group compared with the waitlist group for all patients, and specifically for those with dementia. Carer satisfaction with GP communication was not significantly different between the groups at 12 months, however carers of people with dementia in the intervention group reported higher enablement (that is, better ability to understand and cope with their situation). We found no difference in GP management of dementia between intervention and control groups, based on the number of tests and referrals to specialists or care services. It may be that the intervention had a stronger emphasis on identification of dementia than on these aspects of management, due to the time spent addressing attitudinal barriers to dementia identification.

Comparison with Other Studies

Considering how little is known about the trajectory of quality of life across the stages of dementia or its responsiveness to change [49]; it was an optimistic choice of primary outcome measure for a GP based educational intervention. Quality of life is a complex multi-dimensional construct, with no strong common or unique predictors identified across the stages of dementia (reviewed by [50]). The other primary outcome measure for this study, patient depression score, is consistently but moderately associated with decreased quality of life in dementia, especially in the early stage [50] but also difficult to address in people with dementia, with both psychological and pharmacological approaches to treatment having mixed and marginal effects

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3 (reviewed by [51]). Although improvement in patient related outcomes such as quality of life
4 and depression scores may be the ultimate goal, and are certainly important outcome measures,
5 their responsiveness to changes in GP in diagnosis and management may be slow, and
6 dependent on the effectiveness of downstream support services. Most other GP-based
7 interventions for dementia have used behaviour, performance and practice of the health
8 professional as the primary study outcomes [30-34].
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15 The improvement of dementia detection compared with waitlist by GPs following our practice-
16 based educational intervention is consistent with previous studies using a small group
17 workshop, decision support software or an interactive seminar approach [32, 33]. The GPCOG
18 proved to be an effective element of the intervention [52]. Adherence to management guidelines
19 was not improved by any of these interventions, but was improved in a study that combined the
20 educational intervention with appointment of dementia care managers [53]. Despite the lack of
21 change in adherence to management guidelines in our study, in terms of test ordering and
22 referrals, the improvement in satisfaction with GP communication and/or enablement in
23 patients and carers in the intervention compared to the waitlist, suggest some other changes in
24 GP management of dementia patients, not measured here. An external audit process conducted
25 by independent clinical research staff may be more effective at capturing dementia-related
26 management during GP clinical encounters, than the GP self-report by audit process used in this
27 study.
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42 Satisfaction with GP communication encompasses a number of factors (including provision of
43 adequate time, exploring patients' needs, listening, explaining, giving information and sharing
44 decisions) and is a strong predictor of overall satisfaction with primary care [54]. Effective GP-
45 patient communication can potentially have a significant impact on patients' quality of life; it is
46 positively associated with psychological quality of life in people with dementia and with
47 physical, psychological, social and environmental quality of life in elderly patients without
48 dementia [9]. Despite the higher satisfaction with GP communication found in this study, there
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3 was no concomitant difference in quality of life measures for patients or carers at 12 months as a
4 result of the intervention. Importantly though, the improvement in the rate of dementia
5 identification in the intervention group compared to the waitlist, did not result in a decline in
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7 any of the quality of life domains, a concern expressed previously by both carers and GPs [55-
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13 The improvement in enablement scores for carers of people with dementia in the intervention,
14 compared to the waitlist group, at 12 months indicates carers' increased capacity and confidence
15 with respect to treatment and self-management. Since enablement is related more to the
16 communication and empathy characteristics of the GP, than to the fulfilment of patient or carer
17 expectation regarding service outcomes [54, 58] there may have been some change in the GP
18 management of dementia patients that was not captured by monitoring rates of tests and
19 referrals. Unfortunately the improvement in enablement scores was not accompanied by any
20 difference in quality of life scores for carers. This is consistent with the literature; there is little
21 evidence that support-based interventions for caregivers of people with dementia are effective
22 [59-62].
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34 *Strengths and Limitations*

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36 This study is strengthened by the use of individual and contemporaneous home assessment of
37 each participant, meaning that the project assessed current dementia status using a
38 standardised instrument (CAMCOG-R) rather than relying on administrative data such as GP
39 records, commonly used in GP research. The educational intervention used activities that had
40 proved effective in previous research; was specifically designed to address a number of
41 identified barriers to GP identification and management of dementia; and was personalised to
42 each GP. An additional strength is that the effect of the intervention was assessed not only on
43 detection and management of dementia, but also on patient and carer outcomes, thus capturing
44 the last (and essential) translational output from the intervention.
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3 While retention of GPs in the study was excellent, a limitation was the 6% higher than expected
4 drop-out rate for patients, and the relatively high (and differential) loss to follow-up of carers.

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6 The results must, therefore, be interpreted with caution. The observed improvement in GP
7 identification of dementia in the intervention group compared with waitlist did not lead to
8 differences in management in terms of referrals to medical specialists or care services. Since GP
9 learning was not directly measured, and the adherence to dementia guidelines was assessed by
10 self-reporting of dementia related tests and care and specialist referrals by GPs, it is possible
11 that some may have improved their practice but did not record it. [63]
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19 The relatively short follow up period for this study is also a limitation. An educational
20 intervention combined with structured care management resulted in a reduction in the decline
21 of health-related quality of life for dementia patients after 18 months, but not 12 months [53]
22 suggesting that improvements to quality of life measures may manifest slowly.
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28 *Implications for Clinicians and Policymakers*

29 This trial illustrates that a simple academic detailing intervention, though more expensive than
30 large group teaching, can produce significant improvements in GP dementia identification, and
31 that these can translate into improved communication with consumers and enablement for
32 carers of people with dementia. Given the huge impact that dementia will have on health
33 services in the future, and the benefits to both the individual and the health system from timely
34 diagnosis and carer enablement, this is an important finding for both clinicians and policy
35 makers.
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45 *Future Research & Conclusion*

46 This trial raises a number of questions for future research. One concerns the best way to
47 improve GP management of dementia according to guidelines. Dementia management is
48 complex and ranges from diagnostic assessment through to a primary care team approach to
49 those living with dementia in the community, and on to management in residential aged care.
50 Further research on how best to do this, and also how best to teach it, is urgently needed.
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3 Another question concerns the long term effects of better identification of dementia; further
4 longitudinal studies in primary care are needed for this. Funders should consider longitudinal
5 studies of dementia in primary care which capture the experience of consumers and carers from
6 prior to diagnosis, as in this study, and throughout their journey to explore the complex
7 interactions between personal, health system and broader community factors on the dementia
8 pathway.
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6
7

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20 **Competing interests:** All authors have completed the ICMJE uniform disclosure form at
21 www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and
22 declare that (1) DP and HB have sat on advisory boards for Pfizer, Novartis, Janssen, Lundbeck
23 and Nutricia, and been speakers sponsored by Pfizer, Novartis (HB only) and Janssen (HB only).
24 HB has been an investigator on projects funded by Pfizer, Novartis, Janssen, Lundbeck, Lilly and
25 Sanofi, and acted as a consultant for Merck and Baxter; (2) All other authors have no competing
26 interests to declare.
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35 **Details of contributors:** All authors had full access to data (including statistical reports and
36 tables) and take responsibility for the integrity of the data and accuracy of the data analysis. CDP
37 conceived and developed this study, drafted the manuscript, had overall management of the
38 project and is guarantor. KM assisted in study design, data management and statistical analysis,
39 and drafted the manuscript. NS assisted in study design, and managed operations at the Adelaide
40 site. JG assisted in study design, and managed operations at the Melbourne site. JM assisted in
41 study design. PD assisted in study design, and managed operations at the Bendigo site. PM
42 assisted in study design and drafted the manuscript. NP developed the educational intervention,
43 assisted in study design. GH developed the educational intervention, assisted in study design. SG
44 assisted in study design, provided project management and drafted the manuscript. NW
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3 performed the statistical analyses. HB assisted in study design and managed operations at the
4
5 Sydney site. All authors read and approved the final manuscript.

6
7 **Ethical approval:** Ethics approval was sought and granted initially from the Newcastle
8
9 University Human Research Ethics Committee (Approval No. H-151-1205), and following this,
10
11 from the appropriate Ethics Committees at each site. All participants gave
12
13 written informed consent.

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15 **Data sharing:** no additional data available.
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Table 1 | Characteristics of GPs, patients and carers in the Waitlist and Intervention groups at baseline.

	Class or mean (SD)	Waitlist	Intervention
Patient characteristics		(n=552)	(n=1478)
Gender ^a	Male	259 (47%)	671 (45%)
	Female	293 (53%)	805 (55%)
Age (years)	Mean (SD)	81.2 (4.4)	81.3 (4.2)
IRSAD ^b	Mean (SD)	6.7 (2.5)	7.1 (2.5)
CAMCOG score	Mean (SD)	90.6 (7.8)	90.0 (8.2)
CAMCOG diagnosis	Impaired	43 (7.8%)	124 (8.4%)
	Not Impaired	505 (92%)	1352 (92%)
Carer characteristics		(n=21)	(n=90)
Gender	Male	6 (29%)	25 (28%)
	Female	15 (71%)	65 (72%)
Age (years)	Mean (SD)	70.3 (12.8)	73.0 (16.3)
IRSAD	Mean (SD)	6.9 (2.2)	6.5 (2.5)
General Practitioner characteristics		(n=55)	(n=113)
Gender ^a	Male	28 (58%)	63 (58%)
	Female	20 (42%)	46 (42%)
Age (years)	Mean (SD)	51.5 (9.9)	50.4 (8.5)
Practice Size	Solo	10 (22%)	17 (16%)
	2-4 GPs	12 (27%)	38 (36%)
	More than 5 GPs	23 (51%)	52 (49%)
Number of patients in study	Mean (SD)	10.0 (6.6)	13.1 (11.6)

^a Gender was not disclosed by all patient or GP participants

^b Index of Relative Social Advantage and Disadvantage

Table 2| Baseline outcome measures of patients, dementia patients and their carers in the Waitlist and Intervention groups.

	Waitlist Mean (SD)	Intervention Mean (SD)
Patient measures	(n=552)	(n=1478)
Geriatric Depression Scale (GDS)	1.9 (1.9)	2.1 (2.1)
WHOQoL – BREF:		
Physical	70.4 (15.3)	69.5 (15.0)
Psychological	72.1 (12.9)	70.8 (12.6)
Social	79.7 (13.6)	78.8 (13.2)
Environmental	81.4 (10.8)	80.6 (11.4)
GPAQ:		
Communication	81.4 (15.5)	80.5 (14.4)
Enablement	67.7 (31.8)	66.0 (32.1)
GP management of dementia patients^a	(n=63)	(n=192)
Number of tests per patient (0–3)	0.79	1.13
Number of referrals per patient (0–2)	0.24	0.31
Dementia patient measures^b	(n=43)	(n=124)
Accessed Memory Services (% yes)	6 (14%)	13 (12%)
Geriatric Depression Scale (GDS)	3.5 (3.2)	3.3 (2.8)
WHOQoL – BREF:		
Physical	66.45 (15.94)	63.80 (14.98)
Psychological	67.44 (13.71)	64.80 (12.56)
Social	73.58 (12.90)	76.65 (12.69)
Environmental	76.04 (10.57)	74.60 (14.01)
GPAQ:		
Communication	74.4 (14.2)	75.8 (15.1)
Enablement	57.0 (33.7)	60.2 (34.6)
Carer measures	(n=21)	(n=90)
Beck Depression Inventory (BDI)	10.3 (8.6)	8.5 (6.3)
WHOQoL – BREF:		
Physical	69.6 (16.7)	70.2 (13.8)
Psychological	68.4 (14.4)	69.0 (10.9)
Social	76.0 (19.2)	77.1 (12.2)
Environmental	77.5 (12.5)	77.2 (11.6)
GPAQ:		
Communication	67.9 (21.1)	78.4 (16.8)
Enablement	50.0 (35.8)	61.2 (36.4)

^a participants with GP audit of possible, probable or definite dementia

^b participants with CAMCOG < 80

Table 3| Twelve month outcome measures of patients, dementia patients and their carers in the Waitlist and Intervention groups

			Intervention vs. Waitlist	Adjusted p-value (GEE)
	Waitlist Mean (SD)	Intervention Mean (SD)	Difference at 12 months adjusted for baseline and site Mean (95% CI) or OR (95% CI)	
Patient measures	(n=416*)	(n=1188*)		
Geriatric Depression Scale (GDS)	2.1 (2.2)	2.1 (2.0)	-0.04 (-0.22 to 0.14)	0.6832
WHOQoL – BREF:				
Physical	68.7 (15.6)	68.8 (14.9)	0.45 (-0.83 to 1.73)	0.4880
Psychological	71.5 (12.9)	71.0 (12.3)	0.67 (-0.65 to 2)	0.3183
Social	77.7 (12.9)	77.1 (12.2)	-0.04 (-1.5 to 1.42)	0.9593
Environmental	81.1 (10.8)	79.9 (11.6)	-0.35 (-1.77 to 1.07)	0.6272
GPAQ:				
Communication	78.3 (16.4)	79.7 (15.0)	2.1 (0.27 to 3.93)	0.0242
Enablement	63.4 (34.9)	64.3 (32.5)	1.23 (-3.71 to 6.18)	0.6248
GP management of dementia patients^a	(n=44)	(n=166)		
Number of tests per patient (0–3)	0.64	0.55	OR: 1.01 (0.52 to 1.97)	0.9729
Number of referrals per patient (0–2)	0.16	0.18	OR: 1.50 (0.55 to 4.10)	0.4285
Dementia patient measures^b	(n=34)	(n=82)		
Accessed Memory Services (% yes)	3 (11%)	9 (13%)	OR: 2.15 (0.32 to 14.49)	0.4333
Geriatric Depression Scale (GDS)	3.1 (2.9)	2.7 (2.0)	-0.41 (-1.24 to 0.42)	0.3335
WHOQoL – BREF:				
Physical	65.4 (16.0)	66.0 (12.6)	2.55 (-1.23 to 6.34)	0.1864
Psychological	66.4 (15.0)	65.2 (12.6)	2.63 (-0.8 to 6.07)	0.1334
Social	73.6 (13.2)	75.0 (11.6)	0.79 (-3.7 to 5.29)	0.7297
Environmental	77.1 (13.6)	75.6 (12.2)	0.54 (-3.01 to 4.09)	0.7660
GPAQ:				
Communication	72.6 (18.6)	78.6 (15.3)	7.44 (2.02 to 12.86)	0.0072
Enablement	55.8 (36.1)	63.9 (33.3)	5.65 (-8.68 to 19.98)	0.4395
Carer measures	(n=15)	(n=55)		
Beck Depression Inventory (BDI)	8.2 (6.2)	7.3 (4.4)	-2.67 (-6.93 to 1.59)	0.2195
WHOQoL – BREF:				
Physical	76.3 (10.4)	69.8 (12.3)	-5.15 (-13.02 to 2.72)	0.1995
Psychological	71.4 (7.6)	69.0 (11.3)	1.58 (-2.56 to 5.71)	0.4556
Social	73.8 (16.0)	73.3 (13.5)	5.88 (-2.89 to 14.66)	0.1889
Environmental	81.0 (6.5)	77.6 (11.1)	-1.53 (-5.77 to 2.70)	0.4786
GPAQ:				
Communication	75.0 (13.2)	77.1 (19.0)	1.91 (-8.02 to 11.85)	0.7060
Enablement	42.9 (33.8)	64.1 (37.1)	24.77 (4.15 to 45.40)	0.0185

^a participants with GP audit of possible, probable or definite dementia at 12 months

^b participants with CAMCOG < 80 at 12 months

Table 4| Sensitivity and specificity of the GP Audit (compared to CAMCOG-R, a standardized instrument used to measure the extent of dementia) in the Waitlist and Intervention groups at baseline and 12 months

	Baseline		12 months		Intervention vs. Waitlist Difference at 12months ^a OR (95% CI)	Adjusted p-value (GEE)
	Waitlist (n=548)	Intervention (n=1476)	Waitlist (n=415)	Intervention (n=1187)		
Sensitivity ^b	18 (43%)	55 (45%)	7 (29%)	47 (65%)	6.00 (1.92 to 18.73)	0.0020
Specificity ^c	429 (91%)	1196 (90%)	272(88%)	844 (88%)	0.79 (0.38 to 1.65)	0.5298

^a adjusted for baseline and site

^b patients with CAMCOG-R score <80 that were judged by GP as having possible, probable or definite dementia

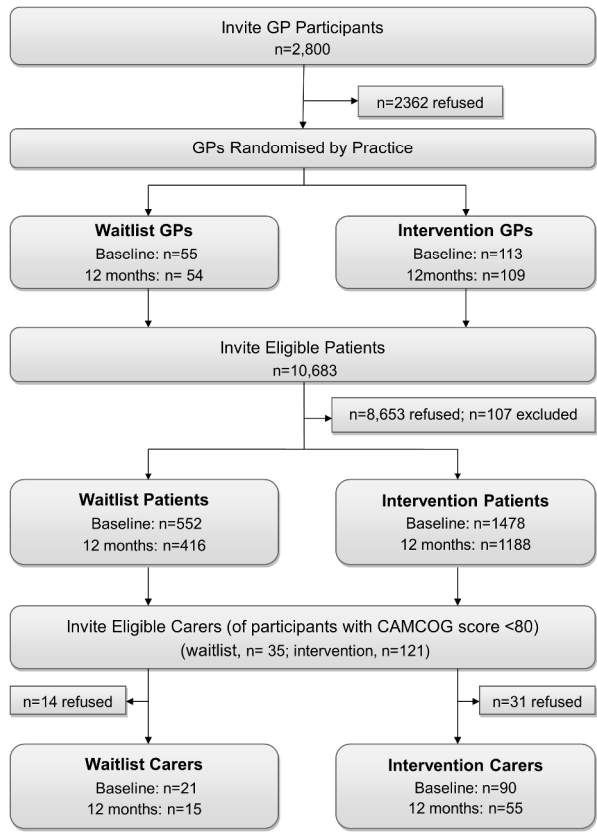
^c patients with CAMCOG-R score ≥80 that were judged not to have dementia by their GP

FIGURE LEGEND

Figure 1 Flow of participants through the study. Baseline patient interviews were conducted May 2007 to November 2009; 12 month interviews were conducted August 2008 to December 2010.

For peer review only

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Checklist of Items for Reporting Trials of Nonpharmacologic Treatments*

Section	Item	Standard CONSORT Description	Extension for Nonpharmacologic Trials	Reported on Page No.
Title and abstract†	1	How participants were allocated to interventions (e.g., “random allocation,” “randomized,” or “randomly assigned”)	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status	2
Introduction				
Background	2	Scientific background and explanation of rationale		4-5
Methods				
Participants†	3	Eligibility criteria for participants and the settings and locations where the data were collected	When applicable, eligibility criteria for centers and those performing the interventions	6
Interventions†	4	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental treatment and comparator	7
	4A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants	7 (and Pond et al 2012)
	4B		Details of how the interventions were standardized	7
	4C		Details of how adherence of care providers with the protocol was assessed or enhanced	7-8
Objectives	5	Specific objectives and hypotheses		5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)		9-10
Sample size†	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	When applicable, details of whether and how the clustering by care providers or centers was addressed	10

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Randomization– sequence generation†	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how care providers were allocated to each trial group	6 (and Pond et al 2014)
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		6 (and Pond et al 2014)
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		6
Blinding (masking)†	11A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co-interventions were blinded to group assignment	7-8
	11B		If blinded, method of blinding and description of the similarity of interventions†	7-8
Statistical methods†	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	When applicable, details of whether and how the clustering by care providers or centers was addressed	10
Results				
Participant flow†	13	Flow of participants through each stage (a diagram is strongly recommended)--- specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe deviations from study as planned, together with reasons	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	Fig 1
Implementation of intervention†	New item		Details of the experimental treatment and comparator as they were implemented	11
Recruitment	14	Dates defining the periods of recruitment and follow-up		Fig 1
Baseline data†	15	Baseline demographic and clinical characteristics of each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	12, Table 1

Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by “intention-to-treat”; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)		Tables 1-4
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)		12-13 & Tables 1-4
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory		NA
Adverse events	19	All important adverse events or side effects in each intervention group		NA
Discussion				
Interpretation†	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	14
Generalizability†	21	Generalizability (external validity) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	15-16
Overall evidence	22	General interpretation of the results in the context of current evidence		14-17

*Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.

†This item was modified in the 2007 revised version of the CONSORT checklist.