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Providing reviews of evidence to COPD patients: controlled prospective 12-month trial

M Harris1, BJ Smith2, AJ Veale2, A Esterman3, PA Frith4 and P Selim5

1 Flinders Human Behaviour and Health Research Unit, Flinders University, Adelaide, Australia; 2 Respiratory Medicine and Sleep Disorders Unit, The Queen Elizabeth Hospital, Adelaide, Australia; 3 School of Nursing and Midwifery, University of South Australia, Adelaide, Australia; 4 Respiratory Services, Flinders Medical Centre, Adelaide, Australia; and 5 Safety, Quality and Risk Management, The Queen Elizabeth Hospital, Adelaide, Australia

The aim of this study was to evaluate a novel patient-held manual designed to reduce the evidence–practice gap in chronic obstructive pulmonary disease (COPD). The intervention manual contained summaries of research evidence. It was developed using current best practice for patient information materials and designed to cause discussion of evidence between patient and doctor. A controlled before-and-after study was employed in two similar but geographically separate regions of metropolitan Adelaide, South Australia. Participants had moderate to severe COPD, with 249 included at baseline and 201 completing the study. Evidence-based COPD management was measured using an indicator with three components: rates of influenza vaccination, bone density testing, and pulmonary rehabilitation. A survey of behavioral steps leading to practice change was conducted with the trial. Analysis, by median split of socioeconomic disadvantage, showed significant difference between study arms for only one component of the indicator of evidence-based practice, enrolment in pulmonary rehabilitation and only for the most socioeconomically disadvantaged stratum. For both socioeconomic strata, more intervention participants than control participants reported remembering being given the information material, reading part or all, and finding it very or quite helpful. Other significant differences were restricted to the stratum of greatest socioeconomic disadvantage: reading all of the material, learning from it, referring back, and talking to a doctor about a topic from the material. Above 90% of all participants who received the manual reported reading from it, 42% reported discussing topics with a doctor, but only 10% reported treatment change attributable to the manual. We have found that people with COPD will read an evidence manual developed using current best practice. However, the study demonstrated improvement for only one of the three components of an indicator of evidence-based disease management for only the most socioeconomically disadvantaged stratum of participants. Future interventions should be designed to better translate reading uptake into evidence-based disease management.

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Key words: chronic obstructive; clinical trial; evidence-based medicine; patient participation; pulmonary disease

Introduction

Strategies to reduce the gap between research evidence and clinical practice have the potential to greatly improve health outcomes.1 Most strategies to date have targeted health professionals only. They have improved practice to some extent but many have not been cost-effective and results have been inconsistent from study to study.2 There have been fewer studies of strategies, that include patients.2–3 In most of these studies, the patient has not been informed about evidence; their role has been as delivery channel for reminders to the doctor. Patients are increasingly expected to participate in decision making and disease management, especially in chronic disease; therefore, research is needed on strategies that provide patients with their own reviews of evidence and encourage them to discuss this evidence with their doctors. We conducted a study on patients with chronic obstructive
pulmonary disease (COPD), who were given a manual that contained summaries of the evidence for treatments used in COPD, and gave suggested opening questions for discussing this evidence with doctors. The manual was a relatively low-cost intervention, developed using current best practice regarding information presentation and terminology for patient information materials. The study assessed the impact of this manual on clinical decisions. Initial 3-month assessment showed little treatment change, but a longer period is probably required to demonstrate benefits, such as improved vaccination rates, from this type of intervention. We now report results at 12 months.

**Study aims**

The aim of this study was to show whether providing summaries of evidence to people who have COPD leads to improved application of that evidence in their medical care. Application of evidence was measured using three evidence-supported medical interventions for COPD: influenza vaccination, bone density testing, and pulmonary rehabilitation. The evaluation of the manual included an assessment of outcomes and a process evaluation. A survey of all participants was part of the process evaluation and is reported here.

**Hypothesis**

The primary hypothesis to be tested was: Compared with patients who have been given a conventional pamphlet, patients who have been given the COPD Evidence Manual will have increased self-reported rates for each of the following:

1. rate of influenza vaccination within the previous 15 months (allowing a 3-month delay in obtaining an annual vaccination)
2. rate of bone density testing within the previous 42 months (allowing a 6-month delay in 3-yearly testing)
3. enrolment in pulmonary rehabilitation after receiving the manual.

Although it was not primarily designed to increase patient mastery and knowledge of COPD, patient communication with the regular doctor, and patient satisfaction with provision of information, we wished to ascertain whether the manual improved these outcomes. Disease-related information can cause anxiety if provided insensitively and while checks and adjustments were made during preparation of the manual to avoid causing distress, we also wished to ensure that the manual did not increase anxiety. The following additional outcome measures were therefore included:

- Mastery of COPD, as measured by the Mastery domain of the Chronic Respiratory Questionnaire (CRQ)
- Knowledge of COPD, as measured by a test adapted from Hermiz, et al
- Communication with usual doctor, as measured by the Communication and Comfort and the Rapport subscales of the Medical Interview Satisfaction Scale (MISS) (slightly modified to exclude questions inapplicable in COPD)
- Satisfaction with disease-related information, as measured using the question “I have enough information about my lung condition” and the response options scale from the MISS
- Anxiety, as measured by the short form Spielberger State Anxiety Inventory.

**Methods**

**The intervention manual**

The study trialed a manual for patients that summarized Cochrane Reviews of evidence about COPD treatments, and provided additional background topics. To encourage discussion of evidence with doctors, a tip or a suggested question that a patient could ask their doctor accompanied each summary. Questions were used, rather than overt requests to consider evidence, in keeping with usual patient behavior in consultations. The manual used very plain language, lay terminology, small page size and large print, question-and-answer format, and illustrations of people with COPD engaging in activities of daily living as well as in clinical settings.

Research-based recommendations on the design of patient information materials were used as a guide to design of the manual, though we noted that these recommendations were based on measures of patient satisfaction rather than health outcomes or behaviors.

Of 22 reviews, 16 were based on Cochrane reviews with others based on Global Initiative for
Chronic Obstructive Lung Disease (GOLD) guidelines or comprehensive reviews from journals.

Recruitment

Patients with moderate to severe COPD were sought (according to GOLD criteria). Patients were excluded if they had lung cancer, dementia or other major, currently unstable illness, and if the patient or carer did not have at least a basic ability to read English.

Potential participants were identified through inpatient admission for COPD and at respiratory outpatient clinics at three teaching hospitals in Adelaide, South Australia. Invitations, signed by the patient’s doctor, were mailed to patients after discharge, or handed to the patient by the doctor at clinic. A reminder was sent if there was no response after 3 weeks. Recruitment continued progressively from March 4, 2003 to March 5, 2005.

Allocation and blinding

Contamination of the control group, both patient to patient and via a doctor, was likely with this intervention. A controlled before-and-after design was therefore adopted, using patients from two geographically separate areas of metropolitan Adelaide, South Australia. The two areas appeared demographically similar and each was served by a large public hospital providing a similar range of services with occasional exchange of medical staff. Control participants received a simple, single sheet foldout pamphlet containing information about COPD in keeping with usual practice.

Because of the nature of the intervention and allocation, interviewers could not be blinded but they were trained to administer questionnaires, record answers, and give the information materials in a consistent way. Participants were blind to their intervention/control status because study explanation stated that different types of information were being tested and that each participant would receive one type at first and the other at the end of the study.

Data collection and delivery of intervention

Data was collected by interviewer administration, and the intervention manual and control pamphlet were handed to participants at the end of baseline data collection.

Participants’ general practitioners (GPs) received prior information about the trial through local general practice organizations. In addition, intervention participants were given an order form which they could hand to their GP so that the GP could order a free copy of the manual.

Baseline comparisons

Baseline comparison between groups was made using the outcome measures (given below) and additional demographic and disease-related variables that were potentially associated with use of the manual: gender, use of oxygen therapy (as indicator of severity of COPD), smoking status, age, years of formal education, Index of Relative Socio-Economic Disadvantage for postcode, living alone, overall score for the Medical Interview Satisfaction Scale, and dyspnea, fatigue and emotional function domains of the CRQ.

Sample size

As shown in Table 1, the calculated minimum sample size was 98 participants per arm. To allow for some loss of participants and other possible factors (e.g., adjustment for any group differences), our recruitment target was 120 per arm.

Process measures

The hypothesized link between provision of the manual and improved COPD management implied a series of causal steps including reading by the patient, discussion at a consultation, and treatment change. Steps are shown in Figure 1. At 12 months, participants were asked a series of closed survey questions to assess each of these steps.

| Table 1 Components of primary outcome measure |
|-----------------|-----------------|---------------------------------|
| Component       | Estimated initial rate/target rate (%) | Sample size requireda |
| Influenza vaccination current (within last 15 months) | 80/95 | 88 |
| Bone density monitored (within last 42 months) | 10/30 | 71 |
| Participation in pulmonary rehabilitation | 25/45 | 98 |

a Design was nonrandomized, but baseline differences between groups were not expected and standard sample size calculations were used. Table shows minimum sample size per arm for changes in proportion for components of the primary outcome measure with alpha set at 0.05 and power 80% (with continuity correction).
Analysis and imputation

Baseline demographic and clinical comparisons were made using the chi-square test for dichotomous variables, or Fisher’s exact test if numbers in any cells were less than five, and Student’s t-test for continuous variables.

For all outcomes except enrolment in pulmonary rehabilitation, change scores to 12 months were analyzed using analysis of covariance, with adjustment for baseline score, to remove the effect of regression to the mean. Poisson modeling was used to compare proportions attending pulmonary rehabilitation. If any baseline difference was found, adjustment by propensity scoring was planned. The conventional 0.05 probability level for statistical significance was used throughout. Missing interviews were excluded from the analysis. Missing data elements (needed only for the Medical Interview Satisfaction Scale which contained 5.1% missing data) were imputed by expectation-minimization imputation and used SPSS 12 For Windows software (SPSS Inc., Chicago, IL, USA). Data were otherwise analyzed using Stata 8.2 software (StataCorp, College Station, TX, USA).

Results

Participant flow

Numbers of participants at each stage of the trial are shown in Figure 2.

Baseline comparisons

Table 2 shows baseline demographic and clinical comparisons. Intervention and control groups were similar, apart from measures of socioeconomic disadvantage, previous attendance at pulmonary rehabilitation and living alone. A propensity score was therefore created for each participant by including all baseline measures in a logistic regression with the grouping variable as the dependent variable. This score was included in analysis of covariance models.
for outcomes to adjust for baseline differences. Propensity score means were 0.75 for intervention participants and 0.24 for control participants. Socioeconomic disadvantage appeared to be an effect modifier therefore subsequent outcomes analyses were done using median split of this variable, which had the effect of reducing the power of the study.

### Table 2  Baseline comparisons between intervention and control groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention group (n = 125)</th>
<th>Control group (n = 124)</th>
<th>Significance</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Proportion male (%)</td>
<td>69/125 (55)</td>
<td>65/124 (52)</td>
<td>0.66</td>
<td>$\chi^2$</td>
</tr>
<tr>
<td>ii. Proportion on oxygen at baseline (%)</td>
<td>43/125 (34)</td>
<td>31/124 (25)</td>
<td>0.12</td>
<td>$\chi^2$</td>
</tr>
<tr>
<td>iii. Proportion smoker at baseline (%)</td>
<td>23/125 (18)</td>
<td>29/124 (23)</td>
<td>0.38</td>
<td>$\chi^2$</td>
</tr>
<tr>
<td>iv. Mean age</td>
<td>73.6</td>
<td>73.1</td>
<td>0.64</td>
<td>t</td>
</tr>
<tr>
<td>v. Mean years of formal education</td>
<td>10</td>
<td>10</td>
<td>0.18</td>
<td>t</td>
</tr>
<tr>
<td>vi. Mean index of socioeconomic disadvantage for postcode</td>
<td>1002.41</td>
<td>938.85</td>
<td>&lt;0.001</td>
<td>t</td>
</tr>
<tr>
<td>vii. % Living alone*</td>
<td>23/100 (23)</td>
<td>45/101 (45)</td>
<td>0.001</td>
<td>$\chi^2$</td>
</tr>
<tr>
<td>Additional clinical baseline comparisons:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>viii. Mean MISS score (possible range 1–7)</td>
<td>5.0</td>
<td>5.2</td>
<td>0.07</td>
<td>t</td>
</tr>
<tr>
<td>ix a. Mean CRQ dyspnea (possible range 1–7)</td>
<td>3.2</td>
<td>3.1</td>
<td>0.50</td>
<td>t</td>
</tr>
<tr>
<td>ix b. Mean CRQ fatigue (possible range 1–7)</td>
<td>3.5</td>
<td>3.6</td>
<td>0.70</td>
<td>t</td>
</tr>
<tr>
<td>ix c. Mean CRQ emotional function (possible range 1–7)</td>
<td>4.8</td>
<td>4.8</td>
<td>0.83</td>
<td>t</td>
</tr>
<tr>
<td>Outcome measures:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a. Proportion (%) current flu vaccination</td>
<td>110/125 (88)</td>
<td>108/124 (87)</td>
<td>0.83</td>
<td>$\chi^2$</td>
</tr>
<tr>
<td>1b. Proportion bone density test in last 3½ years (%)</td>
<td>39/125 (31)</td>
<td>39/124 (31)</td>
<td>0.97</td>
<td>$\chi^2$</td>
</tr>
<tr>
<td>1c. Proportion ever attended pulmonary rehabilitation* (%)</td>
<td>19/100 (19)</td>
<td>3/101 (3)</td>
<td>&lt;0.001</td>
<td>Fisher’s exact</td>
</tr>
<tr>
<td>2. Mean MISS mastery (possible range 1–7)</td>
<td>4.9</td>
<td>5.0</td>
<td>0.91</td>
<td>t</td>
</tr>
<tr>
<td>3. Mean knowledge (possible range 0–16)</td>
<td>12</td>
<td>11</td>
<td>0.10</td>
<td>t</td>
</tr>
<tr>
<td>4a. Mean MISS communication and comfort (possible range 1–7)</td>
<td>5.0</td>
<td>5.2</td>
<td>0.19</td>
<td>t</td>
</tr>
<tr>
<td>4b. Mean MISS rapport (possible range 1–7)</td>
<td>5.3</td>
<td>5.5</td>
<td>0.20</td>
<td>t</td>
</tr>
<tr>
<td>5. Mean “Enough information” score (possible range 1–7)</td>
<td>4</td>
<td>4</td>
<td>0.72</td>
<td>t</td>
</tr>
<tr>
<td>6. Mean state anxiety score (possible range 20–80)</td>
<td>32.2</td>
<td>32.1</td>
<td>0.97</td>
<td>t</td>
</tr>
</tbody>
</table>

MISS, Medical Interview Satisfaction Scale; CRQ, Chronic Respiratory Questionnaire.

*Data available only for participants who completed to 12 months.

Bold indicates statistical significance at the 0.05 probability level.

### Outcomes

Outcome measures at 12 months are shown in Table 3. One of the three components of the primary outcome measure, enrolment for pulmonary rehabilitation, showed significant change for the most socioeconomically disadvantaged stratum. There

### Table 3  Outcome change scores at 12 months by socioeconomic disadvantage median split

<table>
<thead>
<tr>
<th>Group</th>
<th>Socioeconomic disadvantage level</th>
<th>Intervention</th>
<th>Control</th>
<th>Significance level for comparison of interventions and control groups*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Higher (n = 22)</td>
<td>Lower (n = 78)</td>
<td>Higher (n = 72)</td>
<td>Lower (n = 29)</td>
</tr>
<tr>
<td>1a. Flu vaccination rate (%)</td>
<td>+7</td>
<td>-1</td>
<td>+5</td>
<td>0.83</td>
</tr>
<tr>
<td>1b. Bone density test within 3 years, rate (%)</td>
<td>+6</td>
<td>+16</td>
<td>+7</td>
<td>+17</td>
</tr>
<tr>
<td>1c. Pulmonary rehabilitation rate (%)</td>
<td>+18</td>
<td>+12</td>
<td>0</td>
<td>+7</td>
</tr>
<tr>
<td>8. CRQ mastery (mean)</td>
<td>-0.1</td>
<td>0</td>
<td>0</td>
<td>0.70</td>
</tr>
<tr>
<td>9. Knowledge (mean)</td>
<td>0</td>
<td>+1</td>
<td>+1</td>
<td>+2</td>
</tr>
<tr>
<td>10. Enough information (mean)</td>
<td>+1</td>
<td>+1</td>
<td>+1</td>
<td>+1</td>
</tr>
<tr>
<td>11. MISS rapport (mean)</td>
<td>-0.1</td>
<td>-0.1</td>
<td>-0.5</td>
<td>-0.1</td>
</tr>
<tr>
<td>12. MISS Communication &amp; comfort (mean)</td>
<td>-0.2</td>
<td>0</td>
<td>-0.4</td>
<td>0</td>
</tr>
<tr>
<td>13. Anxiety (mean)</td>
<td>+2.0</td>
<td>+2.2</td>
<td>+2.0</td>
<td>+2.6</td>
</tr>
</tbody>
</table>

CRQ, Chronic Respiratory Questionnaire; MISS, Medical Interview Satisfaction Scale.

*Using analysis of covariance on change score, controlled for baseline measure and propensity score, except for pulmonary rehabilitation rate (1c), which was analyzed using Poisson modeling with robust errors, adjusted for baseline rate.

Bold indicates statistical significance at the 0.05 probability level.
was a nonsignificant trend in the same direction for pulmonary rehabilitation in the most socioeconomically advantaged stratum. There were no other significant differences and few trends in favor of either group for primary and secondary outcomes.

**Processes**

Process survey results are shown in Table 4. For both socioeconomic strata, significantly more intervention participants than control participants reported that they remembered receiving the information material, read part or all of it, and found it very or quite helpful. Other significant differences were restricted to the stratum with greatest socioeconomic disadvantage. More intervention participants in this stratum reported that they read all of the material, learned from it, referred back after first reading, and talked to a doctor about a topic from the material. For all other comparisons, nonsignificant trends showed greater completion of process steps by intervention participants.

Figure 3 shows an examination of process steps for the complete intervention group only. Above 90% of participants who received the manual reported reading at least some of it. Forty-two percent reported talking to their doctor about a topic from the manual but only 10% reported that this led to treatment change.

**Discussion**

**Findings**

The study did not find that providing summaries of evidence to people with COPD led to improved application of evidence in their medical care.

### Table 4  Process survey results

<table>
<thead>
<tr>
<th>Socioeconomic disadvantage level</th>
<th>Intervention</th>
<th>Control</th>
<th>Significance level for comparison of interventions and control groupsa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>Higher (n = 22)</td>
<td>Lower (n = 78)</td>
<td>Higher (n = 72)</td>
</tr>
<tr>
<td>Remember receiving</td>
<td>22 (100)</td>
<td>71 (91)</td>
<td>53 (74)</td>
</tr>
<tr>
<td>Read part or all</td>
<td>20 (91)</td>
<td>71 (91)</td>
<td>46 (64)</td>
</tr>
<tr>
<td>Read all</td>
<td>18 (82)</td>
<td>51 (65)</td>
<td>38 (53)</td>
</tr>
<tr>
<td>Learned something</td>
<td>15 (68)</td>
<td>42 (54)</td>
<td>27 (37)</td>
</tr>
<tr>
<td>Referred back</td>
<td>13 (59)</td>
<td>38 (49)</td>
<td>14 (19)</td>
</tr>
<tr>
<td>Very or quite helpful</td>
<td>19 (86)</td>
<td>62 (79)</td>
<td>34 (47)</td>
</tr>
<tr>
<td>Talked to doctor</td>
<td>8 (36)</td>
<td>34 (44)</td>
<td>11 (15)</td>
</tr>
<tr>
<td>Treatment changed</td>
<td>2 (9)</td>
<td>8 (10)</td>
<td>2 (3)</td>
</tr>
</tbody>
</table>

aChi-square test.

bFisher’s exact test, if numbers were small.

However, the study did find that a patient-held manual containing summaries of evidence, which was developed using current best practice, was more likely than a conventional pamphlet to be remembered, read, and considered helpful by people with COPD. People with greatest socioeconomic disadvantage reported greatest use of the manual. Interestingly, approximately 50% of the people who read the manual subsequently discussed a related topic with their doctor but very few reported treatment change attributable to the manual. This
suggests that either these discussions were not patient requests for treatment change, or if they were, doctors did not make the treatment changes requested by patients.

**Comparison with findings of other studies**

A comprehensive review found a lack of other studies on the effects of patient-held evidence summaries on clinical decisions in chronic disease. However, there have been outcome and process evaluations of other kinds of information materials for people with chronic disease and of evidence-based information for other target audiences. Best practice development methods do not appear to have been used for most of these materials and they had little success in influencing the behavior of target audiences and their doctors. An exception is a guidebook for people with irritable bowel syndrome, developed using current best practice, and found to reduce primary care consultations and perceived symptom severity.

**Limitations**

Some design limitations of our study may have meant that some positive outcomes were not detected. Only three aspects of COPD management were measured for the primary outcome. Other, unmeasured changes may have been prompted by the manual. The duration of the trial may have been insufficient to demonstrate change because only a few of the evidence summaries would be relevant to any one participant over a 12-month period. Higher than expected baseline rates among people who volunteered for the study for components of the measure of best practice had the effect of reducing the power of the study. The need to stratify analyses and include propensity scores to adjust for unforeseen baseline differences further reduced power.

The control pamphlet was included to control for the attention effects of giving information materials and for any positive effects from introductory disease-related information that was included in the manual, along with the evidence information which was being trialed. However, the control pamphlet could have weakened the apparent effectiveness of the manual. The pamphlet contained some advice on dealing with exacerbations, stopping smoking, influenza vaccination, pulmonary rehabilitation, and home oxygen, even though research support for this advice was not provided. Ensuring control for nonspecific aspects of the trial intervention may have meant that effects which would be seen in clinical practice were not demonstrated in the trial. Though it was freely available in treatment settings, 83% of control participants said that they have not seen this pamphlet earlier. The control condition did not therefore accurately reflect usual practice.

Nonblinded interviewers could have influenced the results in spite of standardizing of methods, though greater blinding is difficult with this type of study. Practice nurses and respiratory nurses have a growing role in behavior change for self-management of chronic disease. By focusing on the doctor and patient as key figures in decision making, the trial may not have accounted for the potential of nurses to increase patient participation in evidence-based decision making.

**Future work**

This study has shown that summaries of evidence, developed according to current best practice, are read by patients, including those with high socioeconomic disadvantage. However, if these evidence summaries are to be used in decision making, they must not only be read but they must also lead to behavior change for patients and doctors. More needs to be known about what actually happens in the consultation to improve our understanding of how the informed patient might influence the doctor's decision making as a basis for future interventions. Recent advice proposes that behavioral interventions should be guided by theory and research relating to the operation of the intervention so that weak links in the causal chain can be identified and strengthened. Our study showed the doctor–patient consultation to be a weak link for interventions such as the COPD manual. In recent studies involving recordings of general practice consultations, most decisions were doctor-led rather than shared- or patient-led. Research is now being conducted into doctors' and patients' perceptions of obstacles and facilitators to an increased role for patients, and into doctor-targeted and patient-targeted interventions to increase patient participation in medical decisions. Such studies can be used to inform the design of future interventions, which not only provide summaries of evidence to patients but also facilitate
their participation in decision making and trigger treatment change.

**Ethics committee approvals**

Ethical approval for all components of this evaluation was obtained from the committees of The Queen Elizabeth Hospital, the Flinders Medical Centre, the Repatriation General Hospital, and the Commonwealth Department of Veterans Affairs. General practitioner organizations for the areas covered by these hospitals also approved the study.

**Competing interests**

PF is a member of Advisory Boards for COPD with ALTANA Pharma and Boehringer Ingelheim/Pfizer, member of the Global Education Council for COPD with ALTANA Pharma, and committee member of the International COPD Coalition (sponsored by Novartis, Pfizer, Altana Pharma, Boehringer Ingelheim, GlaxoSmithKline and AstraZeneca). Other authors declare no competing interests.

**Funding**

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**Intervention manual**

A copy of the manual used in the trial is available on request from the corresponding author.

**References**


