Managing with Learning Disability and Diabetes: OK-Diabetes – a case-finding study and feasibility randomised controlled trial

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Scientific summary

OK-DIABETES: feasibility study and RCT

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Scientific summary

It is estimated that approximately 1.2 million people in the UK have a mild or moderate learning disability. Reports, such as MENCAP's *Death by Indifference: 74 Deaths and Counting. A Progress Report 5 Years On* (London: MENCAP; 2012) and the *Confidential Inquiry into Premature Deaths of People with Learning Disabilities* (Heslop P, Blair P, Fleming P, Hoghton M, Marriott A, Russ L; Bristol: Norah Fry Research Centre; 2007), suggest that health problems in people with a learning disability are more severe than those in the general population and that these are not always identified or treated adequately. The prevalence of diabetes in individuals with a learning disability has been estimated to be higher than that of the average population.

Although self-management of type 2 diabetes is encouraged in the general population, its value has not been explored in people with a learning disability. This project sought to explore the feasibility of conducting a definitive Phase III randomised controlled trial (RCT) to evaluate the cost-effectiveness of supported self-management (SSM) of type 2 diabetes in people with a learning disability and comprised the following: (1) a study of case finding and recruitment; (2) the development of materials to implement and evaluate a RCT of SSM; and (3) a feasibility RCT of SSM and treatment as usual (TAU) versus TAU.

A study of case finding and recruitment

Objectives

1. To develop and evaluate a case-finding method to identify participants who have a mild to moderate learning disability and type 2 diabetes, who are not taking insulin and who might be suitable for SSM.
2. To estimate the unmet health-care needs of consenting participants.
3. To develop procedures for determining, and recording, capacity and obtaining consent.
4. To identify candidates for recruitment into a feasibility RCT.

Design

A cross-sectional observational study.

Setting

Three cities in West Yorkshire, UK: Bradford, Leeds and Wakefield.

Target population

Adults aged ≥ 18 years who:

- have type 2 diabetes, on diet alone or treated by hypoglycaemic agents other than insulin
- have a mild to moderate learning disability
- have intellectual deficits not attributable to neurological problems acquired in adult life
- are living in the community
- have the mental capacity to consent to participate in the research.

Procedures

- A search strategy to enable staff working in primary care to identify potential participants. The strategy included Read Code-based searches of primary care case registers that were developed for the project.
- Simple recruitment strategies for third-sector and community services.

- Accessible information and consent materials produced in collaboration with people with a learning disability and the organisations that support them.
- A standardised interview and data extraction form (for general practice records) to describe, and identify, current health-care needs.

After referral, potential participants who consented to initial contact were checked for eligibility and visited to obtain consent. All potential participants were interviewed to (1) identify those who met entry criteria and obtain informed consent, (2) establish current diabetes management and physical health state, (3) identify supporters and their role in diabetes management and (4) elicit preference for further assistance with diabetes self-management and consent to further researcher contact.

Outcomes

The feasibility of case ascertainment, an estimate of eligibility and a characterisation of the eligible population.

Sample size

We estimated that we could recruit 350 participants from 50% of the general practices in the three cities in the UK, enabling us to estimate the proportion eligible for the feasibility RCT to within 5.2%, with a two-sided 95% confidence interval (CI). We found lower than expected recruitment rates as a result of underestimating the use of insulin in this population, less than expected young-onset type 2 diabetes and stronger bias of learning disability registers to more severe cases. However, we found higher than expected agreement to further research contact. We revised the target to 120 participants to enable recruitment to the feasibility RCT.

Results

From a total of 365 referrals, we identified 325 individuals from 60% of general practices and third-sector organisations in the three cities, yielding 172 valid referrals and 147 (95% CI 39.8% to 50.6%) eligible and consenting participants. Contact and recruitment typically took multiple attempts, both for consent to contact and to complete researcher visits.

Of those who consented, the mean age was 54.4 years [standard deviation (SD) 12.8 years] and female-to-male ratio was 50 : 50. In total, 130 out of 147 individuals (88%) named a key supporter and 113 (77%) had a supporter who was involved in diabetes management. Comorbidity was common and 98% of individuals were on at least one other (non-diabetes) general practice disease register.

Non-response rates were high (45/147, 31%) for requests to general practices for medical data. When data were available, glycaemic control was better than expected: mean glycated haemoglobin (HbA_{1c}) level was 54.5 mmol/mol (SD 14.8 mmol/mol) or 7.1% (SD 1.4%). Obesity was a major problem, with 65% of participants having a body mass index (BMI) of > 30 kg/m^2 and 21% with a BMI of > 40 kg/m^2. Many participants reported low mood, dissatisfaction with lifestyle and diabetes management and an interest in change.

A total of 132 participants (90%) were willing to be recontacted for further research.

Developing a self-management intervention and materials for use in a randomised controlled trial of supported self-management

Objectives

1. To identify existing information resources on diabetes self-management suitable for people in our target group.
2. To develop a standardised but flexible intervention, including written materials to aid SSM of type 2 diabetes.

3. To field test the intervention and assess it for acceptability and feasibility of delivery.
4. To develop and field test a simple measure of adherence to the intervention.
5. To develop materials for estimating the resource use of participants outside the RCT, the costs of intervention in a RCT and the subsequent resource in both arms of the RCT.

Design

Literature reviews with narrative synthesis and consensus-based problem-structuring.

Outputs

1. Self-management materials derived from existing literatures in learning disability and diabetes and chronic disease self-management, and from content of related care pathways, such as that for obesity.
2. A measure of both provider and participant adherence.
3. Data collection tool for health economic analysis.

Results

We developed a brief (typically three or four contact sessions) SSM package, trained two diabetes specialist nurses in its use and field tested it for acceptability.

We developed a measure of adherence with elements recording both provider adherence (fidelity) and participant adherence.

We were unable to identify any practicable learning disability-specific instruments for recording resource use in this population or any quality-of-life measures that would supersede the standard ones.

Feasibility randomised controlled trial of supported self-management

Objectives

1. To estimate recruitment, retention and follow-up rates for a definitive (Phase III) trial.
2. To assess the acceptability, and feasibility, of implementing the intervention developed earlier in the project via adherence, dropouts and negative outcomes.
3. To test the feasibility of using a standardised adherence measure to assess delivery and use of self-management techniques.
4. To provide a detailed description of what treatment is delivered to each arm.
5. To assess the feasibility of collecting a range of physiological, psychological, behavioural and cost-effectiveness outcome measures and maintaining the blind for subjective outcomes.
6. To measure the variability in the main outcomes [especially HbA_{1c} level, blood pressure (BP), BMI and EuroQol-5 Dimensions (EQ-5D)].
7. To qualitatively explore any challenges to the validity of data collection.
8. To qualitatively explore any aspects of the experience of research participation or of involvement in SSM that may need modification in a definitive trial.
9. To develop a checklist of potential negative outcomes.

Design

An individually randomised parallel-group feasibility RCT of SSM and TAU versus TAU.

Target population

Participants who:

1. were identified in the case-finding study and are still not using insulin
2. are still living in the community

3. have evidence of suboptimal diabetes control: HbA_{1c} level of > 6.5% (48 mmol/mol), a BMI of > 25 kg/m^2 or self-reported physical activity below national guideline levels
4. have mental capacity to consent to participation in the trial.

People with a learning disability without supporters were included, as were those who had a supporter who declined to participate.

Technology

Standardised SSM of diabetes, delivered by trained and supervised diabetes specialist nurses, was provided to the intervention arm. Every participant was given an easy-read guide to self-management of type 2 diabetes. Usual care was otherwise delivered according to usual local practice.

Data collected (baseline and 4–6 months following randomisation)

1. Recruitment and retention rate.
2. Variability of, and the percentage abnormal (on standard criteria), for:

    i. HbA_{1c} level, BMI, BP and thyroid function
    ii. vascular risk markers (triglycerides, glucose, cholesterol and renal function)
    iii. QRISK®2 score: a composite measure of risk of cardiovascular events
    iv. microvascular risk marker (microalbuminuria)
    v. participant mood measured using the Patient Health Questionnaire-2.

3. Description of uptake and adherence to intervention on both arms.
4. Description and comparison of usual care across arms, medication use and negative outcomes, such as hospital contact, falls and increased distress.
5. Health economic data (health-related quality of life, the EQ-5D, and NHS and supporter costs).
6. Qualitative data (positive and negative experiences of implementing self-management and further detail regarding experience of TAU).
7. Withdrawals from treatment or follow-up and related unexpected serious adverse events.

Sample size

A minimum of 80 individuals were required for the feasibility RCT, randomised 1 : 1 to the intervention versus TAU.

Results

We contacted 127 out of 132 (96%) participants who had consented to contact for further research and 82 out of 127 (65%) were eventually randomised into the feasibility RCT. Of these, 42 out of 82 (51%) individuals either could not name a key supporter or had a supporter who declined to participate. The feasibility RCT sample was similar across demographic characteristics to the group in the initial case-finding sample, although they had slightly higher BMI and HbA_{1c} level. The mean baseline HbA_{1c} levels in those randomised was 56 mmol/mol (SD 16.5 mmol/mol) or 7.3% (SD 1.5%) and the mean BMI was 34 kg/m^2 (SD 7.6 kg/m^2).

All SSM sessions were completed by 35 out of 41 participants allocated to SSM. Independent review of attendance at, and content of, self-management sessions was obtained from all those participants engaging with the intervention (37/41), showing that the method for adherence measurement was appropriate and simple to complete.

Candidate primary outcomes HbA_{1c} level and BMI were obtained for 75 out of 82 (91%) and 77 out of 82 (94%) participants, respectively. The mean HbA_{1c} level and BMI at follow-up were similar in intervention versus TAU arms, respectively: HbA_{1c} level of 54.0 mmol/mol (SD 13.5 mmol/mol) versus 54.6 mmol/mol (SD 19.6 mmol/mol) or 7.1% (SD 1.24%) versus 7.1% (SD 1.79%); and a BMI of 34.2 kg/m^2 (SD 8.7 kg/m^2)

versus 34.1 kg/m^2 (SD 8.5 kg/m^2). From the analysis of individual change scores, there was evidence that change in either HbA_{1c} level or BMI as outcome measures would be sensitive to change in a Phase III trial.

Most participants reported a positive experience of the intervention, although many found it difficult to make consistent changes. A low response rate was a challenge to obtaining data for an economic analysis, and we noted that participants struggled to understand the standardised questions in EQ-5D.

Conclusions

- We were able to develop a case-finding method that identified eligible individuals who were interested in participation from the target population.
- We were able to develop participant information and consent materials and use them to recruit research participants who had mental capacity to consent.
- Many of the consenting participants had health needs that would benefit from improved self-management. Obesity and inactivity were more of a problem than poor glycaemic control; this probably reflected the ability of supporters to influence outcomes that depended upon medical intervention rather than lifestyle change.
- Recruitment was resource-intensive but yielded a sample willing to participate in research and who expressed an interest in changing their diet, activity levels and diabetes self-management.
- It therefore proved possible to recruit and retain people with a mild to moderate learning disability in a randomised trial (RCT) aimed at improving supported diabetes self-management.
- We were able to develop a simple quantitative measure that recorded participant and provider adherence to content, delivery and enactment of the intervention and enabled reporting of an adherence measure.
- Adherence to the intervention was high; the main barrier to delivering the intervention was inconsistency in the involvement of supporters.
- We were not able to obtain candidate primary outcome measures in a complete and timely manner from general practice records, but we were able to obtain them at research visits in > 90% of participants.
- There were high numbers of missing data for secondary outcomes that depended on responses from general practice records, including those necessary to establish costs for an economic evaluation.
- Quality of life was difficult to assess because of the lack of participant understanding of the structured assessment.
- We found no evidence that research participation or exposure to the SSM intervention had an adverse effect on participants.
- Our results of HbA_{1c} levels for the feasibility RCT participants at baseline were 56.1 mmol/mol (SD 16.5 mmol/mol) [7.3% (SD 1.5%)] and at follow-up were 54.3 mmol/mol (SD 16.7 mmol/mol) [7.1% (SD 1.5%)]. A clinically important reduction in HbA_{1c} level is usually taken to be at least 5.5 mmol/mol (0.5%), which is equivalent to an effect size of 0.333 (based on the SD of 16.5 mmol/mol). For a definitive trial to have 90% power ($\alpha < 0.05$), a sample size of 194 participants per arm would be required; we estimate that this would require 18–24 months of recruiting from a population of about 9 million.

Implications for health care

For people with a learning disability who do not find attendance at a group educational programme easy, support from a diabetes nurse who is familiar with the principles of self-management would be a helpful alternative.

Our findings suggest that one fruitful approach may be a specific weight management intervention aimed at reducing high levels of obesity and inactivity. This would meet the main needs of people with type 2 diabetes and a learning disability and support diabetes prevention goals. New approaches will be needed to encourage and engage key supporters and embed change for longer-term maintenance of weight change.

Recommendations for research (numbered in priority order)

1. The majority of participants were on a learning disability register. However, only a minority of referrals resulted from searching those registers. Research is needed into effective ways of identifying those adults with milder learning disabilities who are not on a primary care register, and who are in need of support in using health care, for whom reasonable adjustments have been made.
2. Research to evaluate more intensive and sustained interventions for type 2 diabetes in adults with a mild or moderate learning disability, including those prescribed insulin.
3. Research into new approaches to increasing supporter involvement in interventions aimed at improving the physical health of those with a mild or moderate learning disability and in identifying new ways of supporting those who do not have a consistent social support structure.
4. Research to evaluate whether or not weight management programmes (including commercial programmes) of known effectiveness in the general population are similarly effective in adults with a mild or moderate learning disability once reasonable adjustments have been made.
5. Research into improving ways of assessing quality of life in adults with a learning disability, who did not always understand the (unmodifiable) wording of questions in EQ-5D.

Trial registration

This trial is registered as ISRCTN41897033.

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