A multi-centre randomised controlled trial of motivational interviewing in teenagers with diabetes

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Channon S\textsuperscript{1}, Huws-Thomas MV\textsuperscript{2}, Rollnick S\textsuperscript{3}, Hood K\textsuperscript{4}, Cannings-John R\textsuperscript{5}, Rogers C\textsuperscript{6}, Gregory JW\textsuperscript{7}

Running title: Motivational Interviewing with teenagers

Affiliations:

1. Sue J Channon D Clin Psych, Consultant Clinical Psychologist, Department of Child Psychology, Cardiff and Vale NHS Trust
2. Michelle V Huws-Thomas MSc, Lecturer in Mental Health, School of Nursing and Midwifery studies, Cardiff University
3. Stephen Rollnick PhD, Professor of Healthcare Communication, Department of General Practice, Cardiff University
4. Kerenza Hood PhD, Director, South East Wales Trial Unit, Cardiff University
5. Rebecca L. Cannings-John MSc, Statistician, Department of General Practice, Cardiff University
6. Carol Rogers, RGN, School Nurse, Department of School Health Nursing, Cardiff and Vale NHS Trust
7. John W. Gregory MD, Professor of Paediatric Endocrinology, Department of Child Health, Cardiff University

Correspondence to S. Channon,
Child Clinical Psychology Department,
Children’s Centre,
St David’s Hospital, Canton, Cardiff CF11 9XB
E-mail: sue.channon@cardiffandvale.wales.nhs.uk

Additional information can be found in an online-only appendix at http://care.diabetesjournals.org
Objective
To examine the efficacy of Motivational Interviewing with teenagers aged 14-17 years with Type 1 diabetes.

Research Design and Methods
In a randomised controlled trial analysed by intention to treat, 66 teenagers with Type 1 diabetes attending diabetes clinics in South Wales UK were randomly assigned to the intervention group (38) and to the control group (28). Teenagers in the intervention group received Motivational Interviewing and the control group received support visits. All participants received individual sessions over 12 months. The main outcome measures assessed at baseline, 6, 12 and 24 months were serum glycosylated haemoglobin concentrations (HbA1c), psychosocial self-report questionnaires including quality of life and well-being measures.

Results: Sixty patients had complete data at 12 months. At the end of the intervention (12 months) the mean HbA1c in the Motivational Interviewing group was significantly lower than in the control group (p=0.04), after adjusting for baseline values. At 24 months (when N=47) this difference in HbA1c was maintained (p=0.003). There were differences in psychosocial variables at 12 months, with the Motivational Interviewing group indicating more positive well-being, improved quality of life and differences in their personal models of illness (all p<0.01). Some of these differences were maintained at 24 months.

Conclusions: Motivational Interviewing can be an effective method of facilitating teenagers with type 1 diabetes to make behaviour changes with subsequent improvement in their glycaemic control.

Trial Registration: Clinicaltrials.gov ID: NCT00326573
Type 1 diabetes is the third most common chronic illness in teenagers (1). It imposes physical and emotional burdens on young people and their families (1) and can have a profound effect on quality of life (2). The beneficial effects of favourable glycaemic control in the prevention of long-term complications are well documented (3). However, recognition of the impact of psychosocial factors on self-care during adolescence has led to a focus on psychosocial interventions to improve outcomes.

A review of educational and psychosocial interventions for adolescents with type 1 diabetes (4) concluded that there was a need for more well-designed trials of such interventions, particularly in the UK healthcare context. Motivational Interviewing (MI), a counselling approach to facilitate behaviour change (5), has been demonstrated to be effective in adults in some healthcare settings (6,7) and there is preliminary evidence of its effectiveness in improving glycaemic control and psychological well-being in teenagers with type 1 diabetes in short-term, uncontrolled trials (8,9). The multi-centre randomised controlled trial reported here was developed to replicate and extend the findings of the pilot study (8) employing a fully powered design and an evaluation of longer-term outcomes.

RESEARCH DESIGN AND METHODS
Aims and Hypotheses
The aim of this study was to examine the impact of MI, compared to the control intervention of support visits, on serum HbA1c concentrations and psychosocial functioning in adolescents with type 1 diabetes. We hypothesised that, compared to the control group, MI would improve psychosocial functioning and reduce HbA1c concentrations.

Design
This study was designed as a multi-centre trial of a complex intervention, providing a phase II level of evidence of efficacy (10). Each intervention was delivered by one person for all participants in their arm of the study. Following randomisation, participants received either MI or support visits for one year with a 12-month follow-up. The interventionists worked independently from the diabetes clinics. Clinic staff were unaware which children were participating in the study and participants were unaware to which arm of the trial they had been randomised. The study received ethical approval from the local research ethics committees.

Participants
Participants were recruited from five diabetes services between January and September 2002. The centres with diabetes clinics ranging between 49 and 220 patients were all in the industrially developed region of South Wales. All individuals aged between 14 and 17 years with type 1 diabetes, regardless of glycaemic control, attending diabetes clinics in the participating centres were eligible, with the following exceptions: less than one year since diagnosis, learning disabilities, other medical conditions affecting diabetes management, medical care predominantly managed elsewhere or accommodated by social services.

Recruitment
The diabetes nurse specialists for each centre sent information about the study to all eligible patients and to their parent/guardian. Following consent to contact, the young people were seen by the researcher and given further
information about the study. Informed consent was obtained from both the young person and their parent/guardian prior to randomisation.

Sample size
In order to detect a difference of 1% in mean HbA1c (SD = 1.2%) at a 5% significance level with 90% power, 30 patients per group would be required. To allow for a loss to follow-up rate of 25%, we aimed to recruit 80 patients.

Randomisation
Participants for each centre were all recruited and completed the baseline assessments prior to being randomised into one of two groups using randomly permuted blocks of four. One group received MI and, to control for the effect of additional contact, the control group received support visits. Randomisation was completed independently and remotely stratified by gender and clinic.

Interventionists
There were two female interventionists, both with a nursing background. The MI interventionist was in training as a Health Psychologist.

Interventions
The MI intervention (described in Channon et al (11)) used the ‘menu of strategies’ approach (12,13) eliciting patient views then exploring discrepancies between beliefs and behaviour. While no two MI sessions will be the same as they are patient-driven, they are likely to include the following aspects:

i) Awareness-building. The clinicians role is to help the patient articulate their simultaneously held but conflicting beliefs about behaviour change. In making decisions about changing behaviour, individuals weigh up the benefits of making the change against the personal costs which may be social, emotional or financial. Their ambivalence about making that change reflects the balance of those benefits and costs, the clinicians role is to elicit them and increase the patient's awareness of them.

ii) Alternatives. Once the patient is more aware of the costs and benefits of their behaviour, alternatives to the current behaviours are considered.

iii) Problem-solving. Having identified alternative behaviours, the costs and benefits of the different options are discussed.

iv) Making Choices. The selection of an alternative behaviour to implement rests with the patient.

v) Goal-setting. Once the alternative behaviour has been chosen the clinician and patient set a goal that is realistic and achievable in the time between appointments.

vi) Avoidance of confrontation. One of the central tenets of motivational interviewing is avoidance of confrontation, to reduce resistance and argumentation. Instead the style is eliciting, using open-ended questions to encourage participants to articulate their concerns and goals.

The control intervention was non-directive psychological support with the aim of providing support, information and education in a patient-centred style. Both interventionists received fortnightly supervision to ensure quality control and, where possible, interviews were audi-taped. A sample of the MI tapes was also reviewed by external MI trainers to ensure fidelity of the method to the tenets of MI. In neither group was advice given regarding changes in insulin regimen, all these issues were directed to the participant’s diabetes team.

For participants in the MI group the frequency and location of appointments was determined by the participants to fit with the patient-driven principles of MI. In the control group the pattern of visits was more structured, with appointments
arranged every 6-8 weeks, a frequency based on contact data from the pilot study, to control for anticipated level of contact in the MI group.

Intervention delivery took place between July 2002 and September 2003, mostly in participants’ homes with some interviews conducted in cafes or parks etc and lasting between 20 to 60 minutes. Interviews finished after a maximum of 12 months contact for each individual. The mean number of visits was 6 for the control group participants and 4 within the MI group.

Primary and secondary outcome measures
The primary outcome measure was mean serum HbA1c concentration measured at baseline, 6, 12, 24 months. The secondary outcome measures were psychosocial questionnaires completed independently by the participants. The measures used (and domains they measure) were: Diabetes Quality of Life Measure for Youths (DQoLY) (14) (life satisfaction, disease impact and disease related worries); Child Health Locus of Control CHLC (15)(locus of control in relation to health issues); Modified Health Care Climate Questionnaire (HCCQ) (16) (perceptions of the degree of autonomy support from their healthcare providers); Diabetes Knowledge scale (DKN) (17) (knowledge about diabetes); Self-Efficacy for Diabetes scale (SEDS) (18)( self-efficacy beliefs); Well-being Questionnaire (WBQ) (19) (depressed mood anxiety and positive well-being); Diabetes Family Behaviour Scale (DFBS) (20)(diabetes specific family support); Personal Models of Diabetes Scale (PMDS) (21) (personal beliefs and models of illness) All the questionnaires were completed at baseline and 12 months, with Diabetes Quality of Life and Well-being Questionnaire also completed at 24 months.

Data collection and collation
The baseline HbA1c and psychosocial data collection were completed prior to the start of the intervention. All capillary blood samples for HbA1c measurement were mailed to a single independent clinical biochemistry department and analysed by high-pressure chromatography. The coefficients of variation within and between the HbA1c assays were <1.15% and <1.75% respectively. Questionnaire data were collated and coded onto SPSS Software Version 11. Follow-up data was collected between June and September 2004.

Statistical Analysis
In order to compare the two groups a repeated measures analysis of covariance (ANCOVA) was performed with HbA1c concentrations at 6, 12 and 24 months and the baseline measurement treated as covariate. Analysis is presented for the effect of the intervention immediately post intervention as well as the overall analysis across all time points.

For each of the psychological scales, participants with ≤ 20% of scale items missing were imputed by using the mean values of the remaining items. ANCOVA was used to compare the groups with respect to their individual psychosocial measurements at 12 and 24 months, again using baseline as the covariate. To allow for multiple comparisons, a Bonferroni correction was used.

Exploratory analysis of the associations between changes in key psychosocial outcomes during treatment (0-12 months) with subsequent changes in HbA1c (12-24 months) was conducted.
within groups using Pearson’s correlation coefficients.

All analyses were carried out on an intention to treat basis.

RESULTS

The flow diagram (Figure 1) shows the trial profile. From the original 169 eligible patients, 80 agreed to participate and were randomly allocated to either MI (n=43) or support visits (n=37). One participant randomised to the control group was ineligible. A total of 13 patients (5 in MI group, 8 in Control group) declined to participate after randomisation but prior to the first visit. Analyses were based on the remaining 66 participants of whom 60 had complete HbA1c data at 12 months.

Demographic characteristics
Participants in the MI and control groups were well matched for age (mean (SD) 15.3(0.97) and 15.4(1.19) years respectively), duration of diabetes (9.2(1.96) and 9.1(1.47) years), ethnicity (all caucasian), gender (47% and 50% male) and socioeconomic status (median group 4 and 3). There were no significant differences between the two groups with respect to the baseline characteristics of age, duration of diabetes, gender and HbA1c. The mean HbA1c for the five participating centres ranged from 8.4% to 10.0% and for the participants the range was 8.8% to 10.3%. There were a variety of insulin regimens across both groups with participants all injecting insulin 2-4 times daily.

Attrition
More participants withdrew from the MI intervention in the first six months (n=10) than in the control group (n=4) but this was not statistically significant (p=0.24). There were no significant differences between these participants and those who continued with respect to their baseline characteristics, HbA1c and psychological outcomes.

Primary outcome measure – serum HbA1c concentration
At the end of the year-long interventions, the mean HbA1c concentrations between the two groups were significantly different (F=4.276, p=0.04 see table 1) after adjusting for baseline. This effect was maintained one year after completion of the intervention, 24 months after starting the study (F=9.707, p=0.003).

Although every effort was made to ensure a complete HbA1c data set for each participant, this was not achieved due to lost or insufficient samples, participants discontinuing the study or being unavailable for sampling. The analysis of the mean HbA1c concentrations in the 47 participants with a complete data set (i.e. four measurements) is shown in Table 1. The patterns of change were similar to those seen when all participants’ data, including those with incomplete data, were analysed.

Secondary outcome measures - Psychosocial questionnaires
There were no baseline differences between groups in any of the psychosocial measures.

Differences were found between groups in well-being, quality of life and personal models of illness after 12 months (all p<0.001, see table 2). Compared to the control group, the MI group had higher life satisfaction, lower life worry, experienced less anxiety and had more positive well-being. The MI group also perceived their diabetes to be more serious and placed greater importance on controlling it. They had stronger beliefs that certain actions were more likely to help prevent future
complications of diabetes and perceived it to have a smaller degree of impact on their lives.

At 24 months, although fewer questionnaires were completed (n=34) significant differences were still found between the two groups with respect to life worry and anxiety (F=17.795, p=0.001 and F=18.908, p<0.001 respectively). Satisfaction and impact were also significant at 24 months (F=7.007, p=0.012 and F=8.129 p=0.008 respectively).

Exploratory analysis of the associations between changes on key psychosocial measures during the intervention phase and subsequent levels of glycaemic control showed that increasing worry and reduction in satisfaction from 0-12 months in the MI group were significantly associated with improvements in HbA1c from 12-24 months (r=-0.40, p=0.03 and r=-0.61, p<0.001 respectively). There were no significant associations between these measures and subsequent control in the support group (r=0.31 and r=0.22 respectively) and the directions of association were the opposite of those found in the MI group.

DISCUSSION

The results of this study show that MI can be an effective method of working with teenagers with diabetes, producing long-term improvements in glycaemic control, psychological well-being and quality of life. Their personal models of illness indicated a stronger belief that self-care could make a difference to diabetes outcomes.

The study reported here is the first randomised-controlled trial of MI in childhood diabetes. It extends the evidence and confirms the beneficial impact of psychosocial interventions based on the principles of MI that have been previously reported in smaller-scale studies (8,9). Furthermore, this study is one of very few which demonstrate, using a randomised control study design, the potential of a psychosocial intervention to improve glycaemic control in children with diabetes over a time period as long as two years (4). Given the potential benefit of improved glycaemic control on the future risks of developing microvascular complications of diabetes, our results suggest that psychosocial interventions such as MI may be of value in addition to pharmacological developments in reducing the longer-term adverse consequences of diabetes.

This was a robust study across centres representing a variety of demographic and clinical contexts with high quality intervention delivery, closely monitored to ensure adherence to the documented approaches. However, there were also some recognised weaknesses. By using two interventionists the outcome could be interpreted as therapist effect rather than resulting from MI. However both interventionists were closely supervised to ensure fidelity to the method of their respective interventions and this design was selected as the best possible for this phase of intervention development. The next phase would be a multi-centre trial with multiple interventionists.

Another possible explanation for the improvement in glycaemic control in those receiving MI may relate to changes in insulin regimen. Unfortunately this data was not collected during the trial but a retrospective analysis of a sub-sample of participants shows no evidence of a difference in frequency of change in insulin regimen between groups (data not shown). This would be a measure that would need to be incorporated into any larger scale trial.
Some attrition was inevitable in a multi-centre clinical trial with a two-year period of data collection. The volume of questionnaires was overwhelming for participants, leading to the decision at 24 months to collect psychosocial data only on well-being and quality of life to avoid the risk of losing all the follow-up data. There were few exclusion criteria and as a result we recruited some participants who already experienced good glycaemic control in whom behaviour change may have been unrealistic. Within a service setting it might be more appropriate to focus this intervention on young people with an HbA1c above 8% in whom there was a degree of readiness to change, a group who realistically would be the target for the clinical teams.

The results show a rise, albeit statistically non-significant, in HbA1c concentrations in the control group during the first six months with a return to baseline levels after one year. This phenomenon persists whether data for all participants or only those with complete data sets are analysed and was not seen in those receiving MI. A possible explanation for this rise is a seasonal effect as this data period coincided with winter when glycaemic control is known to deteriorate in children, presumably due to decreased levels of physical activity (23).

The results of our study demonstrate an association between changes in certain psychological variables and changes in HbA1c, the latter increasing in significance with time. Although cause and effect cannot be assumed, if psychological factors were to impact on HbA1c it might be anticipated that such psychological changes would precede changes in self-care which consequently led to changes in HbA1c concentrations. Our analyses suggest that MI might highlight concerns (with the reduction in satisfaction between baseline and 12 months) but also facilitate the patients’ perception that they had the capacity to make changes that in turn would lead to reduction in HbA1c. One possible theoretical explanation for these results could be taken from the work by Draycott and Dabbs (23,24) who mapped the principles of cognitive dissonance onto the principles and method of MI. The method of MI incorporates the principle of ‘deploying discrepancy’ in which the patients core values and personal aspirations are contrasted, through empathic listening, with the behavioural problem under discussion. It is hypothesised that this experience of discrepancy could trigger the motivation to change behaviour.

A systematic review of the literature of psychosocial interventions in childhood diabetes concluded that well-designed studies of such interventions are required, and our study meets many of their criteria. It has demonstrated that a psychosocial intervention can have a significant impact on psychosocial variables and HbA1c concentrations in a representative group of teenagers. Further work is required to determine whether MI is more suitable for certain subgroups of children and whether the independence of the intervention from the clinic, both in terms of venue and practitioners, is essential to its success. Furthermore, to maximise the value of this intervention, it would be important for the intervention to be part of routine care. Given the shortage of skilled child psychologists and psychiatrists available to support paediatric diabetes services, the next research priority is to identify the key components of MI which successfully result in behaviour changes in teenagers with a view to developing training of clinicians working in paediatric diabetes services to use these skills as part of everyday clinical care.
ACKNOWLEDGEMENTS

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References


Table 1. Mean (SD) HbA1c levels at baseline, 6, 12 and 24 months for participants with complete data

<table>
<thead>
<tr>
<th></th>
<th>MI group</th>
<th>Control group</th>
<th>Difference between groups</th>
<th>95% CI</th>
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<tr>
<td>N</td>
<td>27</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>9.3 (2.11)</td>
<td>9.0 (1.56)</td>
<td>0.3 (1.90)</td>
<td>(-0.80, 1.40)</td>
</tr>
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<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>27</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>9.0 (1.63)</td>
<td>9.5 (1.93)</td>
<td>-0.5 (1.76)</td>
<td>(-1.52, 0.52)</td>
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<td>6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>27</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>8.7 (1.84)</td>
<td>9.2 (1.78)</td>
<td>-0.5 (1.81)</td>
<td>(-1.55, 0.55)</td>
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<td>12 months</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>N</td>
<td>27</td>
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<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>8.7 (1.88)</td>
<td>9.1 (1.51)</td>
<td>-0.4 (1.73)</td>
<td>(-1.40, 0.60)</td>
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<td>24 months</td>
<td></td>
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<td>Measure</td>
<td>Sub-scales</td>
<td>Intervention</td>
<td>Control</td>
<td>F, p value</td>
</tr>
<tr>
<td>-----------</td>
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</tr>
<tr>
<td></td>
<td>Mean (sd)</td>
<td>Mean (sd)</td>
<td>F, p value</td>
<td></td>
</tr>
<tr>
<td>DQoLY (14)</td>
<td>Satisfaction*</td>
<td>33.28 (9.88)</td>
<td>45.55 (10.79)</td>
<td>F=31.769, p&lt;0.001</td>
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<td>Impact*</td>
<td>50.49 (12.05)</td>
<td>61.05 (18.48)</td>
<td>F=9.553, p=0.003</td>
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<tr>
<td></td>
<td>Worries*</td>
<td>17.71 (7.15)</td>
<td>30.23 (11.59)</td>
<td>F=22.209, p&lt;0.001</td>
</tr>
<tr>
<td>CHLC (15)</td>
<td>Total</td>
<td>15.88 (2.59)</td>
<td>16.40 (1.95)</td>
<td>F=0.034, ns</td>
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<tr>
<td>HCCQ (16)</td>
<td>Total</td>
<td>78.06 (20.34)</td>
<td>84.25 (13.30)</td>
<td>F=0.010, ns</td>
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<td>DKN (17)</td>
<td>Total</td>
<td>11.16 (1.86)</td>
<td>11.75 (1.77)</td>
<td>F=1.406, ns</td>
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<td>SEDS (18)</td>
<td>Total</td>
<td>175.92 (22.73)</td>
<td>169.85 (27.45)</td>
<td>F=0.733, ns</td>
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<td>WBQ (19)</td>
<td>Depression</td>
<td>10.08 (2.25)</td>
<td>11.85 (1.81)</td>
<td>F=4.326, p=0.044</td>
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<td>Anxiety</td>
<td>6.03 (2.23)</td>
<td>11.55 (3.69)</td>
<td>F=41.267, p&lt;0.001</td>
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<td>Energy</td>
<td>6.19 (1.86)</td>
<td>7.20 (2.31)</td>
<td>F=2.086, p=0.156</td>
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<td>Positive well-being</td>
<td>14.48 (3.20)</td>
<td>10.24 (3.27)</td>
<td>F=22.923, p&lt;0.001</td>
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<td>Total well-being</td>
<td>40.56 (4.51)</td>
<td>30.31 (5.90)</td>
<td>F=39.419, p&lt;0.001</td>
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<td>DFBS (20)</td>
<td>Importance</td>
<td>145.56 (20.64)</td>
<td>155.57 (16.45)</td>
<td>F=1.162, ns</td>
</tr>
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<td>PMDQ (21)</td>
<td>Likely</td>
<td>32.58 (5.06)</td>
<td>22.84 (4.02)</td>
<td>F=64.776, p&lt;0.001</td>
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<td>Worry</td>
<td>41.46 (6.25)</td>
<td>29.52 (5.54)</td>
<td>F=59.056, p&lt;0.001</td>
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<tr>
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<td>Agree/ disagree</td>
<td>33.19 (8.76)</td>
<td>24.78 (5.98)</td>
<td>F=13.605, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>135.55 (15.30)</td>
<td>111.66 (10.97)</td>
<td>F=44.642, p&lt;0.001</td>
</tr>
</tbody>
</table>

* lower score indicates higher quality of life.
Figure 1. Flow chart of participants through each stage of the trial.

RECRUITMENT

Assessed for eligibility across 5 centres
Cardiff, Newport, Swansea, Bridgend,
and Merthyr Tydfil
n=169

Randomised
n=90
(M1 = 43, Control = 37)

1 randomised in control
group but not eligible

DECLINED TO PARTICIPATE
n=4

DECLINED CONTACT
from researcher
n=16

AGREEED AND CONSENT
SIGNED
n=89

ALLOCATE

CONTROL GROUP

DECLINED PRIOR TO 1st VISIT
n=5 (total sample n=38)

DECLINED INTERVENTION AFTER 1st VISIT
n=4 (total sample n=34)

CONTROL GROUP

DECLINED PRIOR TO 1st VISIT
n=8 (total sample n=38)

DECLINED INTERVENTION AFTER 1st VISIT
n=3 (total sample n=36)

INTERVENTION PHASE 1-12 MONTHS

DECLINED TO PARTICIPATE
n=4

DECLINED CONTACT
from researcher
n=16

AGREEED AND CONSENT
SIGNED
n=89

OPTED OUT OF INTERVENTION BETWEEN 2-4 VISITS
n=6 (total sample n=36)

OPTED OUT OF INTERVENTION BETWEEN 2-4 VISITS
n=5 (total sample n=34)

"1 patient discussed:
accidental death"

Participants continuing
treatment at 6 months
n=52

12 months
Complete HbA1C data
M1 n=34, Control n=23

24 months
Complete HbA1C data
M1 n=30, Control n=26
Complete data remain n=47
Data remain at 12 months n=3

FOLLOW UP PHASE 24 MONTHS