DIABETIC Medicine Diabetes UK

Effects of the Diabetes Manual 1:1 structured education in primary care

Journal:	*Diabetic Medicine*
Manuscript ID:	DME-2007-00675.R2
Manuscript Type:	Original Article
Date Submitted by the Author:	n/a
Complete List of Authors:	Sturt, Jackie; University of Warwick, Health Sciences Research Institute, Warwick Medical School Whitlock, Sandra; University of Warwick, Health Sciences Research Institute, Warwick Medical School Fox, Claudie; Newman University College, Dept of Psychology Hearnshaw, Hilary; University of Warwick, Health Sciences Research Institute, Warwick Medical School Farmer, Andrew; University of Oxford, Department of Public Health and Primary Health Care Wakelin, Melanie; Queen Mary University of London, Institute of Health Sciences eldridge, sandra; Queen Mary University of London, Institute of Health Sciences Education Griffiths, Frances; University of Warwick, Health Sciences Research Institute, Warwick Medical School Dale, Jeremy; University of Warwick, Health Sciences Research Institute, Warwick Medical School
Keywords:	patient education, primary care, RCT, diabetes, complex intervention

Title: Effects of the Diabetes Manual 1:1 structured education in primary care

Dr Sturt JA*, Warwick Medical School
Ms Whitlock S, Warwick Medical School
Dr Fox C, Newman University College
Dr Hearnshaw H, Warwick Medical School
Dr Farmer AJ, University of Oxford
Ms Wakelin M, Queen Mary University of London
Dr Eldridge S, Queen Mary University of London
Dr F Griffiths, Warwick Medical School
Prof Dale J, Warwick Medical School

*Corresponding Author- Dr J A Sturt, Warwick Medical School, University of Warwick, Gibbet Hill, Coventry, CV4 7AL, Telephone: 02476 573753 , Fax: 02476 528375, Email: Jackie.sturt@warwick.ac.uk

Abstract

Aims

To determine the effects of The Diabetes Manual for improving the control, diabetes-related distress and confidence to self-care of patients with type 2 diabetes.

Methods

A cluster randomised controlled trial of an intervention group versus a 6-month delayed-intervention control group with a nested qualitative study. Participants were 48 urban general practices in the West Midlands, UK, with high population deprivation levels and 245 adults with type 2 diabetes with a mean age 62-years recruited pre-randomisation. The Diabetes Manual is 1:1 structured education designed for delivery by practice nurses. Measured outcomes were glycaemic control measured by HbA1c, cardio-vascular risk factors, diabetes-related distress measured by the PAID scale and confidence to self-care measured by the Diabetes Management Self-Efficacy Scale. Outcomes were assessed at baseline and 26 weeks.

Results

There was no significant difference in HbA1c between the intervention group and the control group (difference -0.08% (95%CI -0.28 to 0.11). Diabetes-related distress scores were lower in the intervention group compared to the control group (difference -4.5 (95%CI -8.1 to -1.0). Confidence to self-care scores were 11.2 points higher (95%CI 4.4 to 18.0) in the intervention group compared to the control group. The patient response rate was 18.5%.

Conclusions

In this sample the Diabetes Manual achieved a small improvement in patient diabetes-related distress and confidence to self-care over 26-weeks. Further study is needed to optimise the intervention and characterise those for whom it is more clinically and psychologically effective to further support its use in primary care.

Trial registration: ISRCTN06315411

Key word: patient education, diabetes, primary care, complex intervention

DMSES Diabetes Management Self-Efficacy Scale
PAID Problem Areas in Diabetes Scale
CI confidence intervals
HbA1c Glycated haemoglobin
HCP Health Care Professionals
PCTs Primary Care Trusts

Introduction

Self-management education for patients with type 2 diabetes has been shown to improve clinical and psycho-social outcomes[1]. Following success of group education programmes for patients with diabetes and a UK health policy recommendation from the National Institute of Clinical Excellence (NICE), there has been an emphasis on provision and evaluation of group education[2-5]. Evidence from cardiac rehabilitation programmes demonstrate that group approaches may be less acceptable to some patients[6]. Following the model of the Heart Manual, a programme of work was undertaken to develop a structured intervention for one to one delivery with patients with type 2 diabetes that could be delivered with minimal practitioner support[7 8]. UK guidelines on the format of structured education programmes recommend theory-based principles of adult learning and a variety of learning techniques to be used. The Diabetes Manual was developed using social learning theory to employ self-efficacy enhancing strategies such as positive mastery experiences, vicarious learning, emotional adjustment and verbal persuasion[9].

Using the MRC complex intervention framework[10], the intervention development work (Fig 1) commenced in 2001 with a needs assessment focus group study followed by a primary care survey of people living with diabetes and simultaneous GP and practice nurse interviews to identify desirable programme content[11 12]. In 2003, lay and health professional development panels were established to explore the theoretical approach, develop the curriculum and write the Diabetes Manual workbook, audio-tape scripts and nurse training course. Nurse training syllabus development followed[13]. This development work, and the mechanisms through which the intervention meets the UK standards for structured education, have been reported fully elsewhere[14].

Figure 1. Flowchart of the development of the Diabetes Manual 1:1 intervention

The aim of the resulting intervention is to enhance patients' self-efficacy towards a series of lifestyle and health related behaviours mediating clinically important outcomes[9]. We therefore set out to evaluate the intervention in UK general practice settings in order to understand its impact in a population in which socio-economic challenges persisted.

The aims of this study were to (i) determine feasibility and impact of delivering the Diabetes Manual pragmatically in primary care (ii) determine the short term effectiveness for improving glycaemic control, diabetes-related distress and confidence for self-care at 6-months compared to usual care in individuals with type 2 diabetes.

Patients and Methods

Study design

The Diabetes Manual trial was a two-arm cluster randomised controlled trial with participating practices randomised to intervention or 6-month deferred intervention. Ethical permission was granted in June 2004. NHS R&D approval was granted by participating primary care trusts (PCTs). The trial protocol is described in detail elsewhere[15].

Practices and participants

General practices in which the nurse had undertaken post-registration diabetes care training were invited to participate from June 2004- Nov 2005. Practices were drawn from 24 PCTs across the West Midlands, United Kingdom. This population is characterised by urbanisation, ethnic diversity, seasonal population transience and high social deprivation. Patient eligibility was adults with type 2 diabetes, not taking insulin and able to read and write English and during the first 12 months of the study, a most recent HbA1c over 8%. We experienced low recruitment over this period and one year

into the trial an agreed protocol change was implemented to reduce the patient eligibility to an HbA1c of over 7% [15].

Screening eligibility

Eligible patients were identified from practice registers. All patients on each practice list were allocated a consecutive number. Within each individual practice list, these numbers were randomly ordered using excel software and a reordered list was generated from which consecutive patients were then invited in blocks of 8 to12. Patients were invited by a single letter from their general practitioner. Recruitment continued until the list was exhausted or recruitment closed for the practice prior to planned and timed block randomisation and subsequent nurse training. Aggregated, anonymised HbA1c, blood pressure (BP), serum cholesterol, body mass index (BMI) and basic demographic data of the entire eligible practice populations were collected to identify any difference between the study participants and the eligible population.

Baseline assessment and random allocation

The practice nurse conducted pre-randomisation baseline clinical assessments of consented patients and gave them a self-completion booklet of questionnaires along with a reply paid envelope. Practices were allocated in blocks into intervention or delayed intervention groups by a statistician blind to practice identity using computer-aided minimisation [16]. We minimised on the basis of mean HbA1c of consented patients, cluster size (number of patients recruited per practice), and practice level Quality and Outcomes Framework (QOF) aspirational points[17]. Once block allocation was complete, the intervention nurses undertook their training.

Interventions

The Diabetes Manual is underpinned by self-efficacy theory with component parts designed to develop confidence for self-care and reduce diabetes-related distress[9]. The intervention arm practice nurses undertook two-day training, summarised alongside other components in table 1, and following training they held a 15 minute face to face consultation with patients to introduce the 12-week Diabetes Manual programme. Patients worked independently through the workbook. Nurse telephone support was provided in weeks 1, 5 and 11. Intervention fidelity was assessed using audio-recorded telephone support consultations and completion of telephone proformas following each call. The deferred intervention arm continued usual care, and following twenty-six week data collection, nurses undertook training and delivered the Diabetes Manual to their participating patients.

Table 1 The Diabetes Manual: components comprising the intervention

Outcomes and assessment

Outcome are glycaemic control measured by HbA1c, blood-pressure, serum cholesterol, body mass index (BMI), diabetes-related distress, measured with the Problem Areas in Diabetes scale (PAID)[18 19], and confidence to self-care, measured with the Diabetes Management Self-efficacy Scale (DMSES)[20 21]. Patients were assessed at baseline and 26 weeks by the practice nurse. The PAID, DMSES and demographic data were administered by questionnaire mailed by the research team at 24 weeks.

Sample size and rate of recruitment

We originally sought power of 90% (alpha = 0.05) to detect a 0.6% difference in individual patient HbA1c between intervention and control arms [15]. An intra cluster correlation for HbA1c, derived from unpublished data from East London general practices, of 0.043 was used[22]. A lower rate of patient recruitment in the first twelve months led to fewer patients per practice. We compensated for this by

recruiting more practices. We estimated that with analysable data on a mean of five patients per practice in 50 practices the power of our study to detect a 0.6% difference would be 80% (accounting for between cluster correlation and variable cluster size as described above). This gives a lower power than we originally aimed for but was a realistic target.

Statistical analysis

Data were double entered. To account for clustering by practice, outcomes were analysed using population averaged models with robust standard errors (using generalised estimating equations). Patient and practice level covariates including practice self-assessed quality of diabetes care indicators,[17] geographical location of practice, level of patient outcome at baseline, patient age, gender and socio-economic status were incorporated in the analysis. In addition, a covariate was incorporated to determine whether the effect on HbA1c was different for patients recruited before or after the protocol change. Generalised linear models were used instead of generalised estimating equations for outcomes with a negative intracluster correlation coefficient. The assumptions underlying the final models were checked by examination of residuals. We undertook analysis of complete data. Intention to treat analysis was subsequently carried out on all randomised patients with missing data set to equal baseline values for all primary and secondary outcomes. Estimates of effect size for the PAID measure were calculated and the size of effect determined using standard guidelines[23 24].

Qualitative study

Nested qualitative work was undertaken with participating patients and nurses to answer several research questions surrounding the impact and feasibility of the intervention, the preparedness of the nurses following training, strengths and weakness of intervention components and levels of diabetes understanding and management strategies. Data were collected from (i) patient focus groups and (ii) semi-structured interviews (iii) nurse-completed telephone proformas and (iv) a nurse focus group. This paper reports on (iii) and (iv).

Results

245 people with diabetes (table 2) from 48 practices (table 3) participated in the trial. Total number of patients meeting the eligibility criteria was 2,257. Thirty nine practices had data available on the number of patients they had invited to participate which totalled 1,394 patients (mean per practice =35.7). Mean data was substituted for the 9 practices where these data were missing and the total number of invited patients was estimated to be 1,716. Subsequently 73 patients were found to have been invited in error as a result of incomplete practice records. Confirmed response rate for 39 practices was 18.5%. Figure 1 shows their progress through the trial. Follow-up data for the primary outcome and clinical data were available for 202/245 participants. Questionnaire data were obtained for 148/245 participants. Characteristics of non-participating eligible patients and participating patients are similar for all clinical variables.

Table 2 Aggregated eligible population data and baseline characteristics of trial groups

Table 3: Characteristics of general practices

Figure 2. Flowchart of patient progression through the Diabetes Manual trial

Clinical Outcomes

The between group difference in HbA1c at 26 weeks was -0.08% (95%CI -0.28 to +0.11) (p=0.39) after adjusting for baseline HbA1c level, sex, age and index of multiple deprivation (table 4). Recruitment of patients before or after the change to the HbA1c eligibility criterion had no significant effect on the HbA1c level at 6 months, nor a significant interaction with

treatment group, after adjusting for baseline HbA1c. No statistically significant effects were detected between the groups in relation to changes in blood-pressure, serum cholesterol and BMI. Intention to treat analysis maintained the between group difference in HbA1c of -0.08% (-0.23 to +0.08) (p=0.33).

Psychological outcomes

At follow-up, the mean PAID score was lower by 4.5 points (95%CI -8.1 to –1.0) indicating lowered diabetes-related distress in the intervention group compared to the delayed intervention group (p=0.012) after adjusting for baseline (table 4). This difference gave a small effect size[23]. The mean DMSES score was 11.2 points higher (95%CI 4.4 to 18.0) indicating increased confidence to self-care in the intervention group than in the delayed intervention group (p=0.0014) after adjusting for baseline and sex. Completeness of PAID and DMSES data was only 50% for the intervention group and 69% for the delayed intervention group. Intention to treat analysis confirmed the lowering of the PAID scores by 2.5 points (95%CI -4.9 to –0.1) (p=0.044) and the increase in DMSES scores by 6.2 points (95%CI 1.3 to 11.0) (p=0.013) although inevitably the effect sizes were reduced.

Table 4 HbA1c, PAID and DMSES findings at 6-months

The characteristics of the participants according to their completeness of PAID and DMSES data (table 5) indicates that key variables on which some notable differences between the groups are observed are primarily those related to demographic characteristics such as ethnicity, age and postcode as oppose to psychosocial and biomedical status. Missing patient-reported demographic and outcome data are greater across all variables for those who did not complete these outcome measures.

Table 5 Baseline characteristics of intervention participants according to completeness of both PAID and DMSES data at 6 month follow-up

Patient engagement with the Diabetes Manual

Nurses were asked to complete a telephone proforma following each of the 3 telephone support calls. Documenting patient reported data following consultations was established practice for participating nurses and represented an authentic way of capturing patient reported process data regarding engagement. Data included length of the call, stage the patient had reached, issues requiring support and intended goals for the following period. Four researchers worked with 10 sets of proformas each to develop the typologies of intervention engagement. Thereafter analysis was undertaken by two researchers and 80% agreement was reached. Twenty nurses completed 249 proformas for 81 patients. The mean length of call was 9 minutes. We identified 3 typologies, *Embracers* (n=24, 30%), *Dippers* (n=34, 42%) and *Non-embracers* (n=23, 28%).

Embracers reported adherence to the programme plus described behavioural and attitudinal change,

"*More positive, is changing outlook on life. Now swimming three times a week, joined gym, has lost one stone in weight"*.

Dippers reported dipping into components of the programme like the relaxation tape or the physical activity aspects

"Finding relaxation tape helpful and is using once a day. Is generally feeling less tense and feels can relax more".

Alternatively, Dippers adhered to the programme until distracting life events occurred, a spouse became ill, they went on holiday or became busy at work. They used the programme as an information resource and attempted some behavioural change which was not sustained

"*Has found manual really useful. Knows should do more exercise, feels will try more in better weather"*.

Non-embracers reported deriving no benefit, whether or not they reported reading it

"Book well written, easy to read but didn't contain anything didn't already know".

Embracers and dippers reported positive outcomes in terms of increased self-efficacy and behavioural change or attitudinal changes and new or reinforced diabetes knowledge.

Feasibility of delivery in primary care
One focus group was undertaken with 11 (50%) intervention arm practice nurses following six-month data collection. The focus group was facilitated by two clinician /researchers who had undergone focus group facilitation training. The data was analysed by a facilitator and the principle investigator. Nurses reported that delivering the intervention had positively impacted on their job satisfaction as they felt confident to help people to self-care

"(I feel) good, simply good because…what we are doing is having an impact on their life and they can see the impact it's having on their life".

Delivering the Diabetes Manual had extended their own learning and practice experience and it confirmed for them that they were already delivering the correct information *"It has brought things to me that….Oh yeah, I'd forgotten, I haven't mentioned that for a while to patients"*.

The nurses identified difficulties in recalling intervention components addressing unfamiliar elements of care delivery like open questioning and telephone support. These developing skills were found to be useful for people with other chronic conditions and they were positive about the value and feasibility of the programme for use in primary care.

Discussion
The aim of the 1: 1 Diabetes Manual programme was to enable people with diabetes to gain skills and confidence, quickly and progressively in the management of their diabetes [14]. The aim of this trial was to establish whether the Diabetes Manual was effective in improving clinical and psychosocial outcomes at 6-months [15]

This is the first trial of a 1:1 structured education programme for people with type 2 diabetes to be undertaken in the UK. In our pragmatic, primary care based trial, patients receiving the Diabetes Manual programme experienced small improvements in diabetes-related distress and confidence to self-care although there were no statistically significant reductions in HbA1c and measured cardio-vascular risk factors. Ninety-six percent of participating practices were located in urban areas, 33% of which were located in the most deprived areas of the UK[25]. The study patient population was representative of an unselected, urban, multi-ethnic and socio-economically deprived population. The research took place during a period of high audit activity and improved prescribing to meet and improve pay for performance targets. The background to routine care was of a sharp reduction in HbA1c which reduced the potential to demonstrate improved control.

A small improvement in psychological wellbeing was demonstrated although a low patient response rate of 18.5% limits the generalisability of the findings. A prolonged recruitment period of 18 months, incorporating a protocol change to widen eligibility, was a consequence of low response. Several research design issues operating at the practice and patient level might explain the low recruitment. Within practices, recruitment success relied heavily on the time and motivation of practice nurses working in demographically challenged practices. The availability of dedicated research nurses could have improved recruitment and retention. For patients, there was a single point of invitation and reliance on family members to encourage participation in some ethnic minority groups. Multiple invitations, community worker involvement and greater support for clinicians might have resulted in greater access to, and interest in, the study. The intervention itself was burdensome with 1 hour a day required to read the workbook, take action and record progress and may be a reflection of a more general reluctance of many people with diabetes to engage in structured education. Although as the telephone proforma findings show, at least 28% of this group only participated in the limited contact with the practice nurse and not with the more substantive self-directed components suggesting that many in the intervention group self selected the size of the burden.

The minimisation process produced reasonably balanced groups with respect to the factors that we thought were prognostically most important and had therefore used in the minimisation. Some other factors such as practice size were less well balanced, but we do not expect that this to have had an undue influence on our results.

Recent studies[1 3 26] of type 2 diabetes education and self-care with longer follow-up have demonstrated statistically and clinically significant reductions in clinical variables. These studies have used a range of delivery approaches, for example, 1:1, group, single and multiple delivery sites. There are no reviews currently published which identifies the most effective and comprehensive format for diabetes self-care education. The Diabetes Manual aimed to utilise minimal nursing time and whilst this study demonstrated that telephone support could be provided within 10 minutes (mean = 9 mins) and increased workload was not reported qualitatively in the nurse focus groups, we do not have data on concurrent or subsequent consultation rates. The nursing support provided may indeed be insufficient. We hypothesise that facilitator effect is weakened with multiple site studies and multiple facilitators. These latter two factors may account for our inability to detect a change in HbA1c and the small effect size on psychosocial variables. This may represent a more realistic effect size for interventions designed for wide dissemination. Self-efficacy is regarded as one of the strongest predictors of behaviour change [27] and the small increase in self-efficacy demonstrated in this population suggests that there is potential for strengthening the Diabetes Manual components and targeting to improve self-care performance in many primary care settings.

Pre-and post intervention PAID scores in the literature consider a 20 point reduction to be a large effect and 6-9 a medium effect[23]. Our participants experienced a 4.5 point reduction which is considered a small effect. Hernmanns et al [19] were unable to detect diabetes-related distress with a PAID score of 23- 40 (0-100 scale). Our population had a mean baseline distress level of 21. A typical unselected outpatient score of 20-30 has previously been found[18 23]. The Diabetes Manual reduced distress in a population who were not experiencing diabetes-related distress at commencement, therefore making it more challenging to show an effect. Consistent with previous research our control group experienced little change in their PAID score over the 26-week follow up period[28]. In line with previous authors, we believe that the small improvements in diabetes-related distress in the intervention group were real[23].

There is both research evidence [6] and more recent anecdotal evidence from the UK that group provision of health-related education does not suit everyone and alternative structured education

programmes need to be available to account for the needs of a diverse population. The Diabetes Manual can be implemented into primary care practice by health professionals experienced in diabetes care following completion of the 2-day facilitator training course (http://go.warwick.ac.uk/studydiabetes/manual). Many research questions remain, particularly on patient targeting based around demographic and socio-economic indicators, the optimum extent of health professional support and optional components of peer or group support. The science of complex interventions is developing apace and concerns surrounding intervention fidelity of multiple components are beginning to be highlighted. Hardeman found only 45% of the *ProActive* intervention was delivered as intended[29 30]. In this present study only 20 of the 28 nurses completed any telephone proformas and so possibly did not undertake the calls. Non-delivered components remain a challenge for complex intervention trials.

Competing interests: JS, SW,HH and JD are employed by the University of Warwick which jointly holds the copyright for the Diabetes Manual with Lothian Health Board. The University of Warwick offers the Diabetes Manual facilitator's course as part of its post-graduate education portfolio. All remaining authors have no competing interests.

Acknowledgements
The evaluation was jointly funded by a Diabetes UK Structured Education project grant and a Department of Health post-doctoral award for JS. Trial management was undertaken by a trial steering group consisting of the authors and the following members of the trial team Rosie Walker, Julie Barlow, Paul O'Hare, Gill Freeman, Antje Lindenmeyer and David Karet and Mike Kingdom from the Warwick Diabetes Research User Group (WDRUG). We would like to thank the wider WDRUG for their advice during the trial and the practices, nurses and people with diabetes who participated.

1. Norris SL, Engelgau MM, Venkat Narayan KM. Effectiveness of self-management training in type 2 diabetes. A systematic review of randomised controlled trials. . *Diabetes Care* 2001;24(3):561-587.
2. DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial *BMJ* 2002;325(746).
3. Deakin TA, Cade JE, Williams R, Greenwood DC. Structured patient education: the Diabetes X-PERT Programme makes a difference. *Diabetic Medicine* 2006;23 (9):944-954.
4. National Institute for Clinical Excellence. *Guidance on the use of patient-education models for diabetes*. London: NHS, 2003.
5. Department of Health. *Structured Patient Education in Diabetes: Report from the Patient Education Working Group*. London: Department of Health, 2005.
6. Dalal H, Evans P. Achieving national service standards for cardiac rehabilitation and secondary prevention. *British Medical Journal* 2003;326:481-484.
7. Department of Health. *The expert patient: a new approach to chronic disease management for the 21st century*. London: Department of Health, 2001.
8. Lewin B, Robertson I, Cay E, Irving J, Campbell M. Effects of self-help post myocardial infarction rehabilitation on psychological adjustment and use of health services. *The Lancet* 1992;339(8800):1036-1040.
9. Bandura A. Self-efficacy theory: towards a unifying theory of behaviour change. *Psychological Review* 1977;84:191-215.
10. Medical Research Council. Medical Research Council framework for the development and evaluation of complex interventions to improve health 2000.

11. Sturt J, Hearnshaw H, Barlow J, Hainsworth J. Supporting a curriculum for delivering type 2 diabetes patient self-management education: a patient needs assessment. *Primary Care Research and Development* 2005;6 291-299.
12. Sturt J, Hearnshaw H, Barlow J, Hainsworth J, Whitlock S. Education for people with type 2 diabetes: what do patients want? *Journal of Diabetes Nursing* 2005;9(4):145-50.
13. Sturt J, Walker R, Whitlock S, Nortley E. Learning by 'walking the talk': curriculum development to teach behavioural interventions to nurses. *International Journal of Behavioural Medicine* 2006;13 (Supplement):135.
14. Sturt J, Taylor H, Docherty A, Dale J, Taylor L. A psychological approach for providing self-management education for people with type 2 diabetes: the Diabetes Manual. *BMC Family Practice* 2006;7(70).
15. Sturt J, Hearnshaw H, Farmer A, Dale J, Eldridge S. The Diabetes Manual trial protocol – a cluster randomized controlled trial of a self-management intervention for type 2 diabetes [ISRCTN06315411]. *BMC Family Practice* 2006;7(45).
16. Altman DG, Bland JM. Treatment allocation by minimisation. *BMJ* 2005;330:843.
17. NHS Health and Social Care Information Centre Quality and Outcomes framework http://www.ic.nhs.uk/services/qof Accessed 13th March 2006.
18. Polonsky W, Anderson B, Lohrer P, Welch G, Jacobson A, Aponte J, et al. Assessment of diabetes-related distress. *Diabetes Care* 1995;18:754-60.
19. Hernmanns N, Kulzer B, Krichbaum M. How to screen for depression and emotional problems in people with diabetes: comparison of screening characteristics of depression questionnaires, measurement of disease-specific emotional problems and standard clinical assessment. *Diabetologia* 2006;49:469-477.
20. Bijl Jvd, Poelgeest-Eeltink Av, Shortridge-Baggett L. The psychometric properties of the diabetes management self-efficacy scale for patients with type 2 diabetes mellitus. *Journal of Advanced Nursing* 1999.;30:352-359.
21. Sturt J, Hearnshaw H. Measuring Outcomes: self-management, empowerment and self-efficacy. . *Diabetic Medicine* 2003;20 suppl 2:78.
22. Personal communication John Robson, Queen Mary University of London, Feb, 2004.
23. Welch G, Weinger K, Anderson B, Polonsky W. Responsiveness of the problem areas in diabetes (PAID) questionnaire. *Diabetic Medicine* 2003;20:69-72.
24. Cohen J. Statistical analysis for the behavioural sciences. *New York. Academic Press* 1985.
25. Barker D, Hayes J, Wagner A. The National Database for Primary Care Groups and Trusts *National Primary Care Research and Development Centre University of Manchester* 2005.
26. di Loreto D, Fanellli C, Lucidi P, Murdolo G, Cicco Ad, Parlanti N, et al. Validation of a counselling strategy to promote the adoption and the maintenance of physical activity by type 2 diabetic subjects. . *Diabetes Care* 2003;26:404-408.
27. Gillis AJ. Determinants of health promoting lifestyle; an integrative review. *Journal of Advanced Nursing* 1993;18:545-53.
28. Snoek F, Pouwer F, Welsh GW, WH P. Diabetes-related emotional distress in Dutch and US diabetic patients:cross cultural validity of the Problem Areas in Diabetes scale. *Diabetes* 2000;23:1305-1309.

29. Hardeman W, Michie S, Fanshawe T, Prevost AT, McLoughlin K, Kinmonth AL. Fidelity of delivery of a physical activity intervention: Predictors and consequences. *Psychology and Health* in press.
30. Williams K, Prevost AT, Griffin S, Hardeman W, Hollingworth W, Speigelhalter D, et al. The *ProActive* trial protocol - a randomised controlled trial of the efficacy of a family-based, domiciliary intervention programme to increase physical activity among individuals at high risk of diabetes [ISRCTN61323766}. . *BMC Public Health* 2004;4(48).

Figure 1. Flowchart of the development of the Diabetes Manual 1:1 intervention

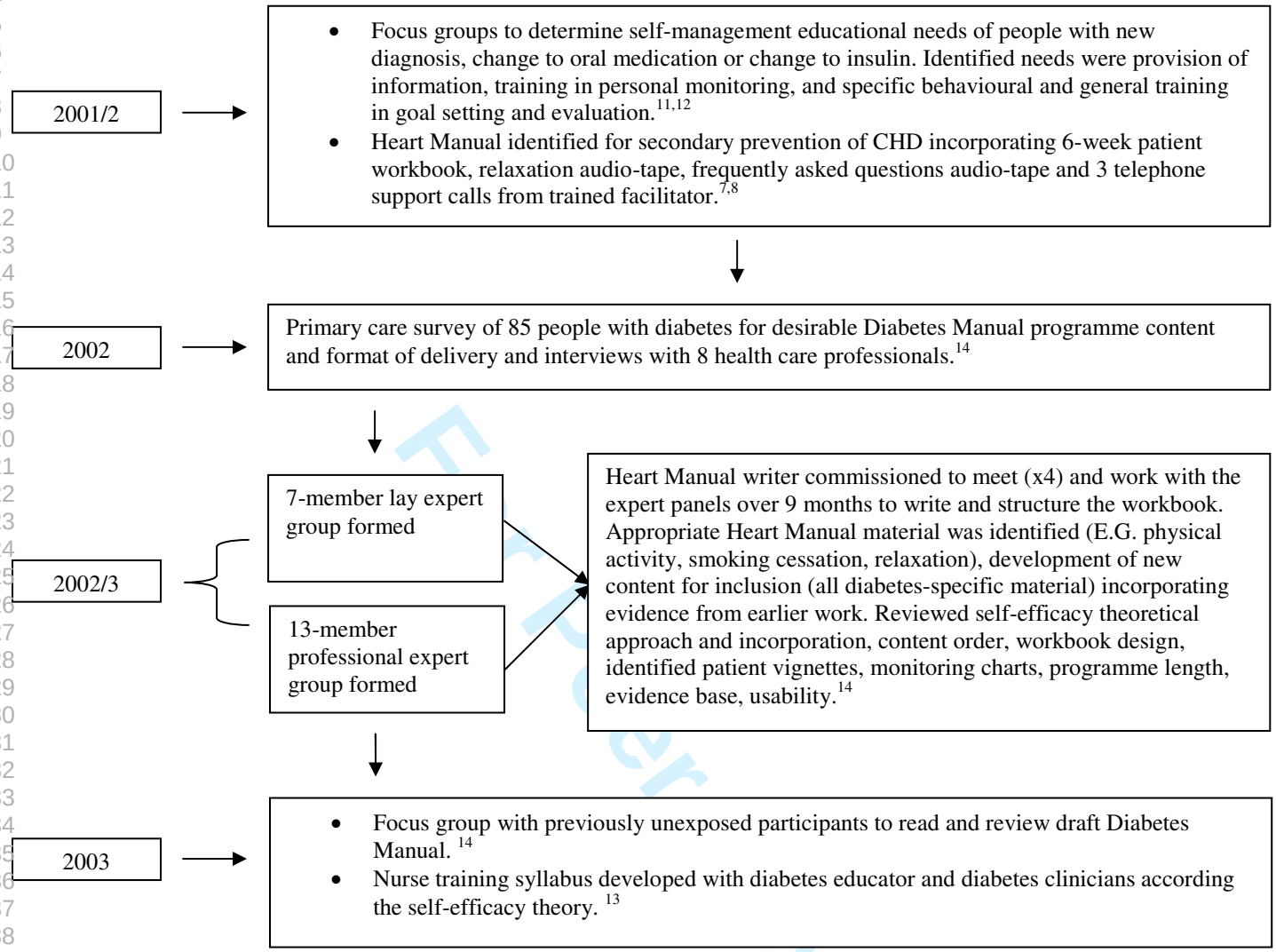

Table 1 The Diabetes Manual: components comprising the intervention

Diabetes Manual programme component	Knowledge and coaching syllabus	Aspects of self-efficacy targeted by intervention
Two-day training for practice nurses experienced in diabetes management.	Self-efficacy strategies to facilitate adult learning, understand intervention structure, practical skill development in telephone support, empowering communication and facilitating relaxation therapy.	Mastery achievements Positive vicarious learning Adjustment to stress Verbal encouragement Outcome expectations
Patient workbook (recommended 1 hour per day over 12 weeks including time to practice new behaviours)	230 page workbook with a reading age commensurate with British tabloid newspapers. Workbook topics includes diabetes facts / metabolism / goal setting and evaluation / exercise/ nutrition / blood glucose monitoring / weight loss / smoking cessation / tests/ complications / medication / stress, anxiety and depression / cholesterol / quizzes to self-evaluate workbook topics/ other peoples stories / self-assessment record sheets to encourage personal evaluation of current and new behaviours and activities	Mastery achievements Vicarious experiences
Relaxation audiotape	A relaxation audiotape was provided and the patient is encouraged within the workbook to use it and to explore alternative relaxation methods.	Adjustment to stress
Question and answer audiotape	An audiotape was provided mirroring a discussion between a general practitioner and a patient to be used as a brief introduction to diabetes and its management. Participants were encouraged to share it with family members.	Promotes mastery achievements Vicarious learning
Practice nurse telephone support	Provided in weeks 1, 5 and 11 using a semi-structured consultation template to assess goal progress; promotion of self-evaluation and re-negotiation, offer support and problem solve.	Mastery experiences Verbal encouragement

Table 2 Aggregated eligible population data and baseline characteristics of trial groups

Patient level factors at baseline	Eligible practice population	Intervention	Delayed Intervention
No. of patients	2,257	114	131
Age (mean,quartiles)		62 (51,71)	62 (53,70)
Age of patient, no. (%)			
≤50 years	(20.5%)	26 (23%)	26 (20%)
51-69 years	(48.5%)	53 (46%)	71 (54%)
≥70 years	(31%)	35 (31%)	34 (26%)
Gender no. (%)			
men	(56%)	70 (61%)	78 (60%)
No. of years since diagnosed with diabetes, no. (%)			
< 1 year		9 (8%)	15 (11%)
1 to 15 years		87 (76%)	105 (80%)
>15 years		8 (7%)	8 (6%)
missing		10 (9%)	3 (2%)
No with other chronic conditions, no. (%)			
Yes		51 (45%)	66 (50%)
missing		11 (10%)	6 (5%)
Ethnicity, no. (%)			
White British/White Irish/White Other	(88%)	92 (81%)	102 (79%)
Mean HbA1c (SD) n=114, 131	8.76	8.89 (1.48)	8.84 (1.46)
Median HbA1c (lower quartile, upper quartile) n=114, 131		8.60 (7.8, 9.6)	8.60 (7.6, 9.9)
Mean Total Cholesterol (SD) n=113, 130	4.62	4.30 (1.06)	4.48 (0.99)
Mean HDL Cholesterol (SD) n=100, 123	1.32	1.23 (0.32	1.35 (0.44)
Median HDL Cholesterol (LQ,UQ) n=100, 123		1.20 (1.0,1.4)	1.30 (1.1, 1.6)
Mean Systolic blood pressure (SD) n=114, 131	138.6	138.4 (18.0	139.8 (15.2)
Mean Diastolic blood pressure (SD) n=114, 131	79.1	78.5 (10.0)	81.6 (10.7
Mean BMI (SD) n=113, 129	31.0	31.8 (6.7)	31.6 (6.1)
Geographic area of patient's home (n & % patients)			
Urban		104 (91%)	104 (79%)
Town/fringe		1 (1%)	3 (2%)
Village/isolated houses		2 (2%)	19 (15%)
missing		7 (6%)	5 (4%)
Patient's home deprived area (n & % of patients)			
in 20% most deprived area of England		24 (21%)	39 (30%)
in 20% least deprived area of England		21 (18%)	16 (12%)
not in 20% most/least deprived area		62 (54%)	71 (54%)
missing		7 (6%)	5 (4%)

Table 3: Characteristics of general practices

Practice level factors at baseline	Intervention	Delayed Intervention
No. of practices	23	25
Mean no. of patients randomised per practice (min, max)	5.0 (1,12)	5.2 (1,12)
Median no. of eligible patients (LQ,UQ)	32 (20,53)	26 (20,55)
Mean no. of patients on practice list (SD)	8215 (4443)	6651 (2981)
Mean no. of patients with diabetes on practice list (SD)	307 (154)	276 (139)
Mean no. of patients with type 2 diabetes on practice list	267 (123)	231 (118)
Median no. of GPs in practice (LQ,UQ)	4 (2, 6.5)	3 (2,5)
Median QOF aspirational points (LQ,UQ)	99 (94,99)	99 (93,99)
Median deprivation index (LQ,UQ)	26 (14,36)	32 (19,41)
Practice Morphology (n & % of practices)		
Urban	23 (100%)	23 (92%)
Town/fringe		1 (4%)
Village/isolated houses		1 (4%)
Practice in deprived area (n & % of practices)		
in 20% most deprived area of England	8 (35%)	9 (36%)
in 20% least deprived area of England	2 (9%)	1 (4%)
Practice randomised before/after change to HbA1c selection criteria (n & % of practices)		
before	13 (57%)	13 (52%)
after	10 (43%)	12 (48%)
Diabetes Qualification of practice nurse (n & % of practices)		
Nationally recognised undergraduate certification/or Diploma	16 (70%)	18 (72%)
Locally recognised Diploma	1 (4%)	4 (16%)
Incomplete Diploma/certificate	3 (13%)	2 (8%)
Workshop/seminar	3 (13%)	1 (4%)

Figure 2. Flowchart of patient progression through the Diabetes Manual trial

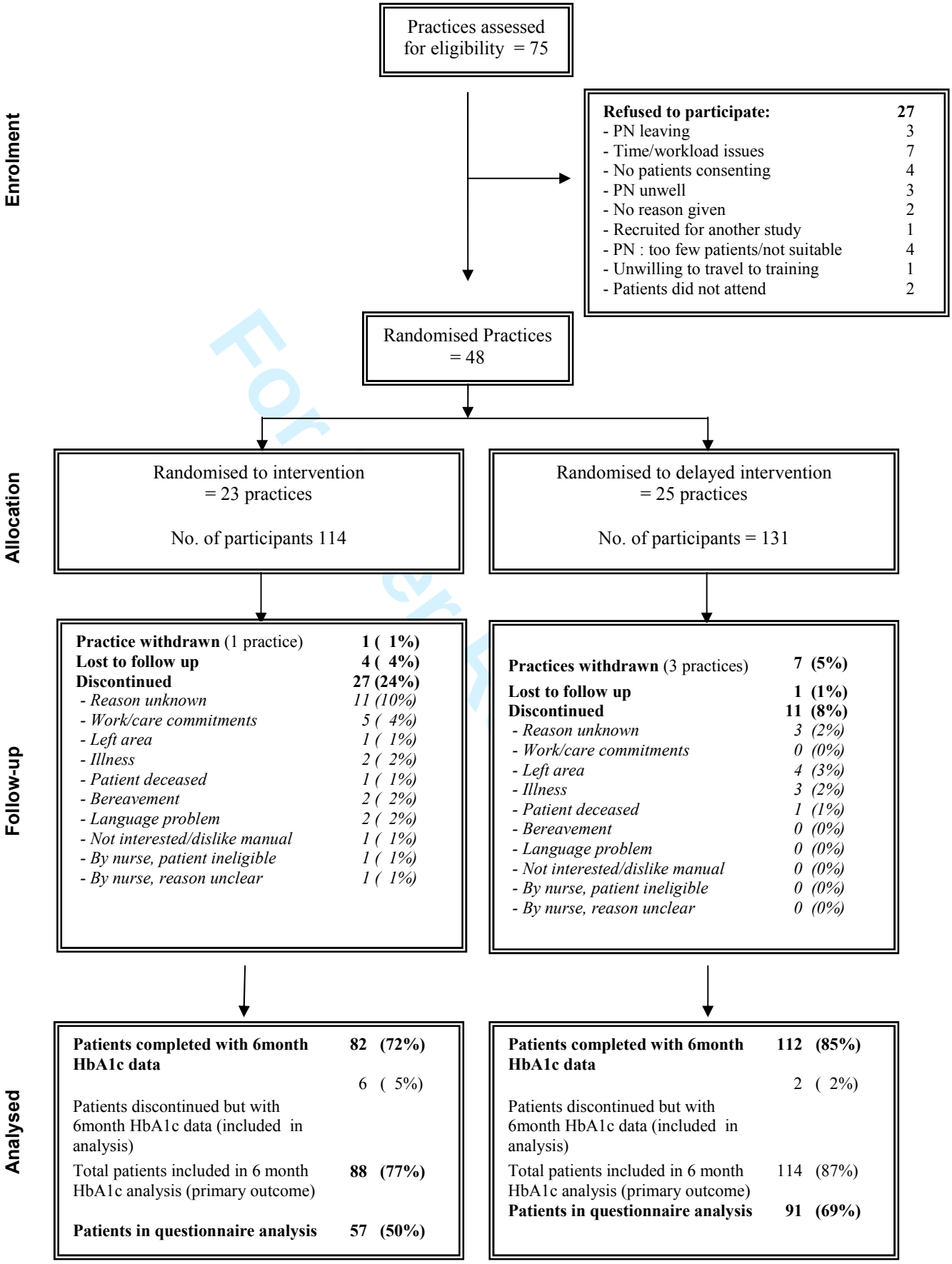

Table 4 HbA1c, Self-efficacy and PAID findings at 6-months.

Outcome	Intervention group		Delayed intervention (control) group		Adjusted mean difference at 6 mths intervention group -delayed intervention group (with 95%CI)	p-value[1]	Intracluster correlation coefficient
	Baseline Mean (SD)	6months Mean (SD)	Baseline Mean (SD)	6months Mean (SD)			
HbA1c n=202 (88,114)	8.92 (1.44)	8.35 (1.41)	8.69 (1.42)	8.37 (1.40)	-0.08 (-0.28 to +0.11) [2]	0.39	0.0253
DMSES n=148 (57,91)	100.4 (26.5)	114.7 (23.3)	103.6 (27.6)	105.4 (29.4)	11.2 (4.4 to 18.0) [3]	0.0014	N/A
PAID n=148 (58,90)	20.5 (15.4)	17.0 (13.6)	21.3 (14.5)	22.1 (16.7)	-4.5 (-8.1 to –1.0) [4]	0.012	N/A

[1] for testing whether difference between groups =0 after adjusting for baseline value of outcome and other covariates as indicated

[2] GEE modelling of HbA1c at 6 month adjusted for baseline HbA1c, sex, age and index of multiple deprivation with robust standard errors adjusted for clustering on practice used to produce 95%confidence interval

[3] GLM modelling of outcome at 6 month adjusted for baseline level of outcome and sex. Clustering on practice was not take into account since the intracluster correlation coefficient was negative (-0.098).

[4] GEE modelling of outcome at 6 month adjusted for baseline level of outcome only. Clustering on practice was not take into account since the intracluster correlation coefficient was negative (-0.011)

Table 5 Baseline characteristics of intervention participants according to completeness of both PAID and DMSES data at 6 month follow-up

Patient characteristics at baseline	Completed PAID & DMSES*	Did not complete PAID & DMSES
No. of patients	56	58
Age of patient		
≤50 years	15 (27%)	11 (19%)
51-69 years	25 (45%)	28 (48%)
≥70 years	16 (29%)	19 (33%)
Gender		
men	33 (59%)	37 (64%)
** No. of years since diagnosed with diabetes		
< 1 year	6 (11%)	3 (5%)
1 to 15 years	46 (82%)	41 (71%)
>15 years	4 (7%)	4 (7%)
Missing	0 (0%)	10 (17%)
** Ethnicity		
White British/White Irish/White Other	51 (91%)	43 (74%)
Missing	0 (0%)	10 (17%)
Median HbA1c (lower quartile, upper quartile)	8.8 (7.8,9.8)	8.4 (7.7,9.4)
**Mean DMSES score (SD)	100.2 (26.7)	98.0 (32.8)
**Mean PAID score (SD)	21.1 (15.2)	22.3 (15.8)
Patient's home postcode		
in 20% most deprived area of England	13 (23%)	11 (19%)
in 20% least deprived area of England	11 (20%)	10 (17%)
Missing	1 (2%)	6 (10%)

* Completed = both baseline and 6 month data for both PAID and DMSES

** observed from patient-reported data