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Personalised care planning for adults with chronic or long-term health conditions (Review)



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[Intervention Review]

Personalised care planning for adults with chronic or long-term health conditions

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ABSTRACT

Background

Personalised care planning is a collaborative process used in chronic condition management in which patients and clinicians identify and discuss problems caused by or related to the patient's condition, and develop a plan for tackling these. In essence it is a conversation, or series of conversations, in which they jointly agree goals and actions for managing the patient's condition.

Objectives

To assess the effects of personalised care planning for adults with long-term health conditions compared to usual care (i.e. forms of care in which active involvement of patients in treatment and management decisions is not explicitly attempted or achieved).

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, PsycINFO, ProQuest, clinicaltrials.gov and WHO International Clinical Trials Registry Platform to July 2013.

Selection criteria

We included randomised controlled trials and cluster-randomised trials involving adults with long-term conditions where the intervention included collaborative (between individual patients and clinicians) goal setting and action planning. We excluded studies where there was little or no opportunity for the patient to have meaningful influence on goal selection, choice of treatment or support package, or both.

Data collection and analysis

Two of three review authors independently screened citations for inclusion, extracted data, and assessed risk of bias. The primary outcomes were effects on physical health, psychological health, subjective health status, and capabilities for self management. Secondary outcomes included effects on health-related behaviours, resource use and costs, and type of intervention. A patient advisory group of people with experience of living with long-term conditions advised on various aspects of the review, including the protocol, selection of outcome measures and emerging findings.

Main results

We included 19 studies involving a total of 10,856 participants. Twelve of these studies focused on diabetes, three on mental health, one on heart failure, one on end-stage renal disease, one on asthma, and one on various chronic conditions. All 19 studies included components



that were intended to support behaviour change among patients, involving either face-to-face or telephone support. All but three of the personalised care planning interventions took place in primary care or community settings; the remaining three were located in hospital clinics. There was some concern about risk of bias for each of the included studies in respect of one or more criteria, usually due to inadequate or unclear descriptions of research methods.

Physical health

Nine studies measured glycated haemoglobin (HbA1c), giving a combined mean difference (MD) between intervention and control of -0.24% (95% confidence interval (CI) -0.35 to -0.14), a small positive effect in favour of personalised care planning compared to usual care (moderate quality evidence).

Six studies measured systolic blood pressure, a combined mean difference of -2.64 mm/Hg (95% CI -4.47 to -0.82) favouring personalised care (moderate quality evidence). The pooled results from four studies showed no significant effect on diastolic blood pressure, MD -0.71 mm/Hg (95% CI -2.26 to 0.84).

We found no evidence of an effect on cholesterol (LDL-C), standardised mean difference (SMD) 0.01 (95% CI -0.09 to 0.11) (five studies) or body mass index, MD -0.11 (95% CI -0.35 to 0.13) (four studies).

A single study of people with asthma reported that personalised care planning led to improvements in lung function and asthma control.

Psychological health

Six studies measured depression. We were able to pool results from five of these, giving an SMD of -0.36 (95% CI -0.52 to -0.20), a small effect in favour of personalised care (moderate quality evidence). The remaining study found greater improvement in the control group than the intervention group.

Four other studies used a variety of psychological measures that were conceptually different so could not be pooled. Of these, three found greater improvement for the personalised care group than the usual care group and one was too small to detect differences in outcomes.

Subjective health status

Ten studies used various patient-reported measures of health status (or health-related quality of life), including both generic health status measures and condition-specific ones. We were able to pool data from three studies that used the SF-36 or SF-12, but found no effect on the physical component summary score SMD 0.16 (95% CI -0.05 to 0.38) or the mental component summary score SMD 0.07 (95% CI -0.15 to 0.28) (moderate quality evidence). Of the three other studies that measured generic health status, two found improvements related to personalised care and one did not.

Four studies measured condition-specific health status. The combined results showed no difference between the intervention and control groups, SMD -0.01 (95% CI -0.11 to 0.10) (moderate quality evidence).

Self-management capabilities

Nine studies looked at the effect of personalised care on self-management capabilities using a variety of outcome measures, but they focused primarily on self efficacy. We were able to pool results from five studies that measured self efficacy, giving a small positive result in favour of personalised care planning: SMD 0.25 (95% CI 0.07 to 0.43) (moderate quality evidence).

A further five studies measured other attributes that contribute to self-management capabilities. The results from these were mixed: two studies found evidence of an effect on patient activation, one found an effect on empowerment, and one found improvements in perceived interpersonal support.

Other outcomes

Pooled data from five studies on exercise levels showed no effect due to personalised care planning, but there was a positive effect on people's self-reported ability to carry out self-care activities: SMD 0.35 (95% CI 0.17 to 0.52).

We found no evidence of adverse effects due to personalised care planning.

The effects of personalised care planning were greater when more stages of the care planning cycle were completed, when contacts between patients and health professionals were more frequent, and when the patient's usual clinician was involved in the process.

Authors' conclusions

Personalised care planning leads to improvements in certain indicators of physical and psychological health status, and people's capability to self-manage their condition when compared to usual care. The effects are not large, but they appear greater when the intervention is more comprehensive, more intensive, and better integrated into routine care.



PLAIN LANGUAGE SUMMARY

Effects of personalised care planning for people with long-term conditions

Background

People with long-term health conditions play an important part in managing their own health. But some of the tasks involved can be complicated, and require confidence and skill. Such tasks include taking medicines properly, monitoring symptoms, adopting or maintaining healthy lifestyles, managing their emotions, solving practical problems, knowing when and how to seek medical advice or community support, and coping with the impact of the condition(s) on their daily lives. Personalised care planning aims to provide support from health professionals that is tailored to the needs of individual patients. Such support recognises patients' concerns, and helps them become more able to manage their own health. Personalised care planning is a conversation, or series of conversations, between a patient and a clinician when they jointly agree on goals and actions for managing the patient's health problems.

Review question

We carried out this systematic review to find out whether a personalised approach, in which patients are encouraged to participate in setting goals and action plans and determining their support needs, leads to better outcomes than when these decisions are taken by health professionals alone.

Results

We found 19 randomised trials published before July 2013 that addressed this issue, involving 10,856 participants with conditions such as diabetes, mental health problems, heart failure, kidney disease, and asthma. The studies looked at a range of different interventions designed to involve patients and support self management. We combined and summarised results from studies that measured similar outcomes and found that involvement in personalised care planning probably led to small improvements in some indicators of physical health (better blood glucose levels, lower blood pressure measurements among people with diabetes, and control of asthma). It also probably reduced symptoms of depression, and improved people's confidence and skills to manage their health. We observed no effect on cholesterol, body mass index or quality of life. We found no evidence of any harms arising from personalised care planning. We found that the process worked best when it included preparation, record-sharing, care co-ordination and review, involved more intensive support from health professionals, and was integrated into routine care. However, the quality of evidence was only moderate, meaning that further research might change these findings.

Conclusion

We concluded that personalised care planning is a promising approach that offers the potential to provide effective help to patients, leading to better health outcomes. More research is needed to work out which aspects are most effective for specific patient groups.



SUMMARY OF FINDINGS

Summary of findings for the main comparison.

Personalised care planning compared with usual care

Patient or population: Adult patients with long-term health conditions

Settings: All settings

Intervention: Personalised care planning

Comparison: Usual care or enhanced usual care

Outcomes	Illustrative comparative effect sizes* (95% CI) Usual care (control) vs personalised care planning (intervention)	No of partici- pants (studies)	Quality of the evidence (GRADE)	Comments
Physical health: blood glucose (HbA1c) Follow-up: 6 to 12 months	The mean difference in blood glucose was 0.24% lower (better) in the intervention groups than in the control groups (95% CI 0.35 to 0.14 lower)	1916 (9 studies)	moderate (variation in intervention types led to significant heterogeneity and risk of bias was unclear)	
Physical health: systolic blood pressure Follow-up: 6 to 12 months	The mean difference in systolic blood pressure was 2.64 mm/Hg lower (better) in the intervention groups than in the control groups (95% CI 4.47 to 0.82 lower)	1200 (6 studies)	⊕⊕⊕⊝ moderate (variation in intervention types led to significant heterogeneity and risk of bias was unclear)	
Physical health: cholesterol (LDL-C) Follow-up: 6 to 12 months	The standardised mean difference in LDL cholesterol did not differ between the intervention and control groups: 0.01 standard deviations (95% CI -0.09 to 0.11)	1545 (5 studies)	⊕⊕⊕⊝ moderate (results were inconsistent)	
Psychological health: depres- sion (PHQ-9, SCL-20, Beck Depression Inventory, CES- D) Follow-up: 1.5 to 12 months	The standardised mean difference in depression scores was 0.36 standard deviations lower (better) in the intervention groups than in the control groups (95% CI 0.52 to 0.20 lower), a small effect in favour of personalised care planning.	599 (5 studies)	⊕⊕⊕⊝ moderate (multiple out- come measures)	In addition, 3 out of 4 studies that used conceptually different measures of psychological outcomes (and so could not be pooled) reported better outcomes for the intervention groups than the control groups. The remaining study was too small to detect an effect.



Subjective health status: condition-spe- cific (PAID-2, Illness Intrusiveness, AQLQ) Follow-up: 12 months	The standardised mean difference in condition-specific health status scores did not differ between the intervention and control groups: -0.01 standard deviations (95% CI -0.11 to 0.10)	moderate (variation in intervention types led to significant heterogeneity) Three studies that measured generic health status (SF-36 or SF-12) found no difference between intervention and control groups: physical component score SMD 0.16 (95% CI -0.05 to 0.38); mental component score SMD 0.07 (95% CI -0.15 to 0.28).
Self-manage- ment capabili- ties: self effica- cy (Stanford, SUPPH, PCDS) Follow-up: 1.5 to 12 months	The standardised mean difference in self-efficacy scores was 0.25 standard deviations higher (better) in the intervention groups than in the control groups (95% CI 0.07 to 0.43 higher), a small effect in favour of personalised care planning.	moderate (variation in intervention types led to significant heterogeneity and risk of bias was unclear) Mixed effects were found in 5 studies that measured other attributes that contribute to self-management capabilities. We also found a positive effect on performance of self-care activities associated with personalised care planning, SMD 0.35 (95% CI 0.17 to 0.52).
Harms associat- ed with person- alised care plan- ning		Only 1 study reported any adverse events (hospitalisation and deaths), but there were no differences between intervention and usual-care groups and no reason to assume that these were due to the intervention.

^{*} CI: Confidence interval

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.



BACKGROUND

Description of the condition

The treatment and management of long-term health conditions (including those associated with physical, psychological, sensory, or cognitive problems) is the greatest challenge facing health systems around the world today (UN Secretary General 2011). Strategies used by health professionals to engage, support and empower people with long-term conditions have an important role in improving health outcomes (George Institute 2011; Wanless 2002). Patients who are better informed, more involved in decisions about their care and more 'activated' (i.e. recognise that they have an important role in self-managing their condition(s) and have the skills and confidence to do so) (Hibbard 2004) experience improved health and better quality of life (Michie 2003; Schmittdiel 2008). Strengthening patients' autonomy and capacity to self-manage their health is pivotal to policymakers' attempts to achieve value for money, particularly in times of economic recession. Some policymakers hope that this may also help to tackle unacceptable health inequalities between socioeconomic groups (Department of Health 2009).

The Chronic Care Model, which has been highly influential internationally, stresses the need to transform health care for people with long-term health conditions from a system that is largely reactive, responding mainly when a person is sick, to one that is much more proactive, focused on supporting people's ability to self-manage their health (Epping-Jordan 2004; Nolte 2008; Wagner 1998). The model advocates an active role for patients, who are encouraged to become both more knowledgeable about factors affecting their condition(s) (including strategies for preventing exacerbations or ameliorating symptoms), and more actively involved in decisions about their care. The clinician's responsibility is to gauge the extent of the patient's knowledge, skills and confidence to self-manage his or her health, to strengthen this where necessary, and to ensure that relevant interventions and support services are available (Department of Health 2011; Von Korff 1997; Year of Care 2011). At the heart of the model is an informed, active patient, supported by a well-prepared, proactive primary care team, working together to develop and implement a personalised care plan.

The rising prevalence of multi-morbidity makes the search for effective ways of developing personalised approaches even more important. Demographic change and longer life expectancy mean that increasing numbers of people have more than one chronic condition, requiring specially tailored approaches to the management of complex combinations of conditions and treatment strategies (Barnett 2012). The specialty-led, single disease framework that characterises the organisation of most medical care is outdated. Ideally, care for people with multiple long-term conditions should be holistic: person-focused rather than disease-focused, and responsive to individuals' experiences of

illness and treatment effects and their personal priorities (Mangin 2012).

In managing long-term health conditions, the aims are: to minimise the negative impacts and maximise the potential for improved functioning and well-being; to strengthen people's capabilities for self-managing their condition; to reduce health risks by improving health-related behaviours; and to minimise dependence on resource-intensive, costly health services. Personalised care planning is seen as a promising way to achieve these goals.

Description of the intervention

Personalised care planning aims to ensure that individuals' values and concerns shape the way long-term conditions are managed. Instead of focusing on a standard set of disease management processes determined by health professionals, this approach encourages patients to select treatment goals and to work with clinicians to determine their specific needs for treatment and support (Reuben 2012). The process involves a shift from reactive care (waiting for people to consult with symptoms) to a proactive approach in which patients are invited to attend specially scheduled care planning consultations. For the purpose of this review, we define personalised care planning as: an anticipatory (forward-looking), negotiated discussion or series of discussions between a patient and a health professional (perhaps with other professional or family members present) to clarify goals, options and preferences and develop an agreed plan of action based on this mutual understanding.

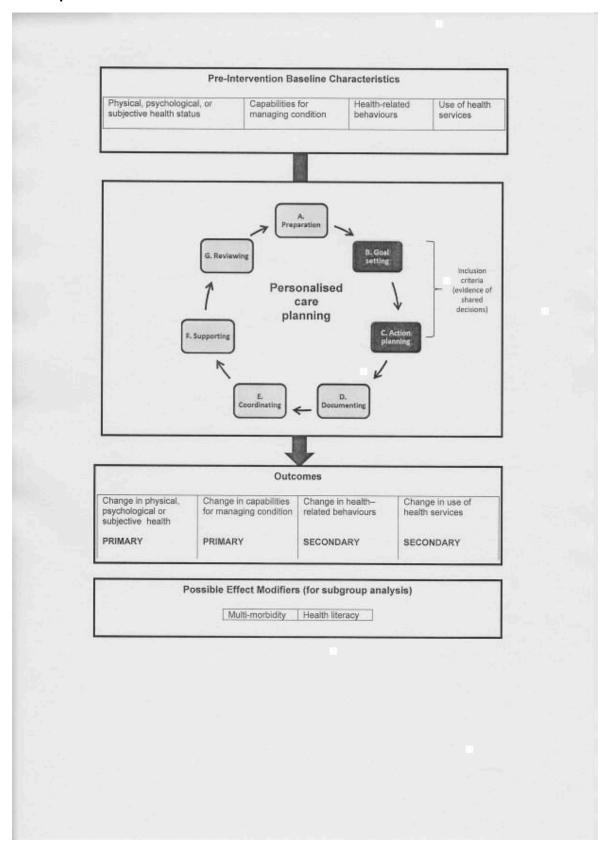
In personalised care planning, patients and clinicians identify and discuss problems caused by or related to the patient's condition(s), giving due consideration to both clinical tests and treatments and the practical, social, and emotional effects of their condition(s) and treatment(s) on their daily lives. They then engage in a shared decision-making process involving goal setting and action planning, focused on determining priorities, agreeing realistic objectives, solving specific problems, and identifying relevant sources of support. In some cases a family member, carer/caregiver or friend may also be included in the discussion. Management options and support needs under discussion might include any or all of the following:

- · clinical tests and treatments,
- self-management information,
- education or support,
- strategies for modifying health-related behaviours, managing stress, or solving practical problems.

A collaborative process in which patient and clinician discuss treatment or management goals (goal setting: see B below) and agree a plan for tackling these (action planning: see C below) are the essential features, but the full process may involve any of the following seven steps (see Figure 1):



Figure 1. Conceptual model for the review





- A. Preparation: the patient may be invited to a preliminary appointment to check their progress and undergo relevant clinical tests. Information (printed, electronic, written, or verbal) may be provided before or during the care planning appointment, to encourage the person to reflect on his or her condition and situation. This might include test results, and information about treatment options, or about health-related behaviours such as diet, exercise or smoking.
- B. Goal setting: aimed at agreeing treatment or management goals, the goal-setting process involves eliciting and clarifying patients' understanding of their condition, their values, outcome preferences and priorities. Patients may be encouraged to talk about their experience of living with the condition, their beliefs and concerns, and their comprehension of, and reactions to, the information provided. The discussion of what matters to them may cover treatment or management options, desired outcomes, lifestyle or behaviour changes, practical, social and emotional challenges, and problem-solving strategies. In personalised care planning, patients have scope to influence the agenda for discussion, and the choice of goals and priorities is not restricted to a prespecified list of professionally determined options.
- C. Action planning: a plan is jointly developed for working towards agreed goals. This may include identifying practical ways in which the patient can achieve their behavioural goals (for example, how and when to take more exercise), referring the patient to external sources of support, either within formal health services (for example, health coaching or rehabilitation services) or in the community (for example, exercise or cookery classes), or peer support. The plan may also include clinician-ordered tests or treatments, referral to other clinical specialists or professionals, educational materials or courses, access to aids or appliances, care assistance or domestic help.
- D. Documenting: the agreed actions are usually documented in a specially-designed record (printed, electronic, or written) for use by the clinician(s) involved in the patient's care or for use by the patient as an aide-mémoire, or for both. These may be either a single shared record, or two separate records containing appropriate detail for clinician or patient.
- E. Co-ordinating: the clinician ensures that all tests, treatments, interventions, education, or support packages agreed in the action plan are available to the patient and provided in a well-co-ordinated fashion. This may include input from multidisciplinary team members, from hospital- or community-based specialists, from educationalists and other staff, or from community organisations or support groups.
- F. Supporting: patient and clinician agree a schedule for regular, systematic follow-up that may involve a number of contacts (face-to-face, telephone, or electronic) to provide appropriate support to help the patient solve problems and achieve his or her goals. This might take the form of health coaching, motivational support, problem solving, or simply checking and reinforcing progress in implementing the agreed plan.
- G. Reviewing: a meeting (face-to-face or remote) during which patient and clinician jointly review progress and plan next steps.

How the intervention might work

Personalised care planning aims to ensure that people receive appropriate support for self-managing their condition alongside any necessary clinical treatments from health professionals. The principles of self management have been developed in a number of theoretical models, mostly from the fields of psychology and behavioural science. They focus on understanding the factors that shape behaviour and those that might help people make the necessary adaptations to improve their health and ability to cope with illness and disability. Of these, Bandura's Social Cognitive Theory (Bandura 1977), Prochaska and DiClemente's 'Stages of Change' trans-theoretical model (Prochaska 1992), and Leventhal's Self-Regulation Theory (Leventhal 1998) are most often referred to. Taken together, these point to the importance of a sense of control or empowerment that can give people the confidence and motivation to take on and persist with new and difficult tasks. Interventions focus on confidence building and equipping individuals with the knowledge and skills to set personal goals and develop effective problem-solving strategies.

A commitment by both clinician and patient to shared decision making is considered essential for personalised care planning. The process is unlikely to succeed if either party is reluctant to participate. In shared decision making, health professionals and patients work together to understand problems, preferred goals and outcomes, sharing information and identifying options with the aim of reaching mutual agreement on the best course of action for the individual patient (Charles 1999; Elwyn 2012b; Entwistle 2012; Glasgow 2005b; Mulley 2012). This approach recognises explicitly that it is usually appropriate to enable people to make decisions about their care, ensuring they are well informed and well supported in the process of deliberation and decision making. Shared decision making takes as its starting point the notion that two types of expertise should be involved in selecting treatment or management options. Clinicians' expertise is based primarily on knowledge of the diagnosis, likely prognosis, treatment and support options, and the range of possible outcomes based on research evidence and population data; patients usually know more about the impact of the condition on their daily life, their personal values, preferences and attitude to risk, and the constraints they may face in implementing any recommended behaviour changes. Both types of knowledge are needed to manage illness successfully, so both parties should be prepared to share information and take decisions jointly.

This concept (shared decision making) has often been applied to 'acute' or 'elective' situations where there are choices between discrete interventions that are professionally controlled (for example, choice between a prescribed medicine or surgery, or choice about whether or not to have a 'preference-sensitive' screening test that only licensed professionals can administer), but it is also central to personalised care planning for longterm conditions when health professionals work with patients to determine goals and priorities (Bodenheimer 2003; Tsai 2005). Effective management of chronic conditions usually involves both tests and treatments prescribed by clinicians and actions that individuals must do for themselves, such as administering medication appropriately, or making lifestyle changes. In some cases, a patient may be better informed about their condition than the clinician, in which case the clinician should respect this expertise and take account of it in the planning process. Some patients may not need support for self management or behaviour change, but, for those that do, collaboratively-set goals and self-selected behavioural targets are seen as more motivational than clinician-assigned goals (Michie 2003). The process involves both shared decisions about how best to manage



the condition, and shared responsibilities for implementing mutually agreed actions (Montori 2006). The experience of working together in a collaborative manner may lead to improvements in people's sense of confidence and well-being. Interventions to promote collaborative goal setting and action planning might, for example, make someone with a long-term condition feel respected, cared about, encouraged and capable of making a meaningful contribution to their state of health (Entwistle 2013).

Why it is important to do this review

Despite widespread support for the principle of personalised care planning, the nature and extent of evidence in support of this approach is unclear. The model has been promoted by the World Health Organization (WHO) and encouraged in a number of countries including Australia, the UK and USA (Singh 2008), but international surveys show that many people with longterm conditions do not receive sufficient support from health professionals to enable them to plan their care and self-manage their condition(s) effectively (Schoen 2011). For example, it has been government policy in England since 2010 to ensure that all people with long-term conditions are involved in a care-planning process (Department of Health 2009). This commitment has recently been strengthened by inclusion of an explicit promise in the National Health Service Mandate that "everyone with long term conditions, including people with mental health problems, will be offered a personalised care plan that reflects their preferences and agreed decisions" (Department of Health 2012). In certain cases people with complex conditions or combinations of conditions may be offered a personal health budget to cover the costs of needs identified during the care planning process (Forder 2012). However, a co-ordinated, personalised approach is not yet the norm in everyday practice. While most people with long-term conditions in England report having some sort of care-planning discussions with clinicians in primary care, only a small proportion experience proactive, systematic support along the lines described above (Burt 2012; Newbould 2012).

Implementing care planning in primary care involves significant organisational and cultural change (Year of Care 2011). Health professionals may be reluctant to embark on this if they do not believe it is warranted by the evidence (Blakeman 2006). They may also be unwilling to adopt this approach if they feel it will be too time-consuming for them or too burdensome for their patients (Coulter 2011). There is a need for more information about which components of care planning are necessary and which may not be, and which types of tools or interventions are helpful (Burt 2013). For example, when it is important to complete the cycle of support and review, and when it might be sufficient to engage patients in goal setting and action planning only. Interventions specially designed for patients, clinicians or both may help to overcome barriers to implementation (see Types of interventions below).

People with multiple co-morbidities or cognitive impairments may find participation in care planning and self management especially difficult (May 2009). There are also concerns that this approach could exacerbate health inequalities if people with low levels of health literacy or communication difficulties are seen as less able to participate or lacking the capacity to self-manage their health (Coulter 2011).

Several systematic reviews have pointed to the importance of a patient-centred, personalised approach to care management.

Patient-oriented interventions to support self management (for example, information provision or educational programmes) have led to improvements in health outcomes for people with diabetes (Deakin 2005; Renders 2000), asthma (Powell 2002) and a number of other chronic conditions (Foster 2007; Murray 2005). Various strategies for increasing people's motivation to adopt healthy behaviours (for example, motivational interviewing or use of written contracts) have led to improved health outcomes for some patients (Bosch-Capblanch 2007; Lai 2010; Rubak 2005; Smedslund 2011). Interventions designed to improve communications and encourage greater patient involvement in decision making have been shown to improve people's knowledge of screening or treatment options, but effects on health outcomes have been mixed (Dwamena 2012; Edwards 2013; Kinnersley 2007; Legare 2014; Levack 2012 (full review in press); Stacey 2014; Wetzels 2007). There is some overlap of focus between this latter group of reviews and the current one, in that they all cover strategies for engaging patients in decisions about their care, but none of the earlier reviews looked specifically at the effects of personalised care planning for people with long-term conditions.

OBJECTIVES

To assess the effects of personalised care planning for adults with long-term health conditions compared to usual care (i.e. forms of care in which the active involvement of patients in treatment and management decisions is not explicitly attempted or achieved).

We addressed the following primary research questions:

- is personalised care planning effective for improving physical health (e.g. lipid measurements)?
- is personalised care planning effective for improving psychological health (e.g. anxiety and depression)?
- is personalised care planning effective for improving subjective health status (or health-related quality of life)?
- is personalised care planning effective for improving people's capabilities for self-managing their condition?

We also looked for evidence to address the following secondary research questions:

- is personalised care planning effective for improving people's health-related behaviours?
- how does personalised care planning impact on rates of use and costs of formal health services?
- what is the relative effectiveness of different types of intervention used to promote personalised care planning?

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials and cluster-randomised controlled trials only.

Types of participants

We were interested in the ways that healthcare professionals and health services engage people in personalised care planning relating to chronic or long-term conditions. Chronic conditions are defined as "diseases of long duration and generally slow



progression" (World Health Organization 2012): for example, heart disease and stroke, cancers, respiratory conditions such as asthma and chronic obstructive pulmonary disease (COPD), diabetes, kidney or liver disease, chronic pain and arthritis, neurological conditions such as epilepsy and multiple sclerosis, HIV/AIDS, and psychiatric conditions such as bipolar, schizophrenia or chronic depression.

We searched for studies where the participants were adults (aged 18 or over) with any long-term physical, psychological, sensory, or cognitive condition or combination of conditions affecting their health, treated in any setting (primary care, secondary care, community care or residential care). This could include people with long-term disabilities not necessarily caused by disease, such as blindness, deafness, mobility, communication problems or intellectual disabilities, if they are receiving treatment from health professionals.

We excluded studies involving simulated patients, or patients requiring treatment for acute or self-limiting problems only.

Types of interventions

The review examined trials that evaluated interventions (including changes to practice styles) that explicitly engaged patients in a shared decision-making process involving both goal setting and action planning as described in Description of the intervention above (B, C).

We excluded studies in which the intervention did not explicitly engage participants actively in determining their goals or priorities and developing a treatment/care/support plan, and those in which they were not encouraged to exert meaningful influence on goals and plans, or where their choices were unduly constrained. We also excluded studies that focused solely on group education programmes without one-to-one clinical engagement, and those designed primarily to engage people in making plans for end-of-life care (advance directives).

Various interventions or practices have been developed to encourage or support personalised care planning. These may be targeted at patients, clinicians or both, and may be used singly or in combination. Examples include the following:

Patient-focused interventions:

- information materials or decision aids for patients (Protheroe 2010)
- computer-based interventions to help patients identify and achieve behavioural goals (Glasgow 2004)
- suggested lists of questions the patient can ask to prompt the clinician to involve them more actively in decisions about their care (Shepherd 2011)
- health coaching and motivational support to help patients clarify objectives, solve problems and achieve behavioural goals (Frosch 2011)
- patient-held records for summarising personal goals and test results (Dijkstra 2005)

Clinician-focused interventions:

 specific training programmes in shared decision making, care planning and/or motivational interviewing (Kennedy 2005)

- guidelines and feedback emphasising the need to elicit patients' preferences during care-planning consultations (Wensing 2003)
- algorithms embedded in clinical record systems to guide the care-planning process (Ell 2010)

Interventions designed to influence the behaviour of both clinicians and patients:

- brief tools for use within care-planning consultations to guide the discussion about options and agreed actions (Elwyn 2012a)
- an electronic or printed template for documenting jointlyagreed actions for use in monitoring and follow-up (Ross 2004).

Not all examples of these kinds of interventions met the review's inclusion criteria. We were primarily interested in the careplanning process itself. This could include any of the above-listed interventions, or others not described above. The point is that personalised care planning should cover whatever is required to help individual patients identify and achieve their own condition-related goals. In some cases both parties may conclude that the patient is managing well and that no additional medical intervention or support is needed.

Our focus was on patient engagement to support and enhance self management of long-term conditions in clinical settings. We excluded studies in which personalised care planning was not a major focus of the evaluation, or where it was not possible to isolate the specific effects of the personalised care planning process.

We originally planned to compare the following types of intervention:

- personalised care planning (as defined above) compared to forms of care where individual involvement in treatment or management decisions is not explicitly encouraged (usual care)
- 'limited' approaches involving goal setting, action planning and no more than two additional steps (preparation, documenting, co-ordinating, supporting, reviewing: see Figure 1) versus 'extended' approaches involving five or more steps in the careplanning cycle
- patient-focused interventions versus those that aimed to change both patient and clinician behaviours

In the event we found even greater diversity among the interventions than predicted, so we added the following comparisons to tease out the likely effects of attributes such as the intensity of the intervention and whether it was integrated into the practice of the patient's usual care provider or an add-on service:

- intensity of intervention (high = at least one contact per month for more than three months; low = shorter duration and fewer contacts)
- integration into usual care (high = usual-care clinician involved in care planning and informed about patients' goals and plans; low = usual clinician not involved, not informed or both).

Types of outcome measures

See Figure 1 for an outline of the conceptual model used in the review, showing primary and secondary outcomes and subgroups. We focused on two main primary outcomes and two secondary outcomes, each of which included a number of potential measures.



Primary outcomes

- Changes in health and well-being, including each of the following three dimensions measured separately:
 - a. physical health: measured instrumentally (e.g. blood pressure, blood lipids, body mass index, HbA1c, urinary albumin, etc.) or by observation or self report (including symptom scales, pain scores).
 - b. psychological health: observation or self-report scales (e.g. depression or anxiety scores).
 - c. subjective health status: patient-reported scales (including health-related quality of life, fatigue, self esteem, coping, activities of daily living, etc.) or proxy reports (clinicians' observations or family member/carer reports).
- Changes in patients' self-management capabilities or indicators relevant to those capabilities: measured by self reports or observations (knowledge of their condition and its treatment or management options, self efficacy, activation, confidence or perceived competence, and ability to access relevant support).

We included validated measures where possible. Non-validated measures were recorded but excluded from the meta-analysis.

Secondary outcomes

- Changes in health-related behaviours: diet, exercise, smoking, use of relaxation techniques, self-management actions, condition-relevant self monitoring, adherence to treatment recommendations, attainment of personal goals.
- Changes in use of formal health services: number and length of hospital admissions, number of outpatient, emergency department, or primary care visits, and, where recorded, effects on the costs of care.

We also recorded any reports of harms or adverse events associated with personalised care planning.

Timing of outcome assessment

We originally intended to group the outcomes into short-term (three months or less), medium-term (six to 12 months) and long-term (more than one year), but this proved difficult to do given the relatively small number of studies, so we have reported only the final outcome measures in each study and pooled these wherever possible.

Selecting outcome measures for use in the analysis

The outcomes listed above are broad categories. In the case of studies that reported more than one outcome within each of these groupings, we adopted the following process: two review authors (AC, AE or SR) independently listed outcomes (without considering either the size of the effect or its statistical significance). Many of the outcome measures used standardised self-completion questionnaires to obtain patients' reports. We pooled outcome data from studies that examined the same constructs, even if the measures were slightly different. Those that looked at different constructs or measured these in very different ways we reported narratively but did not include them in the meta-analysis.

Search methods for identification of studies

Electronic searches

In July 2013 we searched the following databases for all years:

- Cochrane Central Register of Controlled Trials (CENTRAL), The Cochrane Library (July 2013, Issue 7).
- Dissertations & Theses (ProQuest) (1743 July 2013)
- MEDLINE & MEDLINE In-process (Ovid) (1946 to July 2013)
- EMBASE (Ovid) (1974 to July 2013)
- PsycINFO (Ovid) (1967 to July 2013)
- Trial registers (clinicaltrials.gov) (21st June 2013)
- WHO International Clinical Trials Registry Platform (June 2013)

The search strategy was tailored to each of these databases and is reported in Appendix 1. It includes a list of terms developed by the Cochrane Consumers and Communication Review Group that covers most long-term conditions. There were no language restrictions.

Searching other resources

We scanned reference lists of relevant retrieved articles and reviews on this topic, to identify additional papers reporting results from the same study and relevant studies not identified by the electronic searches. We did not systematically search grey literature, conduct handsearches or contact experts. We included relevant studies irrespective of publication status.

Data collection and analysis

Selection of studies

We merged search results using EndNote software, and removed duplicates. Two of three review authors (AC, AE and SR) screened titles and abstracts independently to exclude clearly irrelevant references. Where, in the opinion of at least one review author, the abstract indicated that the study might be eligible for inclusion, or where it was not clear that the study should be excluded, we obtained full-text versions. We linked multiple reports of the same study.

We developed a standard form to record details of each study and reasons for inclusion or exclusion, based on the checklist below. Two review authors (AC, AE or SR) independently scrutinised all identified trial reports to determine eligibility, and recorded the reasons for including or excluding a study, which are documented in a PRISMA flow chart (Figure 2) and in the table Characteristics of included studies. After reviewing all relevant papers independently, the two authors compared notes and discussed any discrepancies. In cases where there was disagreement about eligibility, we referred papers to one of the review authors not involved in the initial selection process (VE, SS or RP).

We used the following checklist to determine eligibility:

- 1. Does the paper present primary data? EXCLUDE if review article, commentary, protocol, etc., but flag for later reference scan.
- 2. Was this a randomised controlled trial (RCT) or clusterrandomised trial (C-RCT)? EXCLUDE if not RCT or C-RCT, but flag for later reference scan to check for eligible studies not previously identified.
- Did the study include adults aged over 18? EXCLUDE if all participants were children or young people aged under 18. INCLUDE if age not stated or if participants included a majority of adults.



- 4. Did participants have one or more chronic conditions? EXCLUDE if participants were healthy people or simulated patients or were consulting for acute (time-limited) conditions.
- 5. Was the intervention concerned solely with planning for end-of-life care (advance directives)? If so, EXCLUDE.
- 6. Was the intervention a patient decision aid only, without one-to-one personalised care planning? If so, EXCLUDE.
- 7. Was the intervention patient education only, without one-to-one personalised care planning? If so, EXCLUDE.
- 8. Was the intervention a psychological treatment only, without one-to-one personalised care planning? If so, EXCLUDE.
- 9. Was personalised care planning with active involvement of the patients in a collaborative or shared decision-making process an explicit component of the intervention?
 - a. Were patients actively involved in planning their treatment or care with a clinician(s), coach or community health worker? INCLUDE IF THIS AND OTHER INCLUSION CRITERIA LISTED BELOW ARE MET
 - b. Did the intervention include both collaborative goal setting and collaborative action planning? INCLUDE.
 - c. Did trial include patient-based outcomes? If not, EXCLUDE; for example if outcomes related to clinicians only. Trials of training programmes for clinicians that included measures of their effects on patients should be considered for inclusion in the review if the training covered personalised care planning.
 - d. Were patients encouraged to set their own goals or priorities and/or were they offered a choice of treatment or support package? INCLUDE if the intention of the intervention was to enable patients to have meaningful influence on goal selection and/or choice of treatment or support package. EXCLUDE if choices were constrained to only a few predetermined options, for example, only a choice between treatment A or treatment B.
 - e. Was the care/action plan pre-prepared so patients had no opportunity to influence it? EXCLUDE.
 - f. Was the care/action plan simply a pre-prepared list of instructions about what to do in particular circumstances? EXCLUDE.
 - g. Is there any other evidence to suggest that the care-planning process did not allow the patient to be involved or to influence it? EXCLUDE

We recorded and reported all studies excluded for any of the reasons listed in criterion 9 (a - g) above (Characteristics of excluded studies). Studies excluded for any of the reasons itemised in 1 - 8 above have not been included in this table, but the numbers in each category are reported in Figure 2.

We collected and report below (Characteristics of ongoing studies) the details (citation details and other relevant information) of ongoing studies.

Data extraction and management

Two of three review authors (AC, AE and SR) independently extracted study characteristics and outcomes from reports.

We used a modified version of the template developed by the Cochrane Consumers and Communication Review Group to extract data from eligible studies (Characteristics of included studies).

Assessment of risk of bias in included studies

We assessed and reported the methodological risk of bias of included studies in accordance with the *Cochrane Handbook* for *Systematic reviews of Interventions* (Higgins 2011) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2011), which recommend explicit reporting of the following individual elements for RCTs: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; completeness of outcome data, selective reporting; and any other obvious sources of bias, such as comparability between groups at baseline or the possibility of contamination between the groups.

For cluster-RCTs we also assessed and reported the risk of bias associated with an additional domain: selective recruitment of cluster participants (Ryan 2011).

In all cases, two review authors extracted data and independently assessed the risk of bias of included studies, with any disagreements resolved by discussion and consensus. We contacted study authors for additional information or for clarification of the study methods, as required. We assessed the risk of bias in respect of random sequence generation. We made provision to exclude studies where this was assessed as high, but in fact we identified no such problems. We included all studies meeting the inclusion criteria in the review regardless of the assessment of risk of bias, but we conducted a sensitivity analysis (by excluding the study) if risk of bias due to method of randomisation or allocation concealment was unclear. The results of the 'Risk of bias' assessment were incorporated into the review through standard tables and narrative commentary, leading to an overall assessment of the risk of bias of the included studies and a judgement about the internal validity of the review's results.

Measures of treatment effect

We calculated effect sizes using mean difference (MD) with 95% confidence intervals (CI) in cases where studies had used the same measure (e.g. HbA1c). For most other outcomes, for example those using a variety of standardised questionnaires or patient-reported outcome measures (PROMS), we used a standardised mean difference (SMD) with 95% CI to summarise the pooled effect of comparable outcomes. We used risk ratios (RR) and 95% CIs for dichotomous outcomes, where relevant, or transformed and treated them as continuous, and summarised them with the rest of the studies (based on the transformation of an odds ratio created from the equivalent two-by-two table). We did not back-transform them due to the variety of scales used in the studies and lack of consensus on which are the most appropriate.

Unit of analysis issues

Inclusion of cluster-randomised trials leads to potential unit of analysis problems. Whenever an adjusted (for clustering) effect was reported, we extracted this for inclusion in the review. No cluster trials reported analyses without adjusting for clustering and hence no further adjustment was necessary.

Dealing with missing data

We used intention-to-treat data in our analyses whenever possible. In cases where data were insufficiently reported in the published paper, we contacted the original authors for clarification and further information. Many studies reported baseline and endpoint



measures which we used to calculate mean change and standard deviation. When available, we estimated the correlation coefficient for the baseline-endpoint values based on alternative studies. When this was not available, we used a correlation value of 0.5 instead (Follmann 1992).

Assessment of heterogeneity

Where studies were considered similar enough (based on consideration of diagnostic categories, type of intervention, outcome measures, or population subgroups) to allow pooling of data using meta-analysis, we assessed the degree of heterogeneity by visual inspection of forest plots and by examining the Chi² test for heterogeneity. We quantified heterogeneity using the I² statistic. An I² value of 70% or more is taken as representing substantial levels of heterogeneity, but this value has to be interpreted in the light of size and direction of effect and strength of evidence for heterogeneity, based on the P value from the Chi² test (Higgins 2011). We did not report pooled results where we detected substantial clinical, methodological or statistical heterogeneity across included studies. We assessed possible clinical or methodological reasons for any variation by grouping studies that were similar in terms of diagnostic categories, intervention types or population subgroups to explore differences in intervention effects.

Assessment of reporting biases

We have not assessed publication bias by use of funnel plots because we had too few studies to do so. Instead we assessed reporting bias qualitatively by looking at the properties of the included studies (for example, if only small studies with positive findings were identified for inclusion, or where authors indicated that there were relevant unpublished studies).

Data synthesis

We pooled data using a fixed-effect meta-analysis because of the small number of studies. In the absence of unit of analysis errors, we combined data from individual and cluster-randomised controlled trials.

Subgroup analysis and investigation of heterogeneity

We aimed to analyse results for the following subgroups to examine factors that might modify any effects (see Figure 1):

- multi-morbidity: people with multiple (i.e. more than one) chronic conditions or disabilities. We considered depression associated with another condition such as diabetes a comorbidity, rather than an example of multi-morbidity.
- health literacy: people who face communication or comprehension problems due to low educational level, minority language, cognitive impairment or intellectual disability.

In practice we were unable to do this due to a paucity of studies measuring these issues, so we have reported any relevant results in the narrative only.

Sensitivity analysis

We used sensitivity analyses to determine the impact of our choices and assumptions. We explored the impact of the inclusion of high/low quality studies in the review (see Assessment of risk of bias in included studies above).

'Summary of findings' table

We prepared a 'Summary of findings' table based on the methods described in chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). We have presented the results for the major comparisons of the review (personalised care planning versus usual care) for each of the primary outcomes (physical health, psychological health, subjective health status, and self-management capabilities), as outlined in the Types of outcome measures section. We have provided a source and rationale for each assumed risk cited in the tables, and have used the GRADE system to rank the quality of the evidence (Schünemann 2011).

Consumer participation

We recruited an expert patient advisory group of six people with experience of living with long-term conditions. Between them they had experience of living with the following conditions: Alzheimer's disease (carer of family member), anxiety, asthma, bilateral above-knee amputation, cataracts, depression, epilepsy, erythromelalgia, irritable bowel syndrome, labyrinthitis, migraine, multiple sclerosis, myeloproliferative disorder, over- and underactive thyroid, peripheral vascular disease, polycystic ovaries, poor circulation, Raynaud's syndrome, rheumatoid arthritis, and tendonitis. They agreed to advise on various aspects of the review, including the protocol, selection of outcome measures, and emerging findings. They were paid a fee for their time.

We sought input and advice from the expert patient advisory group via a secure dedicated website where they could record comments and queries. The website included a short summary of the research plan as background information. We encouraged group members to submit questions about the study at any time via the website. During the development of the protocol we asked them to review the outcomes we had selected for the study. We asked them to indicate which of these should have highest priority in the light of their own experience, to rank all other outcome measures in order of priority and to give reasons for their ranking. We also asked them to let us know if any important outcomes were missing. Participants provided detailed and helpful comments on their rankings. They acknowledged the need to reduce the number of outcomes to make the review manageable, but at least one participant indicated discomfort with this procedure which they felt smacked of standardisation rather than personalisation, giving a professional rather than patient focus to the review. Nevertheless, the results of this exercise supported the choice of outcomes listed above, and no outcomes of any significance were identified as missing from the review.

We asked the group to give their reactions to the findings of the review and to assess the plain language summary to ensure it was comprehensible, accessible and relevant. The group has also been asked to help with disseminating the findings from the completed review.

RESULTS

Description of studies

We restricted the search to randomised controlled trials and cluster-randomised trials evaluating interventions that focused on or included personalised care planning.



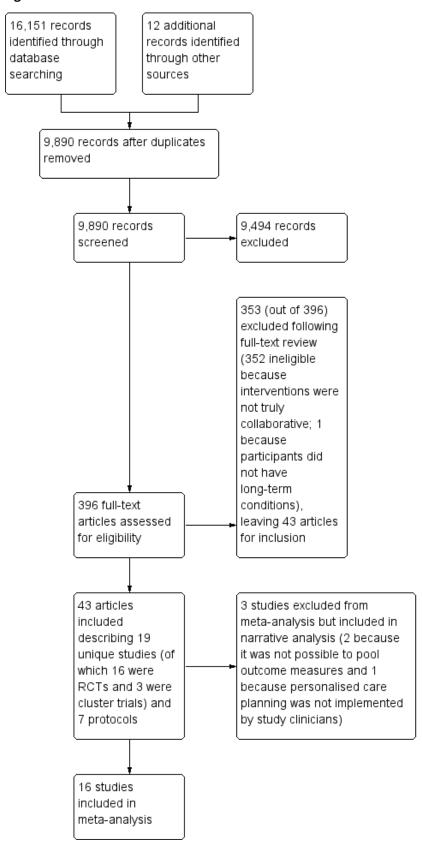
Results of the search

The electronic search yielded 16,151 records. We added a further 12 studies identified in reference scans. Following removal of duplicates, we screened a total of 9890 unique abstracts for eligibility and excluded 9494 of these. We obtained full-text articles for the remaining 396 abstracts and assessed these for inclusion in the review. We excluded a total of 353 articles following full-text analysis. We have listed below (Characteristics of excluded studies)

only those studies where we had to involve a third review author to resolve any uncertainties or differences in the assessments of the first two review authors. We deemed a total of 43 articles eligible for inclusion. These described results from 19 unique studies and seven protocols (Figure 2). We tried to contact the authors of eight of the studies to ask for further information or unpublished data but could not track down current contact details for two. We received helpful replies from five lead authors (Battersby 2007; Ludman 2007; Naik 2011; Stanhope 2013; Wilson 2010).



Figure 2. Study flow diagram.





Included studies

The 19 completed studies included 16 randomised controlled trials (RCTs) (Battersby 2007; Frosch 2011; Hart 1978; Hiss 2007; Katon 2010a; Liu 2012; Ludman 2007; Naik 2011; Schillinger 2009; Shearer 2007; Thom 2013; Tsay 2004; Van der Wulp 2012; Wilson 2010; Wolever 2010; Zoffmann 2006), and three cluster trials (Glasgow 2005a; Kennedy 2013; Stanhope 2013). Thirteen of the included studies were conducted in the USA and one each in Australia, China, Denmark, the Netherlands, Taiwan, and the UK. Details of the studies and the interventions are provided in the table of Characteristics of included studies and summarised in Table 1.

We were able to include 16 of the 19 studies in a meta-analysis. We had to exclude two studies because they used outcome measures that were unique to these studies so could not be pooled (Hart 1978; Stanhope 2013). A third study attempted to evaluate an intervention (a change in practice) that explicitly engaged patients in personalised care planning as we have defined it, but the intervention (the intended new style of practice) was not actually implemented (Kennedy 2013). The authors of this study carried out a process evaluation that confirmed this (Kennedy 2014). We therefore excluded it from the meta-analysis on the grounds that the study cannot tell us anything about the effects of engaging patients in care planning. The only outcome that this study shared in common with others in this review (and therefore could have been pooled) was the Stanford self-efficacy questionnaire. We took the view that inclusion of data from this study would have introduced a negative bias into the meta-analysis.

Participants

There was considerable variation in the size of the studies, ranging from 32 participants (Hart 1978) to 5599 (Kennedy 2013). Together they included a total of 10,856 participants (Table 1). For trials comparing three or more arms, we selected the study arm that most closely met our inclusion criteria, so the data included here represent a subset of those in the published papers for the following studies: Battersby 2007; Ludman 2007; Schillinger 2009; Wilson 2010.

Twelve studies focused on people with diabetes, with or without associated conditions (Frosch 2011; Glasgow 2005a; Hiss 2007; Katon 2010a; Kennedy 2013; Liu 2012; Naik 2011; Schillinger 2009; Thom 2013; Van der Wulp 2012; Wolever 2010; Zoffmann 2006), three focused on mental health (Hart 1978; Ludman 2007; Stanhope 2013), one on heart failure (Shearer 2007), one on end-stage renal disease (Tsay 2004), one on asthma (Wilson 2010), and one on various conditions (Battersby 2007). This last study included eight sub-studies in four different regions in South Australia, half of which were separate but linked RCTs using similar methods and measures (the other four sub-studies used geographic controls so were ineligible for inclusion). The four eligible trials focused on patients with cardiac conditions, respiratory conditions, somatisation and problems of old age.

Only one study used a formal assessment of health literacy: Schillinger 2009 assessed 59% of their participants as having 'limited' literacy according to the Test of Functional Health Literacy in Adults (ToFHLA) scale.

Five studies had participants consisting mainly of people from lower socio-economic groups or from minority ethnic groups or from both (Frosch 2011; Hiss 2007; Kennedy 2013; Schillinger 2009; Thom 2013).

No study focused explicitly on patients with multi-morbidities. One study (Katon 2010a) included patients with depression with diabetes or coronary heart disease or both but, since depression is often a side effect of these conditions, we considered this a comorbidity rather than a study of the effects on people with multi-morbidities.

Interventions

While all studies involved interventions that included personalised care planning (goal setting and action planning), there was considerable variation in the way this was carried out and in the tools and techniques adopted to support the process (Table 1).

All 19 studies included components that were intended to support behaviour change among patients, involving either face-to-face support or telephone support. Three of the interventions took place in hospital clinics (Shearer 2007; Tsay 2004; Zoffmann 2006), the remainder in primary care or community settings. In most cases the intervention focused on changing patients' capabilities and behaviour (15 studies) but four studies (Battersby 2007; Kennedy 2013; Stanhope 2013; Wilson 2010) aimed to change the behaviour of both patients and clinicians.

A variety of tools and techniques were used in the interventions, including patient information packages (DVDs, computer programmes, or booklets); prompts for patients (patient-held records, worksheets or decision aids); structured consultations using coaching methods such as motivational interviewing; training or prompts for clinicians; peer support; and both individual and group visits (see Table 1).

In most cases (14 studies) the care-planning process was led by nurses, or nurses and therapists acting as care managers, service co-ordinators or health coaches. Doctors were actively involved in six of the studies (Battersby 2007; Hiss 2007; Katon 2010a; Kennedy 2013; Liu 2012; Naik 2011) including one study (Naik 2011) where physicians were solely responsible. In two studies the main contact was a peer coach (Thom 2013; Van der Wulp 2012) and in two the intervention was provided by mental health providers including social workers (Hart 1978; Stanhope 2013).

Only five studies relied solely on patients' usual-care clinicians to conduct the intervention (Table 1). In 10 studies the intervention involved contact with additional specially-trained staff or peers not usually responsible for the patient's care. Four studies involved both usual-care clinicians and additional clinicians. Contact between clinicians or peer coaches and patients was face-to-face in 15 studies, while the remaining four studies relied solely or mainly on telephone contact.

We grouped studies according to the number of completed stages in the care-planning cycle (Figure 1). Our prespecified inclusion criteria selected interventions that had completed at least two of the seven collaborative-planning stages (B - goal setting, C - action planning) and some form of follow-up support was included in all 19 studies (F - supporting). Of the other stages, A - preparation for care planning (for example, preliminary information packages or sending test results to the patient so they could review these in advance of the consultation) formed part of the intervention in only four studies, D - documenting (i.e. a record that is explicitly



shared with the patient) featured in seven studies, E - co-ordinating (i.e. the care manager liaising with clinicians and other staff to ensure that all issues identified were dealt with) was reported in five studies, and G - reviewing progress and making further plans was an explicit feature of only three studies. We classified those that had completed only three or four of these stages as 'limited', while those where the intervention involved five or more of the stages were classified as 'extended' (Table 2). Five studies fell into the 'extended' group and only two of these (Battersby 2007; Katon 2010a) covered the entire cycle (A - G).

We also classified interventions according to the intensity of the intervention and the extent to which they were integrated into clinical practice (Table 3). Where studies did not explicitly state that a particular process was carried out (for example, a stage in the care-planning cycle, a precise number of patient-clinician contacts, or co-ordination with usual care providers), we have assumed that these were not features of the intervention and have classified them as 'low' or 'no'. Eight studies fell into the high-intensity group and 11 were low-intensity. A different group of eight studies was classified as integrated with the patient's usual provider, while 11 were not. Only four studies were rated high on both these measures (Battersby 2007; Hiss 2007; Katon 2010a; Liu 2012).

Interventions varied in the extent to which the clinician input was standardised and supervised to ensure fidelity to the design (see Characteristics of included studies). Some studies used tightly-controlled interventions involving closely-supervised clinicians,

while others were more pragmatic in design. Reports from one study (Kennedy 2013) indicated that a majority of participant clinicians had not delivered the intervention as intended.

A theoretical framework can be useful for explaining how the intervention is expected to work, but this was mentioned in only nine of the 19 studies (see Characteristics of included studies). Five studies cited the Chronic Care Model (Battersby 2007; Glasgow 2005a; Kennedy 2013; Ludman 2007; Schillinger 2009), one mentioned Rogers's Science of Unitary Human Beings (Shearer 2007), one was based on Bandura's Social Cognitive Theory (Van der Wulp 2012), one cited Prochaska and di Clemente's Stages of Change theory (Zoffmann 2006) and one was a Chinese adaptation of the Stanford Chronic Disease Self-Management Programme (Liu 2012).

The comparison group was usual care in 12 of the studies. The remaining seven made a comparison between personalised care planning and various forms of enhanced usual care (Glasgow 2005a; Katon 2010a; Kennedy 2013; Naik 2011; Stanhope 2013; Thom 2013; Tsay 2004). Additions to usual care in these studies included provision of health information, group education, or enhanced access to primary care physicians and other clinical staff.

Risk of bias in included studies

Details of our judgements and the rationale for these are included in the Characteristics of included studies table and displayed in Figure 3 and Figure 4.

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

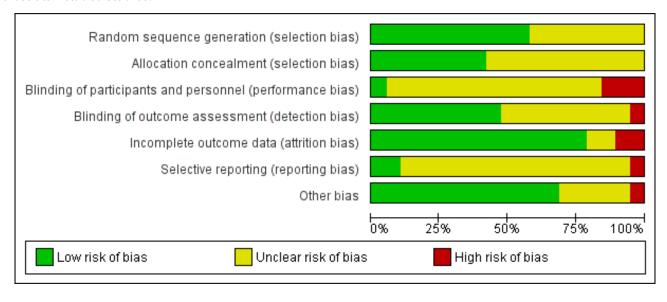




Figure 4. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Battersby 2007	•	•	?	•	•	•	?
Frosch 2011	?	•	•	•	•	?	•
Glasgow 2005a	•	?	?	?	•	?	•
Hart 1978	?	?	?	?	?	?	•
Hiss 2007	?	?	?	?	•	?	•
Katon 2010a	•	•	?	?	•	•	•
Kennedy 2013	•	?	?	•	•	•	•
Liu 2012	•	?	•	•	•	?	?
Ludman 2007	•	•	?	•	•	?	?
Naik 2011	?	•	?	•	•	?	•
Schillinger 2009	?	?	?	•	•	?	•
Shearer 2007	?	?	•	?	•	?	?
Stanhope 2013	?	?	?	•	?	?	?
Thom 2013	•	•	?	?	•	?	•
Tsay 2004	•	?	?	•	•	?	•
Van der Wulp 2012	•	•	?	?	•	?	•
Wilson 2010	•	•	?	•	•	?	•
Wolever 2010	?	?	•	?	•	?	•
Zoffmann 2006	•	?	?	?	•	?	•



Allocation

Just over half of the studies (11 out of 19) reported an acceptable method of random sequence generation. Eight studies did not provide an adequate description of the randomisation process, so we classified these as unclear. Allocation concealment appeared satisfactory in eight of the studies, but it was inadequately described in 11 studies.

Blinding

Blinding of participants and personnel is almost impossible in this type of study, so we classified the risk as unclear for 16 of the studies, since these relied on objective clinical measurements (e.g. blood tests) and we did not consider the risk of non-blinding to be especially problematic. Detection bias was rated high for three studies (Liu 2012; Shearer 2007; Wolever 2010) where both participants and personnel were aware of treatment status and a number of outcomes were subjective. Blinding of outcome assessment was adequate in nine studies, but a further nine provided inadequate evidence. One study (Stanhope 2013) was classified as high risk because it relied on non-blinded clinicians' reports of medication adherence (its primary outcome) with no independent validation of this measure.

Incomplete outcome data

Most studies (15) were rated at low risk in respect of attrition bias, but two provided inadequate information and two were deemed to be at high risk: Battersby 2007 because of very high attrition rates (47% loss to follow-up in the intervention group and 50% in the control group) and Shearer 2007 because of a great deal of missing data: one or more dependent variable pretest scores were missing for 24% of the experimental group and 24% of the control group at baseline, and for 31% and 42%, respectively, at post-test.

Selective reporting

We considered reporting bias to be at low risk in two studies where there were pre-published protocols, at unclear risk in 16 where we found no published protocols, and at high risk in one (Battersby 2007), which reported only statistically significant outcomes and not those that were non-significant. This study comprised a series of linked trials using similar methods, but only one of these sub-studies (Pols 2008) provided sufficient information for some outcome measures to be included in the meta-analysis. We excluded the other sub-studies because it proved impossible to obtain full results from the authors. We did not include outcome measures in the meta-analysis if full data were available for the intervention group only and not the control group.

Other potential sources of bias

We considered other potential sources of bias, such as selective recruitment and fidelity to the intervention. We classified 13 studies as at low risk on these criteria, five were unclear and one (Kennedy 2013) was rated at high risk due to the fact that the intervention was not implemented as intended. The authors reported poor fidelity on the part of clinicians: collaboration between clinicians and patients (shared decision making) at six months was significantly less in the intervention group than in the control group (P = 0.05); only 2% of patients with irritable bowel syndrome were referred to therapists as required in the protocol; and 42% of clinicians failed to use the PRISMS tool which was intended to help patients express

their needs and preferences. A process evaluation (Kennedy 2014) confirmed this impression of very poor fidelity to the intervention.

Effects of interventions

See: Summary of findings for the main comparison

Physical health

Eleven studies examined the effects of personalised care planning on physical health using a variety of standardised clinical indicators, including glycated haemoglobin (HbA1c), blood pressure (systolic (SBP) and diastolic (DBP)), cholesterol (LDL-C), body mass index (BMI), lung function (FEV1) and asthma control (ATAQ) (Table 4). We pooled data from 10 of the 11 studies in at least one comparison, omitting one study from the meta-analysis (Wilson 2010) because it used unique measures (FEV1, ATAQ).

- 1. **Glycated haemoglobin:** (Analysis 1.1) Nine studies (1916 participants) measured HbA1c at six or 12 months post-intervention, giving a combined mean difference (MD) between intervention and control of -0.24%, 95% confidence interval (CI) -0.35 to -0.14, a small positive effect in favour of personalised care planning compared to usual care. Excluding studies with unclear randomisation method and allocation concealment made little difference (MD -0.25%, 95% CI -0.36 to -0.14).
- Systolic blood pressure: (Analysis 1.2): Six studies (1200 participants) measured SBP, giving a combined MD of -2.64 mm/Hg, 95% CI -4.47 to -0.82, a small positive effect in favour of personalised care. However, a sensitivity analysis to exclude studies at higher risk of bias reduced this to -0.64 mm/Hg, 95% CI -3.70 to 0.41.
- 3. **Diastolic blood pressure:** (Analysis 1.3) the pooled results from four studies (751 participants) showed no effect on DBP, MD -0.71 mm/Hg, 95% CI -2.26 to 0.84.
- Cholesterol: (Analysis 1.4) the pooled results from five studies (1545 participants) showed no statistically significant effect on LDL-C, standardised mean difference (SMD) 0.01 mg/dL, 95% CI -0.09 to 0.11.
- Body mass index: (Analysis 1.5) the pooled results from four studies (822 participants) showed no effect on BMI, MD -0.11 kg/ m², 95% CI -0.35 to 0.13.
- 6. Other: a single study of asthma patients (Wilson 2010) reported improvements associated with personalised care planning in lung function: adjusted mean FEV1 as a percentage of predicted value was 76.5% in the intervention group versus 73.1% in the control group, and in asthma control measured by the Asthma Therapy Assessment Questionnaire (ATAQ) (Juniper 1992): odds ratio (OR) of reporting no asthma control problems 1.9, 95% CI 1.3 to 2.9, in favour of personalised care.

Psychological health

Seven studies examined the effects of personalised care planning on psychological outcomes (Table 5). Where studies used more than one measure of psychological outcome, we selected the one that was most conceptually similar to the measures used in the other studies. We pooled results from those studies that used one of four standardised measures of depression symptoms: the Patient Health Questionnaire (PHQ-9) (Kroenke 2001), the Hopkins Symptom Checklist 20 (SCL-20) (Derogatis 1974), the Beck Depression Inventory (Beck 1988), and the Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff 1977).



- 1. **Depression:** (Analysis 2.1) six studies measured depression using one of the above four measures at various time points post-intervention. We were able to pool results from five of the studies (599 participants), giving a SMD of -0.36, 95% CI -0.52 to -0.20, a small positive effect in favour of personalised care. However there was substantial heterogeneity in results from the individual studies. A sensitivity analysis to exclude studies at high risk of bias increased the effect to SMD -0.55, 95% CI -0.76 to -0.34. The remaining study (Glasgow 2005a) reported the proportion of participants with major depression (score 10 or higher on PHQ-9) and found greater improvement in the control group than the intervention group (OR 2.94, 95% CI 1.36 to 6.34; 886 participants).
- 2. Other measures of psychological health: we excluded several other measures of psychological health from the pooled analysis, either because the study included another measure that seemed a better fit, or because the instrument measured a different concept, for example perceived stress or perceived benefits of the condition. Katon 2010a used the Patient Global Rating for Improvement (PGI) in depression measure (Guy 1976) and found that participants in the intervention arm were more likely to report an improvement in their depression symptoms (41/92, 45%) than those in the control arm (16/91, 18%) (<0.001). Ludman 2007, which was a pilot study for Katon 2010a, used the PGI measure but the sample size was too small to detect differences in outcomes. This study also included the Structured Clinical Interview for DSM-IV depression module (SCID) (First 1997), but again they found no effect due to the small sample size. Wolever 2010 used the Perceived Stress Scale (PSS-4) (Cohen 1983a) and the Benefit Finding Scale (Tomich 2004), and found improvements on both measures for the intervention group but not the control group.

Subjective health status

Ten studies used various patient-reported measures of health status (or quality of life), including both generic health status measures and condition-specific ones (Table 6).

- 1. Generic health status: Analysis 3.1 and Analysis 3.2: five studies used the SF-36 patient-reported health status measure (Ware 1992) or the briefer SF-12 (Ware 1996), which reproduces the eight-scale profile of the SF-36 with fewer levels, yielding less precise scores but based on the same constructs. The resulting profile is often presented as two summary scores: the physical component score (PCS) and the mental component score (MCS). Three of the included studies used this method, so we pooled the results from these three studies. The combined analysis from the three studies (345 participants) gave a SMD on the PCS of $0.16,\,95\%$ CI -0.05 to 0.38, and on the MCS of 0.07, 95% CI -0.15 to 0.28. It was not possible to include the remaining two studies in this meta-analysis because one (Kennedy 2013) used only selected sub-scales of the SF-36 and anyway was withdrawn from the meta-analysis for the reasons described above, and the other (Wolever 2010) gave a single score based on the SF-12 without the MCS/PCS breakdown. Neither of these two studies found a difference between the personalised care group and the usual care group post-intervention.
- Other generic measures of health status: Battersby 2007 reported improvements in functioning as measured by the Work and Social Adjustment Scale (WSAS) (Mundt 2002) in all but one of their sub-regional trials. Katon 2010a used the Sheehan Social

- Role Disability scale (Leon 1997), the WHO Disability Assessment Schedule (WHODAS-2) (Ustun 2010), and a global rating scale. They found that participants in the personalised care arm experienced greater improvements at six and 12 months from baseline on both the Sheehan Disability scale (effect size 0.30, P=0.006) and the global quality of life rating scale (effect size 0.39, P=0.005) than those in the usual care group. They found no difference between groups on WHODAS-2. Kennedy 2013 used the Euro-Qol measure (EQ-5D) (Kind 1996), but found no difference between the groups. We have not pooled these data as the measures differ from each other conceptually.
- 3. **Condition-specific health status:** (Analysis 3.3) four studies (1330 participants) included a questionnaire to measure condition-specific health status. In two cases this was the Problem Areas in Diabetes scale (PAID-2) (Welch 1997), one study used the Stanford Illness Intrusiveness scale (Devins 2010), and one the Asthma Quality of Life Questionnaire (AQLQ) (Juniper 1999). We considered that these scales were sufficiently similar to pool the data. The combined results showed no difference between the groups: SMD -0.01, 95% CI -0.11 to 0.10, but this was characterised by heterogeneity between the studies.

Self-management capabilities

Nine studies looked at the effect of personalised care on capabilities related to aspects of self management using a variety of outcome measures (Table 7).

- 1. Self efficacy: (Analysis 4.1). Self efficacy refers to an individual's confidence to carry out necessary tasks or procedures to manage their health or health care. Eleven studies used instruments designed to measure self efficacy for health-related behaviours, seven of which reported improvements. After excluding Kennedy 2013 for the reasons stated above, we pooled results for five of the studies (471 participants) that used similar scales. These included the Stanford self-efficacy scales (Lorig 1996), a scale called Strategies Used by People to Promote Health (SUPPH) (Lev 1996), a Dutch scale referred to as the Diabetes Management Self-Efficacy Scale (Van der Bijl 1999), and the Perceived Competence in Diabetes Scale (PCDS) (Williams 1998) (Table 7). The combined results showed a positive effect of personalised care planning: SMD 0.25, 95% CI 0.07 to 0.43.
- 2. Other self-management capabilities: Self efficacy can be seen as a contributor to, or partial indicator of, capabilities, but its measurement is usually restricted to a limited subset of the capabilities for self management that people with long-term conditions value. A further five studies measured other attributes that contribute to self-management capabilities, including knowledge and understanding (the University of Michigan Diabetes Knowledge Test (Fitzgerald 1998); enablement and activation (the Patient Enablement Instrument (PEI)) (Howie 1998) and the Patient Activation Measure (PAM-13) (Hibbard 2005)); purposeful participation in attaining health goals (Power as Knowing Participation in Change Tool (PKPCT)) (Caroselli 1998); coping (Appraisal of Diabetes Scale (ADS)) (Carey 1990); empowerment (Diabetes Empowerment Scale (DES)) (Anderson 2000); and interpersonal support (Interpersonal Support Evaluation List - ISEL-12) (Cohen 1983b). We did not attempt to pool these data because they measured different constructs. The results from the individual studies were mixed (Table 7). The two studies that used PAM-13 (or parts of it) found evidence of an effect on patient



activation: Wolever 2010 used the PAM-13 scale and found a statistically significant time-by-group interaction in favour of personalised care. This study also noted improvements in reported interpersonal support for the intervention group over the control group using the ISEL-12 scale. Katon 2010a found improvements among the intervention group in two of the four PAM questions they selected, and Tsay 2004 reported an effect on empowerment for the personalised care group compared to the control group, but Shearer 2007 found no effect in relation to the PKPCT.

Adverse events

Only one study (Katon 2010a) reported any harms: 27 participants in the intervention group and 23 in the control group were hospitalised during the course of the study; one person in the intervention group and two in the control group died. There were no differences between intervention and usual care groups and there is no reason to assume that these adverse events were due to the intervention.

Secondary outcomes

Health-related behaviours

Ten studies included measures of the effects of personalised care on health-related behaviours, including exercise, diet, medication adherence and self-care activities (Table 8).

- 1. **Exercise:** (Analysis 5.1) we were able to pool the results from six studies (907 participants) that included patients' self reports on exercise frequency, but found no effect: SMD 0.11, 95% CI -0.02 to 0.24.
- Diet: four studies measured the effect on diet using various different self-report measures (Frosch 2011; Katon 2010a; Liu 2012; Van der Wulp 2012) which could not be pooled. None of these found a difference between the intervention and control groups.
- 3. Medication adherence: five studies measured the effect on medication adherence. Two of these presented patients' self reports on adherence, two gave pharmacy reports and one gave clinicians' reports. We were unable to pool these data because of the diversity of measures used. Frosch 2011 found no effect of personalised care on adherence. Katon 2010a found that patients' knowledge about their medicines and confidence to follow medical regimens improved, but adherence (pharmacy data) did not. Stanhope 2013 reported improvements in medication adherence (clinician report) among the intervention group but not for the control group. Wilson 2010 reported improvements for the intervention group on a number of different pharmacy-derived measures of adherence. Wolever 2010 found an improvement for the personalised care group over the control group on the ASK-20 adherence barrier questionnaire (Matza 2008).
- 4. **Self-care activities:** three of the five studies that measured the impact of personalised care planning on performance of self-care activities (Katon 2010a; Schillinger 2009; Shearer 2007) found improvements in the personalised care group compared to the control group. We were unable to include Katon 2010a in the meta-analysis because of the way the results were reported (blood glucose monitoring mean 4.9 days per week in the intervention group and 3.8 in the control group, RR = 1.28, P = 0.006; blood pressure self monitoring 3.6 versus 1.1 days

per week, RR = 3.20, P < 0.001). The pooled results from the other four studies (520 participants; Analysis 6.1) gave an effect estimate of SMD 0.35, 95% CI 0.17 to 0.52, but with substantial heterogeneity between the studies. The effect reduced to 0.25, 95% CI 0.05 to 0.44 and greater uncertainty with sensitivity analysis.

Attainment of personal goals

Only four of the 19 studies included a report on whether patients felt they had achieved the goals they had set for themselves, and all four gave positive results. Battersby 2007 reported a 60% improvement in problem and goals measurement scores; Glasgow 2005a found improvements in achievement of goals related to healthy eating and physical activity; Hart 1978 found a two-fold improvement in goal attainment among the intervention group which was better than that achieved by the control group; and Schillinger 2009 reported that 88% of participants in the intervention group had succeeded in developing their own goals and repeat action plans, leading to partial or complete success in goal achievement for an average of 2.5 plans per participant. The remaining 15 studies did not report on goal attainment.

Health service use and costs

Three studies included an estimate of the impact of personalised care planning on subsequent resource use (Table 9), but it was not possible to produce a pooled summary of these data.

The analysis reported in Battersby 2007 includes data from eight sub-studies, four of which were eligible for inclusion in our review. They concluded that the small observed reduction in hospital admissions was insufficient to pay for the costs of their model of co-ordinated care. These included costs associated with employing care co-ordinators, administering the trial, training care and service co-ordinators, and engaging service providers.

Wilson 2010 found improvements in medication use associated with personalised care planning, but did not assess whether these were cost-effective.

Katon 2010a included a formal analysis of the cost effectiveness of personalised care from the perspective of the health system. They found that, over 24 months, intervention participants had a mean of 114 (95% CI 79 to 149) additional depression-free days and an estimated 0.335 (95% CI -0.18 to 0.85) additional quality-adjusted life years (QALYs). Intervention participants also had lower mean outpatient health costs of USD 594 per participant (95% CI -3241 to 2053) relative to usual care participants. They concluded that the intervention (TEAMcare) delivered high value for no or modest additional cost.

Subgroup analysis: Effect of type of intervention

We found evidence in relation to HbA1c of differences in effect due to the type of intervention used (Table 2 and Table 3). Extended interventions covering five or more stages in the care-planning cycle (MD -0.43, 95% CI -0.60 to -0.26; 3 trials, 408 participants) were more effective than those that were limited to four or fewer (MD -0.12, 95% CI -0.26 to 0.02; 6 trials, 1508 participants) (Analysis 7.1). High-intensity interventions (those involving one or more contacts a month for more than three months) (MD -0.43, 95% CI -0.63 to -0.24; 5 trials, 847 participants) were more effective than low-intensity ones (MD -0.17, 95% CI -0.29 to -0.04; 4



trials, 1069 participants) (Analysis 8.1) and integrated interventions (those where the patient's usual clinician was informed about the patients' goals and action plans) (MD -0.45, 95% CI -0.70 to -0.21; 2 trials, 358 participants) resulted in greater improvement than those that were not integrated (MD -0.19, 95% CI -0.31 to -0.08; 7 trials, 1558 participants) (Analysis 9.1).

We were not able to repeat these comparisons for the other outcome measures due to the small number of studies in each group. Nor were we able to examine the effect of the clinician's role, for example differences between those interventions that focused on changing clinicians' behaviour as well as that of patients, or those that involved contact with specially trained clinicians or peers in addition to the patient's usual-care clinicians versus those that relied on usual-care clinicians only.

Subgroup analysis: Effect of type of participant

Only one study included a formal measure of health literacy (Schillinger 2009), so we were unable to produce a pooled assessment of its effect on outcomes. No studies focused exclusively on patients with multi-morbidities, so our original intention to assess the effects of personalised care planning for these patients remains unfulfilled.

Of the five studies that recruited a majority of participants from lower socio-economic groups or minority ethnic populations, three found improvements on some outcome measures.

DISCUSSION

Despite the proliferation of studies of various aspects of long-term condition management, personalised care planning (as we defined it) has been assessed in a relatively small number of randomised controlled trials. We found 19 trials that fitted our definition; in other words, they had evaluated interventions designed to encourage and support patients to play an active role in identifying their own goals, determining priorities, and developing plans collaboratively with clinicians.

Fifteen out of the 19 studies reported positive effects for at least one outcome measure. The four studies that found no difference in effect between intervention and control groups (Frosch 2011; Glasgow 2005a; Kennedy 2013; Ludman 2007) evaluated low-intensity interventions, and all but one (Kennedy 2013) were 'add-ons' with no direct involvement of the patient's usual-care clinicians. Ludman 2007 was a small pilot for the larger Katon 2010a study and as such was not powered to distinguish effects between the groups. Kennedy 2013 had problems due to poor fidelity to the intervention, which may explain the lack of effect.

We found moderate-quality evidence that personalised care planning leads to improvements in physical health (blood glucose levels), psychological health (depression), self-management capabilities (self efficacy) and health behaviours (self-care activities). Evidence of impact on condition-specific health status, medication adherence, exercise frequency, resource use and cost effectiveness was mixed. We found no evidence of effects on diastolic blood pressure, cholesterol, body mass index, generic health status, or diet. Interventions that were more comprehensive, more intensive, and integrated into routine care achieved greater benefit than those that were limited, low intensity or not integrated.

Our review suggests that personalised care planning to identify patients' needs for clinical care and self-management support offers promise as an effective way of improving health outcomes for people with long-term conditions.

Summary of main results

Physical health

Eleven studies measured the effects of personalised care planning on various clinical indicators of physical health. Six out of nine studies found improvements in glycated haemoglobin for the intervention group as compared to the control group. Combining these in a meta-analysis gave moderate confidence that personalised care planning for people with diabetes was effective for improving blood glucose control. Six studies included blood pressure among the outcome measures, and the pooled results showed that personalised care planning contributed to a small reduction in systolic blood pressure, but not diastolic. A single study found improvements in lung function and control among asthma patients. No effects were observed on cholesterol levels or body mass index.

Psychological health (depression)

Three out of six studies that measured symptoms of depression reported improvements. The pooled results for five of these studies showed that personalised care planning led to a reduction in symptoms of depression. We were unable to include one study in the pooled analysis due to differences in the way outcome measures were reported. This study found greater improvement in the control group than the intervention group.

Subjective health status (generic and condition-specific)

Impact on subjective health status or quality of life was measured using a variety of different scales, making it difficult to produce a pooled estimate. Six studies measured the effects on generic (as opposed to condition-specific) health status, but only one reported a significant improvement related to personalised care planning. Three studies measured generic health status using the physical component score (PCS) and mental component score (MCS) of the SF-36 and SF-12. We pooled results from these and found no effect. Condition-specific measures of health status are often found to be more sensitive to small effects than generic measures. Four of the included studies measured condition-specific health status (three for diabetes and one for asthma): the pooled results showed a small improvement associated with personalised care planning.

Self-management capabilities

Personalised care planning appears to have a positive effect on people's confidence and skills to self-manage their long-term condition. Seven out of eleven studies that measured the effect on self-management capabilities found improvements. Six studies used comparable instruments to measure self efficacy (one relevant indicator of self-management capabilities). After excluding one large pragmatic trial (Kennedy 2013) in which the intervention was not implemented by clinicians as intended (and was therefore at high risk of bias), pooled results from the remaining five studies showed a small effect favouring personalised care planning.

Secondary outcomes

Ten studies measured the effects of personalised care planning on various health-related behaviours, including exercise, diet,



medication adherence and self-care activities such as blood glucose monitoring or foot care, nine of which found improvements in one or more of these measures. We found a positive effect on self-care activities associated with personalised care planning and a small positive but non-significant effect on daily exercise levels. We were unable to pool data for the other behaviours due to the variety of measures used.

Only three studies included an estimate of impact on resource use and only two of these included cost data. One study found that the intervention was cost-effective, whereas the other study concluded that any savings due to reduced hospitalisation rates were outweighed by the costs of the intervention.

Subgroups

We had hoped to be able to compare the effects of several different facets of interventions on the full range of outcomes. The comparisons we considered important were as follows: those interventions where most of the stages of the care planning cycle were completed (extended) compared to those that completed only four or fewer (limited); those that attempted to change both clinicians' and patients' behaviours against those focused on patients' behaviour only; those classified as high-intensity compared to those that were low; and those that were integrated into the patient's usual care compared to those that were provided as additional services. In the event we had too few studies to carry out these comparisons for any of the outcomes apart from blood glucose measurement, which is applicable to patients with diabetes only. In this case we found that the effects of personalised care planning were greater when more stages of the care planning cycle were completed, when contacts between patients and health professionals were more frequent, and when the patient's usual clinician was involved in the process.

We were unable to estimate the relative effects of personalised care planning on participants with low as opposed to high health literacy, or on those with multiple long-term conditions compared to those with one condition only, because we found only one study that included a formal measurement of health literacy and none of the included studies focused explicitly on multi-morbidity. The results from the five studies that included a majority of participants with lower socio-economic status or from minority ethnic groups were mixed.

Overall completeness and applicability of evidence

The trials included in our review evaluated complex interventions applied mainly, but not exclusively, in primary care settings and involving various different patient groups with different medical diagnoses and different cultural, ethnic and socio-economic backgrounds. Thirteen of the 19 studies were conducted in the USA and 12 of the 19 focused on diabetes. We do not know if the results are generalisable to other settings and other patient groups, but we have no reason to think they are not. There were differences between the included studies in their stated aims and theoretical underpinnings. Few of the authors described personalised care planning in precisely the same manner that we have adopted for this review, and it was not always the primary focus of the evaluations. While all the studies included personalised care planning as a major component, they involved a variety of additional self-management tools and techniques, including information packages, worksheets, group

visits, educational interventions, and peer coaching. We cannot therefore assume that the observed effects were due solely to the planning process itself.

The interventions were delivered by a range of different types of clinicians, including doctors, nurses, other therapists and in two cases, patients as peer coaches (Thom 2013; Van der Wulp 2012). In some cases the work of these clinicians or coaches was carefully structured (including scripts or prompts to guide discussions with patients) and tightly supervised, while other studies relied on brief training courses only. Other interventions were more pragmatic in that they involved usual-care clinicians in the delivery the intervention. This was harder to control and two of the larger studies (Battersby 2007; Kennedy 2013) had problems persuading clinicians to adhere to study protocols, weakening any effects of the intervention.

The wide diversity of outcome measures used in these trials hampered our efforts to pool the data to some extent. Also, the diversity of outcome measures did not necessarily reflect full coverage of important outcome domains. This was especially true in relation to self-management capabilities. We were able to pool results from studies that measured the effect of the intervention on self efficacy, but self efficacy refers to self-perceived cognitive abilities, and the standard measures of self efficacy tend to focus on ability to carry out medically defined tasks. Self-management capability is a broader concept that refers to the capacity and opportunity to manage a condition, to attain valued goals, and more generally live well with the condition. Research to date has not adequately addressed the effects of personalised care planning on people's socially shaped and observed opportunities to manage and live well with long-term conditions.

We were unable to assess the likely impact of personalised care planning on people with multiple long-term conditions or on those with low health literacy. Four of the included studies focused on populations with low socio-economic status, but the diversity of approaches and outcome measures made it impossible to make a reliable assessment of the extent to which the effects may vary between these population subgroups.

Quality of the evidence

Risk of bias was an issue for many of the included studies. None of the studies was assessed as having a high risk of bias in relation to random sequence generation or allocation concealment, but 11 studies provided unclear or no information on these issues. Blinding of participants is almost impossible with this type of intervention and none of the studies achieved this, so we focused on blinding of outcome assessment, which was adequate in nine studies, unclear in nine studies, and high risk in one study. Detection bias, attrition bias and reporting bias should be less problematic, but several studies failed to report these risks adequately and three were assessed as having a high risk of bias in respect of these factors.

We pooled results from studies with different outcome measures that appeared to be measuring the same or very similar constructs (e.g. depression symptoms, self efficacy), but this will have introduced a degree of heterogeneity. We ignored outcome measures that did not appear to have been validated, but we did not attempt an independent assessment of the psychometric properties of the included measures. In certain cases (e.g. self-



management capabilities) we had concerns about the measures used: in many cases these were medically focused and might not have tapped into the factors that were most important to individual patients. We excluded studies where people's choices were restricted to a predetermined set of very narrowly defined goals, but in most cases there were limits to the options considered, undermining the extent to which the process could be said to be truly personalised. It is interesting, and worrying, to note how few studies (only four) included reports on the extent to which patients achieved their personal goals.

Several of the studies were too small and underpowered to detect an effect. Some suffered high rates of attrition and the more naturalistic (pragmatic) studies had problems in encouraging clinicians to implement the intervention as designed. This was a particular problem for the largest study in the group (Kennedy 2013), so we excluded this one from the pooled analysis of effects on self efficacy (the only outcome measure in this study that was possible to pool) because its negative findings would have swamped the others, giving a distorted result.

Potential biases in the review process

Identifying relevant studies in this broad topic area was challenging. We searched a wide variety of databases, including trial registers and lists of unpublished sources such as PhD theses. We scanned reference lists for relevant studies and we searched for additional papers reporting other aspects of eligible studies, such as protocols and additional findings.

Two review authors, working independently, carried out study identification and data extraction, and referred any disagreements to a third review author for resolution. Although we were very careful not to discard relevant studies, we cannot discount the possibility that we may have missed some. In certain cases the interventions were poorly described, making it difficult to judge whether or not personalised care planning had taken place. In cases of doubt, we excluded the studies. The trials listed in the Characteristics of excluded studies table are those that we actively considered for possible inclusion but eventually discarded after discussion by three of the review authors. Most of the excluded studies described interventions that in our view were not truly collaborative.

We used fixed-effect meta-analysis because of the small number of studies in each analysis. This carries the risk that it may yield confidence limits that are too narrow. We checked this by doing a sensitivity analysis using a random-effects model, and found it made no difference to the main findings, apart from self efficacy where the positive effect would disappear.

Agreements and disagreements with other studies or reviews

A 2009 overview of systematic reviews concluded that while there was good evidence that the processes involved in personalised care planning would engage patients more effectively in managing their care, there was little evidence for an impact on health outcomes of doing so (Graffy 2009). We have now shown that there are indeed health benefits from this approach. Other reviews have examined various tools or interventions designed to inform and engage patients, such as decision aids (Stacey 2014), contracts (Bosch-Capblanch 2007), training for health professionals (Dwamena

2012), interactive health communication applications (Murray 2005), and a variety of methods to promote shared decision making (Legare 2014). For the most part these reviews found evidence of beneficial effects on the process of care but not on the outcomes. They focused on specific interventions designed to promote more collaborative forms of decision making and looked at whether the interventions produced the desired effect (i.e. shared decision making). Our starting point was different. We selected studies where a collaborative approach (personalised care planning) had been adopted as the intervention, and we assessed the effects of this on patient outcomes. The distinction is important because it led to the inclusion of a different set of studies, and hence a different assessment of the effects of this type of collaboration between patients and clinicians.

Evidence is accumulating that group-based self-management education can lead to improvements in some health outcome measures (Brady 2013; Foster 2007; Franek 2013; Steinsbekk 2012), but attending a weekly course does not suit everyone and problems with availability, infrequent referral by GPs, and low rates of uptake by patients have been reported, particularly amongst those groups most in need of self-management support (Jordan 2007). One-to-one personalised care planning, coupled with appropriate information, health coaching, problem-solving support and care co-ordination may be a better solution for these people, especially if it is relatively intensive and integrated into routine care (Williams 2011a). Implementing all elements of the Chronic Care Model (patient self-management support, use of clinical information systems, delivery system redesign, provider decision support, linkage to community resources, and organisational development) could help to ensure that the outcome improvements are sustained (Woltmann 2012).

AUTHORS' CONCLUSIONS

Implications for practice

Personalised care planning leads to improvements in certain indicators of physical and psychological health status and people's ability to self-manage their condition, when compared to usual care. The effects appear to be greater when the intervention is more comprehensive, intensive and well-integrated into routine care. Evidence on the relative cost effectiveness of this approach is limited and uncertain.

In its ideal form, personalised care planning is fundamentally different from usual care (Burt 2012). It involves shared control of the consultation and a focus on the patient as a whole person, not just their specific condition. It includes support for self management and behaviour change, and should be the means by which care is co-ordinated and integrated around the individual. Achieving this in practice would require fundamental changes to the organisation and delivery of primary care in most countries to enable a more proactive, anticipatory and integrated approach (Coulter 2013; Stellefson 2013). The context of primary care differs from country to country, so any intervention to support new models of care must be carefully tailored to local circumstances. It will probably require training for health professionals in how to elicit patients' goals and priorities, while avoiding the imposition of an overly directive model of care that could undermine patients' confidence to self-manage their conditions (Williams 2011b). Shared decision making and non-directive motivational interviewing are well-described methods or competencies that



might provide the core of these training schemes (Elwyn 2014), but their introduction into routine care needs to be tailored to local circumstances.

The evidence gathered here suggests that investment in relevant training, support and system redesign could lead to better outcomes for people with long-term conditions. We found some evidence that more intensive and better integrated approaches to personalised care planning and self-management support may work best, but heterogeneity and uncertainties among both the interventions and the outcome measures mean that current evidence cannot support a specific blueprint for widespread adoption. Nevertheless, our review offers a comprehensive conceptual model that we hope will inform future interventions.

Implications for research

We found positive effects on blood glucose, blood pressure, depression, condition-specific health status, self-management capabilities, and self-care activities. This is encouraging, but more trials are required to check the robustness of these findings in diverse settings and to determine which elements of these complex interventions are most likely to be effective.

Support for self management of long-term conditions is a growing area of research. We identified published protocols for seven ongoing studies that may help to address important uncertainties about the effects of personalised care planning. Future studies should examine its impact on patients' self-management capabilities, health behaviours, goal attainment, and resource use, in addition to clinical indicators and psychological outcomes. Studies should focus on longer-term outcomes and include measures of resource use and costs. More studies are also needed to compare outcomes for patients at different levels of health literacy. The lack of studies on multi-morbidity is a serious gap in knowledge that has been noted before (Barnett 2012). Since personalised care planning is potentially an effective way to coordinate care for people with multiple health problems, we would hope to see many more studies addressing this issue.

Ideally trials should be conducted in real-life settings, but this is a difficult topic to study in cluster trials because it involves complex behaviour change and a time commitment from those delivering the intervention. Ensuring fidelity to the protocol can be very difficult in these situations, as evidenced by the experience of the investigators involved in Kennedy 2013. Their very useful process

review (Kennedy 2014) should be read by all researchers planning future trials in this field.

Greater standardisation of outcome measures would be very helpful for future systematic reviews and meta-analyses. Subjective health status and self-management capabilities are key outcomes in studies of care and support for people with chronic conditions, but the field will not advance until there is greater agreement on how to measure these constructs. It is of some concern that so few published studies in this field have attempted to find out whether patients attained their personal goals, as opposed to those determined by clinicians or researchers. This implies a disrespect for patients' interests, values and capabilities—the antithesis of personalised care. Most studies in our review adopted a limited view of patients' capabilities, usually restricted to managing healthrelated procedures and behaviour change. This ignores many of the other resources that individuals, families and communities can contribute to health improvement. We also need more indepth information about patients' experience of personalised care planning to determine which models work best, for whom and in what circumstances. We fervently hope that future studies will remedy these gaps, perhaps by including patient-generated outcome measures, by conducting qualitative research alongside the randomised trials, or both.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Battersby 2007

Methods	~	 · I I A DOT /II	 geographic controls).
MELIIOUS	JUNE UESIEII. OS		

Unit of randomisation: patient

Unit of analysis: patient

Funding sources: South Australian Health Commission; Commonwealth Department of Health and

Aged Care

Conflicting interests: none declared

Participants Country: Australia

Setting: Primary care

Conditions/numbers: 1703 patients with various conditions: Central region: cardiac (n = 271 intervention, 138 control); Southern region: respiratory (n = 165 intervention, 62 control), somatisation (n = 90 intervention, 35 control), aged care (n = 632 intervention, 310 control) - total 1158 intervention, 545

control. (Battersby 2005 p. 663)

Health literacy: n/a

Multi-morbidity: n/a

Interventions Theoretical framework: Chronic Care Model

Focus: Both clinician and patient

Type of intervention: Structured, face-to-face planning and care co-ordination + staff training

Clinicians involved: Service co-ordinators (nurses + allied health professionals - additional) and regular CR

lar GP

Tools: SA HealthPlus Co-ordinated Care. Service co-ordinator assisted the GP to develop a care plan based on a care plan generator. This included patient's self-defined problems and goals. Based on this and the GP's knowledge of the patient, as well as the patient's 'Problems & Goals' statements, the GP and patient made a joint decision on what support and services were needed. Both the GP and the pa-



Battersby 2007 (Continued)

tient signed the care plan, and copies were made for patient, service co-ordinator, other providers and GP. Service co-ordinators received 2 days training + competency assessment and group supervision. The service co-ordinator helped the patient gain access to and co-ordinate community and patient education services and worked with the patient to achieve his or her goals.GPs were paid a fee to develop each care plan and an annual fee to oversee patients' care, supported by the service co-ordinators.

Stages completed: Extended - A, B,C,D,E,F,G

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: Good (training and ongoing supervision), but "The [intervention group] GPs needed reminders to order the services scheduled on the care plan." (p. 62)

Fidelity: Weak. "The intervention was not in place long enough for its full implementation" (p. 62)

Attrition: High. More than 50% of participants lost to follow-up following trial extension (p. 48)

Comparison: Usual care

Outcomes

Health status: *subjective:* Medical Outcomes Study short form (SF-36), Work and Social Adjustment Scale (WSAS); *psychological:* Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI), Hostility and Direction of Hostility Questionnaire (HDHQ) (Pols 2008)

Self-management capabilities: n/a

Health behaviours: n/a

Attainment of personal goals: problems and goals score

Service use: *service use and costs **Adverse events:** none reported

Timing of outcome measures: 12 months; baseline measures not reported

Notes

*Primary outcome. Negative results not reported in full. Author contacted - more papers supplied but no relevant additional data obtained. Data from one sub-trial with complete results (Pols 2008) included in meta-analysis. Pols 2008: power calculation - required sample size of 300 participants to detect 15% reduction in hospital admissions but only 124 recruited, so under-powered.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Pols 2008: randomisation performed by random number allocation (p. S133).
Allocation concealment (selection bias)	Low risk	Pols 2008: random number allocation provided to the research officer by telephone from the local evaluation team (p. S133).
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Pols 2008: GPs were not blinded to participant allocation. All GPs looked after participants in both intervention and control groups, (p. S133)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Pols 2008: research officers were not blinded to participant allocation, but outcome assessments were administered independently by separate contractors using postal questionnaires mailed to participants (p. S134)
Incomplete outcome data (attrition bias) All outcomes	High risk	Pols 2008: High levels of attrition: only 42 out of 89 in the intervention group (47%) and 22 of 44 in the control group (50%) completed the study. Reasons for loss to follow-up reported for study as a whole but not for the two ran-



Battersby 2007 (Continued)		domised sub-trials, so not possible to isolate these. Service use analysed on an intention-to-treat basis but not possible for SF-36 and WSAS
Selective reporting (reporting bias)	High risk	Battersby 2007 reports significant results only for SF-36 and WSAS, not non-significant findings, and RCTs and those with geographical controls are lumped together. Battersby 2005 reports only significant results for SF-36, not total scores or non-significant results for subscales. Cost data include only those who had an inpatient admission prior to entry. These facts are made clear in the papers. Pols 2008 reports full results for SF-36 but not for WSAS, but they state that there was no significant difference in results for WSAS (p. S136).
Other bias	Unclear risk	Work and Social Adjustment Scale has not been validated in a chronically ill population and the work questions were omitted because not relevant to most participants (p. 46).

Frosch 2011

Methods Study design: RCT

Unit of randomisation: patient

Unit of analysis: patient

Funding sources: Robert Wood Johnson Foundation; Foundation for Informed Medical Decision Mak-

ing; National Institute on Aging; National Institutes of Health

Conflicting interests: fees/grants from Foundation for Informed Medical Decision Making

Participants Country: USA

Setting: Primary care

Conditions/numbers: 201 diabetes patients (type 2) (100 intervention, 101 control)

Health literacy: Predominantly poor, uninsured ethnic-minority patients with poorly controlled dia-

betes (p. 2015)

Multi-morbidity: Charlson co-morbidity index - intervention 0.81 ± 1.3 , control 0.66 ± 1.2

Interventions Theoretical framework: n/a

Focus: patient

Type of intervention: Information + structured coaching (phone)

Clinicians involved: Health coach (additional)

Tools: Participants viewed a 24-minute-long DVD plus booklet, followed by up to 5 sessions of telephone coaching with a trained nurse educator. First session was up to 60 minutes, second and third 30 minutes, fourth and fifth 15 minutes. Maximum amount of coaching time was $2\frac{1}{2}$ hours. Purpose was to collaborate with participants in identifying desired and attainable behavioural goals that could have a positive impact on their diabetes management. The coach collaborated with participants to develop a specific behavioural plan, which was then monitored and adjusted as participants attempted to implement their behavioural goals. A single health coach trained in patient-centred approaches to diabetes management and motivational enhancement saw all participants. Participants received a call 1 week after enrolment to remind them to review the brochure and DVD. They were eligible to receive up to 5 sessions of telephone coaching, but there were frequent delays in contact and only 73% completed 5 coaching sessions



Frosch 2011	(Continued)
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Stages completed: Limited - B, C, F

Usual provider aware of patient's goals and action plans: Not stated

Standardisation of clinician input: A single trained clinician provided all coaching sessions.

Fidelity: 73% completed 5 coaching sessions, 15% did not complete any

Attrition: 5% intervention, 14% control lost to follow-up

Comparison: Usual care + booklet

Outcomes

Health status: physical: blood glucose (HbA1c)*, cholesterol, blood pressure, BMI

Self-management capabilities: University of Michigan Diabetes Knowledge Test

Health behaviours: 25-item Summary of Diabetes Self-Care Activities measure (diet, exercise, blood

glucose testing, foot care, smoking), adherence to medications

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Timing of outcome measures: Baseline, 1 month, 6 months

Notes

*Primary outcome. Power calculation - required sample size of 200 participants to detect meaningful difference between the groups on HbA1c.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomised into equally sized control and experimental conditions using a predetermined randomisation sequence concealed in sealed envelopes (p. 2012).
Allocation concealment (selection bias)	Low risk	Sealed envelopes.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Low risk	Not possible to blind participants, but as most outcomes were objective it is unlikely to have a significant effect on risk of bias.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research staff were not blinded to participants' assignments, but primary outcome was biological measure that is not sensitive to unblinding (p. 2016).
Incomplete outcome data (attrition bias) All outcomes	Low risk	84% completed the 6-month survey (p. 2013). Intention-to-treat analysis reported with missing data imputed.
Selective reporting (reporting bias)	Unclear risk	No published protocol.
Other bias	Low risk	Randomisation occurred after participants completed their medical consultations to mask healthcare providers to participants' assignment (P. 2012).



Glasgow 2005a

Methods

Study design: Cluster-RCT

Unit of randomisation: physician

Unit of analysis: patient

Funding sources: Agency for Health Research and Quality

Conflicting interests: none declared

Participants

Country: USA

Setting: Primary care

Conditions/numbers: 886 diabetes patients (type 2) (469 intervention, 417 control)

Health literacy: n/a **Multi-morbidity:** n/a

Interventions

Theoretical framework: Chronic Care Model

Focus: patient

Type of intervention: Information + self-management support (phone or face-to-face)

Clinicians involved: Care manager (additional)

Tools: Diabetes Priority Program. Participants were asked to come 30 minutes early to 2 diabetes-related visits, scheduled 6 months apart, to complete a computerised assessment and action-planning procedure. The CD-Rom-assisted diabetes care enhancement program with touchscreen assessment and feedback to check receipt of lab tests and other clinical procedures (NCQ/ADA Diabetes Physician Recognition Program - PRP) and self-management support, and to develop a self-management action plan focusing on behaviour change in diet, smoking and physical exercise involving personal goals. Three printouts summarised results for participant, physician and care manager (nurse or medical assistant), including prominent notation of areas the participant wished to discuss. Care managers trained in patient-centred self-management support met with participants or scheduled phone calls and organised follow-ups to review progress. The discussion included review of the medical care needs and self-care goals that the participant identified and brainstorming additional strategies that participants could use to overcome barriers to their goals. This took an average of 8 - 10 minutes. The care manager also attempted a brief follow-up call after each visit to review progress and to reinforce strategies developed. These procedures were repeated at the next visit about 6 months later.

Stages completed: Limited - B, C, D, F

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: Care managers received brief training only, none for physicians

Fidelity: 75% of eligible patients participated, 73% discussed print-out with physicians, 77% met care manager, 67% received at least 1 phone follow-up

Attrition: 19% intervention, 15% control lost to follow-up

Comparison: Completion of touch-screen computer assessment with PRP measures + general health risk appraisal + same number of visits + printout on general health risks, without PRP and follow-up calls

Outcomes

Health status: *physical:* HbA1c, cholesterol; *psychological:* Patient Health Questionnaire (PHQ-9); *subjective:* Problem Areas in Diabetes (PAID-2),

Self-management capabilities: n/a



G	lasg	ow	200)5a	(Continued)
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Health behaviours: n/a

Achievement of personal goals: self report

Service use: n/a

Adverse events: none reported

Timing of outcome measures: Baseline, 12 months

Notes

Primary outcome - PRP measures (performance of specified clinical procedures) were excluded because not relevant to this review. Power calculation - required sample size of 32 physicians and 774 patients to detect a moderate effect

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participating physicians were stratified by size of practice and urban/rural setting. Randomisation was conducted by the project statistician, who then notified research staff of condition assignment.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Blinding not described. Not possible to blind participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition rates were approximately equivalent (19% intervention and 15% control). Analyses were conducted on complete cases.
Selective reporting (reporting bias)	Unclear risk	No published protocol.
Other bias	Low risk	No evidence of selective recruitment of clusters. Participating physicians were stratified by size of practice and urban/rural setting. No significant differences between groups at baseline. To avoid contamination, all physicians within a given clinic were assigned to the same condition. To account for clustering of patients within physician. a generalised regression model using a random effect for the physician (a mixed model) was fitted, adjusting for baseline score on the dependent variable with a random physician effect and participants nested within physician (Glasgow 2004a, p. 1168). Outcomes were evaluated using mixed-model regression analyses (to account for clustering) and controlling for baselines scores on the dependent variable and any other potential confounding variables.

Hart 1978

Methods Study design: RCT

Unit of randomisation: patient



Hart 1978 (Continued)

Unit of analysis: patient

Funding sources: not stated

Conflicting interests: not stated

Participants Country: USA

Setting: Community mental health centre

Conditions/numbers: 32 mental health patients (diagnoses unspecified) (16 intervention, 16 control)

Health literacy: n/a **Multi-morbidity:** n/a

Interventions Theoretical framework: n/a

Focus: patient

Type of intervention: Individual therapy

Clinicians involved: Clinician 'scaler' (additional) and psychotherapist (usual)

Tools: The Behavioral Monitoring Process Record (BMPR) was designed to help participants set goals and report on their progress at each subsequent therapy session. A 4-week goal was set with the participant and reviewed each week. Within each problem area, a weekly goal and method of attainment was specified. Participant and therapist jointly assessed the degree of attainment of each goal. Goals had to be observable, definable and measurable and structured in a step-by-step manner. All participants completed an 'intake history' based on two interview sessions. At a third interview session they collaboratively prepared a follow-up guide that consisted of setting treatment goals and predicting 5 levels of goal attainment with an 'expected' level of attainment by the eighth therapy session. 'Collateral persons' (other people significant to the participant, such as spouse or probation officer) helped to identify problem areas and to validate the participant's self report at follow-up. Randomisation took place after the third session.

Stages completed: Limited - B, C, D, F

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: Only 4 therapists involved

Fidelity: Not reported **Attrition:** None reported

Comparison: Same individual therapy without weekly goal setting or monitoring

Outcomes Health status: n/a

Self-management capabilities: n/a

Health behaviours: n/a

Achievement of personal goals: Goal Attainment Scale (GAS) (Kiresuk 1968) - achievement of personal

goals

Service use: n/a

Adverse events: none reported

Timing of outcome measures: Baseline, 3 months

Notes No power calculation reported.



Hart 1978 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details provided.
Allocation concealment (selection bias)	Unclear risk	No details provided.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	No details provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details provided.
Selective reporting (reporting bias)	Unclear risk	No published protocol.
Other bias	Low risk	The collateral person was a source of external validation of the participant's self report. Validation included identification and definition of the participant's problems at intake (pretest score) and input as to the level of functioning on the attainment level of the follow-up guide at the follow-up evaluation.

Hiss 2007

Methods	Study design: RCT
	Unit of randomisation: patient
	Unit of analysis: patient
	Funding sources: National Institutes of Health; National Institute of Diabetes and Digestive and Kidney Diseases
	Conflicting interests: not stated
Participants	Country: USA
	Setting: Primary care
	Conditions/numbers: 197 diabetes patients (type 2) (95 intervention, 102 control)
	Health literacy: recruited from community clinics serving under-insured residents
	Multi-morbidity: n/a
Interventions	Theoretical framework: n/a
	Focus: patient
	Type of intervention: Structured face-to-face meetings



Hiss 2007 (Continued)

Clinicians involved: Nurse care manager (additional) and usual primary care physician

Tools: All participants received a comprehensive evaluation of their diabetes at the community clinic they attended. A report of the evaluation plus appropriate explanations and interpretations was mailed to both the participant and his or her physician. This preceded randomisation. Those in the intervention group then received several individually arranged meetings with a nurse care manager where they discussed problem identification, problem-specific, short-term goal setting and development of a tentative action plan. This was communicated to the primary care physician who participants were advised to contact to follow up identified problems. Then followed a collaborative interaction between nurse, physician, and participant focused on short-term goal attainment, plus proactive and continuous follow-up by the nurse care manager. Long-term goal setting typically occurred during subsequent nurse/participant meetings as the participant gained experience in carrying out the action plan. Short-and long-term goals were participant-specific and based on problems identified in the baseline evaluation. These included family issues, financial status, employment, insurance status, and access to and payment for medical care, as well as medical goals.

Stages completed: Extended - A, B, C, E, F

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: Single nurse care manager

Fidelity: In-person and phone contacts monitored and reported

Attrition: 15% intervention, 19% control lost to follow-up

Comparison: Usual care + evaluation of diabetes with report mailed to participant and physician

Outcomes

Health status: physical: HbA1c, serum cholesterol, systolic blood pressure (SBP), diastolic blood pres-

sure (DBP)

Self-management capabilities: n/a

Health behaviours: n/a

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Timing of outcome measures: Baseline, 6 months

Notes

No power calculation reported.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Not reported.
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported.



Hiss	200	07	(Continued)

All outcomes

Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for. Intervention group: no post-intervention data obtained from 14 participants (moved = 4, long-term care = 1, lost = 7, refused = 2). Control group: no post-intervention data from 19 (death = 3, moved = 3, long-term care = 1, lost = 6, refused = 6).
Selective reporting (reporting bias)	Unclear risk	No published protocol. All outcomes reported, but no intention-to-treat analysis. Missing BP data for 3 in intervention group and 2 controls unaccounted for.
Other bias	Low risk	

Katon 2010a

Methods Study design: RCT

Unit of randomisation: patient

Unit of analysis: patient

Funding sources: National Institute of Mental Health; Group Health Cooperative

Conflicting interests: fees/grants from Wyeth, Eli Lilly, Forest, Pfizer, Prescott Medical, HealthSTAR Communications, World Psychiatry Association, John A Hartford Foundation, Johnson & Johnson,

Samepage, Rewarding Health, Roche Diagnostics, Group Health Cooperative

Participants Country: USA

Setting: Primary care

Conditions/numbers: 214 patients with depression + diabetes and/or CHD (106 intervention, 108 con-

trol)

Health literacy: n/a

Multi-morbidity: yes

Interventions Theoretical framework: n/a

Focus: patient

Type of intervention: Structured, face-to-face self-management support + staff training

Clinicians involved: Nurses (additional), primary care physicians (usual)

Tools: TEAMcare intervention combined support for self care with pharmacotherapy to control depression, hyperglycemia, hypertension, and hyperlipidemia. Participants worked collaboratively with nurses and primary care physicians to establish individualised clinical and self-care goals. In structured visits at each participant's primary care clinic every 2 to 3 weeks, nurses monitored participant's progress in management of depression, control of medical disease, and self-care activities. Treatment protocols guided adjustments of commonly used medicines in participants who did not achieve specific goals. Nurses followed participants proactively to provide support for medication adherence. Using motivational interviewing and coaching, nurses helped participants solve problems and set goals for improved medication adherence and self care (e.g. exercising and self-monitoring blood pressure and glucose levels). Participants received self-care materials including *The Depression Handbook*, a video compact disk on depression care, a booklet and other materials on chronic condition management and self-monitoring devices (e.g. blood pressure or blood glucose meters) appropriate to their condition. Nurses received weekly supervision with a psychiatrist, primary care physician, and psychologist to review new cases and participant progress. Supervising physicians recommended initial choices and changes in medications tailored to the participant's history and clinical response. When targeted levels



Katon 2010a (Continued)

were reached, the nurse and the participant developed a maintenance plan that included stress reduction, behavioural goals, continued use of medications, and identification of prodromal symptoms associated with worsening depression and glycemic control. Nurses then followed up with telephone calls every 4 weeks. Participants with disease control that worsened were offered follow-up visits or telephone calls and protocol-based intensification of treatment regimens.

Stages completed: Extended - A, B, C, D, E, F, G

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: strong - 2-day training course attended by the 3 study nurses + educational materials + weekly case-load reviews with physicians + close monitoring

Fidelity: Data and safety monitoring board, numbers of in-person and phone contacts monitored and reported

Attrition: 12% at 6 months and 17% at 12 months lost to follow-up

Comparison: Enhanced usual care

Outcomes

Health status: physical: HbA1c, systolic blood pressure, LDL cholesterol; psychological: Symptom Checklist-20; Patient Global Rating of Improvement*; subjective: Sheehan social role disability scale, WHO Disability Assessment Schedule (WHODAS-2), quality of life (0 to 10) (NV)

Self-management capabilities: 4 selected questions from short-form Patient Activation Measure (PAM-13)

Health behaviours: diet, exercise, medication adherence

Achievement of personal goals: n/a

Service use: healthcare costs and cost effectiveness, including depression-free days, QALYs, outpatient costs

Adverse events: hospitalisations - 27 intervention, 23 control; deaths: 1 intervention, 2 control.

Timing of outcome measures: Baseline, 6 months, 12 months

Notes

*Primary outcome. Power calculation - 290 participants required to detect a clinically significant difference in SCL-20 depression scores, HbA1c, systolic blood pressure and LDL cholesterol. Only 214 recruited so under-powered.

Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned by computer using a permuted block design with randomly selected block sizes of 4, 6, and 8 patients.	
Allocation concealment (selection bias)	Low risk	Research assistants who were unaware of the intervention status implemented study procedures (Katon 2010a)	
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Single-blind only - not possible to blind participants to intervention, but most outcomes objective so unlikely to affect risk of bias.	
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Clinicians were not blinded to outcome assessments because these were part of the intervention.	



Katon 2010a (Continued)		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fully detailed in Figure 1 of Katon 2010a
Selective reporting (reporting bias)	Low risk	Protocol published (Katon 2010b). Data and safety monitoring board reviewed methods and outcomes every 6 months. Katon 2010a includes description of pre-analysis modifications to protocol.
Other bias	Low risk	Intervention provided by research nurses not involved with control group, in collaboration with primary care physicians

Kennedy 2013

Methods **Study design:** cluster-RCT

Unit of randomisation: general practices

Unit of analysis: patient

Funding sources: National Institute for Health Research; National Primary Care Research and Develop-

ment Centre

Conflicting interests: none declared

Participants Country: UK

Setting: Primary care

Conditions/numbers: 5599 patients with diabetes, COPD, or irritable bowel syndrome from 43 prac-

tices (2295 intervention, 3304 control)

Multi-morbidity: n/a

Health literacy: Recruited from practices with high levels of socio-economic deprivation (p. 2)

Interventions

Theoretical framework: Chronic Care Model, Normalisation Process Theory

Focus: Both clinician and patient

Type of intervention: Structured face-to-face coaching + staff training

Clinicians involved: Nurse (usual), GP (usual)

Tools: Whole System Informing Self-Management Engagement (WISE). The intervention was intended to be feasible to implement widely in primary care, which put practical limitations on the intensity of the intervention. Aim was to take several components and deliver them as a comprehensive package under naturalistic conditions using routine care providers to maximise real-world applicability. Two training sessions were organised for practice staff covering ways of embedding self-management tools in practice systems (session 1) and using core self-management skills in consultations and ensure participants received, or were directed to, appropriate resources (session 2). Fidelity checks and reinforcement sessions were scheduled after training. Two facilitators delivered the training and provided access to self-management support activities and resources. These included a tool to assess patient support needs and priorities (PRISMS); self-help guidebooks; access to community groups and programmes; and enhanced access to psychological therapists for IBS participants.

Stages completed: Limited - B, C, E, F

Usual provider aware of patient's goals and action plans: Yes



Kennedy 2013 (Continued)

Standardisation of clinician input: Weak - 2 training sessions + manual, but low levels of implementation

Fidelity: Poor - shared decision-making at 6 months significantly less in intervention than control group (P = 0.05); only 2% of IBS participants referred to therapists; 42% of clinicians failed to use PRISMS tool (p. 4). Process evaluation (Kennedy 2014) examined reasons for failure to change practice and confirmed that very little personalised care planning took place.

Attrition: 19% at 6 months and 27% at 12 months lost to follow-up

Comparison: Usual care, including information and support

Outcomes

Health status: subjective: Medical Outcomes Study short form (SF-36), Euroqol (EQ5D)*

Self-management capabilities: self efficacy*, patient enablement

Health behaviours: n/a

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: Baseline, 6 months, 12 months

Notes

*Primary outcomes. Power calculation - required sample of 40 practices and 48 participants per condition per practice (total participants = 5760), so slightly under-powered.

Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	Wait-list comparator group. Used a minimisation procedure based on practice size, area deprivation and contractual status, practices were allocated 1:1 to intervention or control. Practices were paired as closely as possible according to their preferred training times, and using a minimisation procedure, 1 practice in each pair was allocated to training in the first year, with the other practice allocated to training at the same time the following year (p. 3).	
Allocation concealment (selection bias)	Unclear risk	Research staff recruiting practices were unaware of the next allocation in the sequence at the time of recruitment (Bower 2012, p. 7). Baseline (and subsequent follow-up) data collection then took place at both practices in a pair at the same time. Proved impossible to recruit participants prior to allocation. Practices required adequate advance notice of their training date, hence it became necessary to inform them of their group allocation prior to participant selection. Authors confident that any resulting bias is small. Recruitment was through electronic health records rather than by professional invitation, but practitioners could exclude patients after identification. These exclusions represented a relatively small proportion of patients (COPD 15% intervention, 11% control; diabetes 11% int., 10% cont; IBS 11% int., 18% cont.).	
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Personnel were not blinded and outcomes were patients' self report.	
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Analyst blind to practice allocation (supplementary file).	



Kennedy 2013 (Continued)			
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis. 81% completed 6 month follow-up and 72.8% the 12-month follow-up. Few differences between intervention and control in completeness of outcome data. Missing values for outcome variables at follow-up were not imputed, but addressed through covariate adjustment.	
Selective reporting (reporting bias)	Low risk	Trial report matched published protocol apart from certain measures that were eventually omitted from the study to make the questionnaire shorter. No evidence of selective outcome reporting.	
Other bias	High risk	Fidelity to the intervention was very poor - shared decision making at 6 months significantly less in intervention than control group (P = 0.05); only 2% of IBS participants referred to therapists; 42% of clinicians failed to use PRISMS tool (p. 4). Kennedy 2014 confirms that very little personalised care planning actually took place, so we have excluded the study from the meta-analysis. No evidence of selective recruitment by clusters. Two trial arms were reasonably well-balanced on all variables at the participant level, but practices in the intervention group were on average slightly smaller (mean list size 4003 vs 4528 patients).	

Liu 2012

LIU ZUIZ	
Methods	Study design: RCT
	Unit of randomisation: patient
	Unit of analysis: patient
	Funding sources: Initiative for Cardiovascular Health Research in Developing Countries
	Conflicting interests: none declared
Participants	Country: China
	Setting: Primary care
	Conditions/numbers: 208 diabetes patients (type 2) (intervention 119, control 89)
	Multi-morbidity: n/a
	Health literacy: n/a, 2 rural communities.
Interventions	Theoretical Framework: Chronic Disease Self-Management Program (CDSMP)
	Focus: patient

Clinicians involved: Nurse (usual), GP (usual), preventive doctor (usual)

Type of intervention: Group visit + face-to-face consultation

Tools: Participants were invited to attend a 12-session (monthly) group visit programme + 60-minute one-to-one visit with healthcare provider at the end of each group visit, if wanted (only ¼ received these). Programme followed Chronic Disease Self-Management Programme (CDSMP) format, including setting goals and making action plans. The format was adapted from the Chinese version of Stanford CDSMP Leaders Manual. The content included topics covered in the generic CDSMP course as well as diabetes specific self-management support topics recommended by Shanghai community diabetes prevention and control guidelines. Groups were led by existing general practice teams consisting of 1 GP, 1 preventive doctor, 1 nurse practitioner and 1 patient. Sessions focused on helping participants build confidence in their ability to deal with diabetes by incorporating self-efficacy-enhancing strategies, including action-planning and feedback, modelling of behaviours by participants for one another, reinterpretation of symptoms, practicing self-management skills, and group problem-solving. Partici-



Liu 2012 (Continued)

pants made 12 1-week action plans over the 12 months. Each group also had a lay leader with diabetes who followed up with group members on their action plans in person or by telephone within 1 week. Staff attended a 1-day training workshop.

Stages completed: Limited - B, C, F

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: GPs and nurses involved in design of scripted programme implemented in 2 rural communities by 3 general practice teams + 1-day training workshop

Fidelity: 75.6% of participants attended 10 or more sessions. Patients who participated were significantly older with a higher prevalence of hypertension than those who declined

Attrition: 15% lost to follow-up

Comparison: Usual care provided by a single GP

Outcomes

Health status: physical: body mass index (BMI), systolic blood pressure (SBP), diastolic blood pressure (DBP); subjective: Self-rated health, energy, health distress, fatigue, illness intrusiveness, depression (Chinese adaptations of Stanford instruments)

Self-management capabilities: self efficacy, symptom management (Stanford)

Health behaviours: exercise (NV), diet (NV)

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: baseline, 12 months

Notes

No primary outcome. No power calculation reported

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was by means of a random number table with a ratio designed to yield no fewer than 20 and no more than 25 participants in a group. (p. 5).
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Participants were aware of their assignments. Both participants and personnel were aware of treatment status and a number of outcomes were subjective.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collection was completed by university students who did not know the participants or their allocation status. All those assessing and analysing the data were blinded to group assignments (p. 5).
Incomplete outcome data (attrition bias) All outcomes	Low risk	98 out of 119 in the intervention group completed the 12-month follow-up and 78 out of 89 in the control group. Reasons for loss to follow-up are documented in the flow diagram (p. 4)
Selective reporting (reporting bias)	Unclear risk	No published protocol, but results presented for all listed outcome measures.



Liu 2012 (Continued)

Other bias Unclear risk No significant differences at baseline apart from prevalence of hypertension

which was higher in the intervention group and fatigue and illness intrusive-

ness which were lower in the intervention group.

Ludman 2007

Methods **Study design:** 4-arm pilot RCT, but only care management arm without group education included here.

Unit of randomisation: patient

Unit of analysis: patient

Funding sources: National Institute of Mental Health

Conflicting interests: none declared

Participants Country: USA

Setting: Primary care

Conditions/numbers: 52 patients with chronic or recurrent depression (26 care management interven-

tion, 26 usual care)

Multi-morbidity: n/a **Health literacy:** n/a

Interventions Theoretical framework: Chronic Care Model

Focus: patient

Type of intervention: Telephone monitoring and care management + staff training

Clinicians involved: Care manager (additional)

Tools: Telephone monitoring and care management - computerised decision support system supported systematic tracking of participant contacts, scripted clinical assessments, automatic application of treatment algorithms, and generation of feedback reports. The care manager (a master's level counsellor) contacted each participant at specified intervals (at least monthly during the first 3 months then at varying intervals) and helped them create a written care plan + education about medicines adherence and motivational enhancement. The care manager communicated with the treating provider when necessary. Care management training involved 4 hours of didactic training, 4 hours of role play, and direct observation of 2 care management contacts, followed by certification + weekly supervision

Stages completed: Extended - B, C, D, E, F

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: Strong - single care manager, 4 hours didactic training + 4 hours

role play + direct observation of 2 contacts + certification + weekly supervision

Fidelity: not reported

Attrition: 18% lost to follow-up

Comparison: usual care

Outcomes Health status: psychological: Structured Clinical Interview for DSM-IV (SCID) depression module, 20-

item SCL depression scale, *subjective*: Patient-Rated Global Improvement (PGI)

Self-management capabilities: n/a



Ludman 2007 (Continued)

Health behaviours: n/a

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: baseline, 3, 6, 9 and 12 months

Notes Author contacted and additional data supplied. Pilot study - no power calculation reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	After baseline interview data manager assigned patients to 1 of 4 treatment groups using computer-generated permuted block design (p. 1066).
Allocation concealment (selection bias)	Low risk	Concealed from interviewers.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Not possible to blind participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers and analysts were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Usual care group participants completed 92% of all blinded follow-up interviews, care management group completed 82%, prof-led group completed 94% and peer-led group completed 83% (p. 1069)
Selective reporting (reporting bias)	Unclear risk	No published protocol. All outcome measures mentioned, though not all in tabular form. For example, detailed results for PGI not reported in full and SCL only in graphical form. Author contacted.
Other bias	Unclear risk	There were some differences between groups at baseline - authors do not report on the significance of these.

Naik 2011

Methods

Study design: RCT

Unit of randomisation: patient

Unit of analysis: patient

Funding sources: Agency for Healthcare Research and Quality; Doris Duke Charitable Foundation; National Institute of Aging; Houston Health Services Research and Development Center of Excellence

Conflicting interests: none declared

Participants

Country: USA
Setting: Primary care



Naik 2011 (Continued)

Conditions/numbers: 87 diabetes patients (45 intervention, 42 control)

Multi-morbidity: n/a
Health literacy: n/a

Interventions Theoretical framework: n/a

Focus: patient

Type of intervention: Group visit + face-to-face consultation

Clinicians involved: Physicians (additional)

Tools: Empowering Patients in Care (EPIC) was a clinician-led, patient-centred group clinic consisting of 4 sessions on setting self-management action plans (diet, exercise, home monitoring, medications, etc.). This was followed by a 1-hour group session and a 10-min consultation with a clinician. Goals focused primarily on diet and exercise changes, home monitoring of blood glucose and medication effects, and communication with primary care providers about medications. The fourth session allowed for constructive reporting and feedback on participants' progress. Three primary care physicians led the sessions. Study clinicians sent a research note to participants' primary care physician after each session, consisting of participants diabetes ABC status, specific DM goals and action plans discussed and any changes made to medications. Action plans for nearly all participants included taking medications prescribed by primary care physicians and discussing subjective and objective effects of medications.

Stages completed: Limited - B, C, F, G

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: strong - 3 study physicians directed the group sessions

Fidelity: not reported

Attrition: 2 drop-outs (2.3%), 12 (14%) did not complete follow-up survey

Comparison: Traditional - 2 x 2-hour group education sessions with a diabetes educator and dietician

followed by a visit with a primary care provider 12 weeks after enrolment

Outcomes **Health status:** physical: blood glucose (HbA1c)

Self-management capabilities: diabetes self efficacy (Stanford)

Health behaviours: n/a

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: baseline, 3 months, 1 year

Power calculation - required 98 participants to detect moderate effect on HbA1c, so slightly un-

der-powered.

Risk of bias

Notes

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	After enrolment participants were randomised using a block randomisation of 10 (p. 454).



Naik 2011 (Continued)		
Allocation concealment (selection bias)	Low risk	Allocation of treatment group assignment was blinded using sequentially numbered and sealed envelopes.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Both participants and personnel were unblinded, but primary outcome was objective so not likely to affect risk of bias.
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Primary outcome is objective so unlikely to be affected by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	43 of 45 participants randomised to EPIC attended some or all of the intervention sessions, as did all 42 of participants randomised to the traditional group. Only 1 person from each group was lost to follow-up and hence had no HbA1c outcome measures. Diabetes Self-Efficacy Scale data were available for 75 participants (87%) at 1-year follow-up.
Selective reporting (reporting bias)	Unclear risk	No published protocol, but both outcome measures reported.
Other bias	Low risk	

Schillinger 2009

Schillinger 2009			
Methods	Study design: 3-arm RCT (only automated telephone self-management support - ATSM and usual care included here)		
	Unit of randomisation: patient		
	Unit of analysis: patient		
	Funding sources: Commonwealth Fund; Agency for Healthcare Research and Quality; California Endowment; San Francisco Department of Public Health; California Healthcare Foundation; National Institutes of Health		
	Conflicting interests: none declared		
Participants	Country: USA		
	Setting: Primary care		
	Conditions/numbers: 226 diabetes patients (type 2, poorly controlled) (112 ATDM intervention, 114 usual care)		
	Multi-morbidity: n/a		
	Health literacy: 59% "limited" health literacy measured with the Test of Functional Health Literacy in Adults (ToFHLA). 42% Spanish-speaking and 12% Cantonese speakers.		
Interventions	Theoretical framework: Chronic Care Model		
	Focus: patient		
	Type of intervention: Structured self-management support (automated phone + nurse follow-up) vs. group visits (not included here)		
	Clinicians involved: Care manager (additional)		



Schillinger 2009 (Continued)

Tools: Improving Diabetes Efforts Across Language and Literacy (IDEALL) project. Automated Telephone Self-Management (ATSM) + follow-up calls from specially trained nurse care manager to promote collaborative goal setting in the form of behavioural 'action' plans. The ATSM is a pre-recorded automated telephone call that participants receive each week. Those answering 'out of range' receive a call back from a nurse care manager who helps participants problem-solve the issue identified in the report or any other concerns, with a focus on collaborative goal setting and action plans. The intervention also included individualised assessment, skills enhancement, health education, follow-up and support, access to community resources and continuity of clinical care. All care manager-participant interactions, including action plans created and achieved, are documented via a standardised record linked to the community health network record and shared with primary care physicians.

Stages completed: Limited - B, C, F

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: Strong (trained care managers)

Fidelity: 94% completed at least 1 ATSM call,

Attrition: 10% lost to follow-up

Comparison: Usual care

Outcomes

Health status: physical: HbA1c, systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI); subjective: Medical Outcomes Study short form (SF-12)

Self-management capabilities: n/a

Health behaviours: diet, exercise. self monitoring of blood glucose, caring for feet, diabetes interfer-

ence

Achievement of personal goals: self report

Service use: cost effectiveness **Adverse events:** none reported

Length of follow-up: baseline, 12 months

Notes

No primary outcome. No power calculation reported.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Blocked randomisation strategy stratified to ensure even distribution of languages (English, Spanish, Cantonese). Assessed success of randomisation using t tests, Chi² and Fisher's exact to compare baseline characteristics (Schillinger 2008 p. 670; Schillinger 2009 p. 560).
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Blinding of participants and personnel not possible, but most outcomes were objective.
Blinding of outcome as- sessment (detection bias) All outcomes	Low risk	Research assistants were masked to participants' group assignment (p. 565).



Schilli	nger 2009 ((Continued)
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Incomplete outcome data (attrition bias)
All outcomes

Low risk

90% completed follow-up interviews at 1 year, HbA1c for 88.2%, BP for 94.1%, BMI for 92.3%. Tested for difference between the 2 interventions due to attrition bias - greater engagement was associated with improvements in self-management behaviour and functional status in both arms, but did not alter size of effect (p. 564).

Selective reporting (reporting bias)

Unclear risk

No published protocol.

Other bias

Low risk

Shearer 2007

Methods Study design: RCT

Unit of randomisation: patient

Unit of analysis: patient

Funding sources: not stated

Conflicting interests: not stated

Participants Country: USA

Setting: Secondary care

Conditions/numbers: 90 heart failure patients (45 intervention, 45 control)

Multi-morbidity: n/a
Health literacy: n/a

Interventions

Theoretical framework: Rogers' Science of Unitary Human Beings

Focus: patient

Type of intervention: Structured case management (phone) + staff training

Clinicians involved: Nurses (additional)

Tools: Telephone-delivered Empowerment Intervention that provided support and information to facilitate collaborative care. The nurses focused specifically on what was important to the participant in self management, goal attainment, and functional health. Empowerment was facilitated through the mutual patient-nurse process to foster the participant's awareness that they had the ability to purposefully participate in change and attain their own self-management goals. A standardised script guided the calls to identify problems, goals and support needs. After sharing concerns and potential solutions, standardised questions related to weight, swelling in legs and abdomen, shortness of breath, chest pain and course of action if they experienced any of these symptoms ensued. The conversation remained open to the participant's needs and concerns, with the nurse providing support, encouragement, and information. Each telephone call was audiotaped to monitor intervention integrity. A summary of content discussed during each telephone call was documented in the participant's electronic medical record.

Stages completed: Limited - B, C, F

Usual provider aware of patient's goals and action plans: Not stated

Standardisation of clinician input: strong (3 trained nurses following standard script, calls moni-

tored)



Shearer 2007 (Continued)

Fidelity: good (participants received 6 phone calls in 12 weeks following discharge)

Attrition: low - 3% lost to follow-up

Comparison: Usual care

Outcomes

Health status: subjective: Medical Outcomes Study short form (SF-36) mental and physical component

scores (MCS/PCS)

Self-management capabilities: Power as Knowing Participation in Change Tool VII (PKPCT)*; Self Man-

agement of Heart Failure scale.

Health behaviours: n/a

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: baseline, 12 weeks

Notes

*Primary outcome. No power calculation reported.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details given.
Allocation concealment (selection bias)	Unclear risk	No details given.
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Both participants and personnel were unblinded and outcomes were subjective.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details given.
Incomplete outcome data (attrition bias) All outcomes	High risk	There was a lot of missing data: 1 or more dependent variable pretest scores were missing in 24.4% of the experimental group and in 24.4% of the control group at baseline, and in 31% and 42.2%, respectively, at post-test. When 25% or fewer responses were found missing within a scale, the participant's scale mean was computed and substituted for a missing value; if less than 75% of the items on a scale were valid, the scale score was treated as missing and the case was excluded from the analysis of that specific outcome.
Selective reporting (reporting bias)	Unclear risk	No published protocol.
Other bias	Unclear risk	PKPCT has not been used with heart failure patients before and some participants struggled to understand it.



Stanhope 2013

Methods Study design: cluster-RCT

Unit of randomisation: community mental health centre

Unit of analysis: patient Funding sources: Janssen

Conflicting interests: fees/grants from Ortho-McNeil-Janssen and Forest Research Institute

Participants Country: USA

 $\textbf{Setting:} \ \textbf{Community mental health centres}, 5/10 \ \textbf{randomised to training in person-centred planning}$

and collaborative documentation

Conditions/numbers: 367 mental health clients (177 intervention, 190 control): schizophrenia (n = 153,

bipolar disorder (n = 88), depression (n = 86), other (n = 40)

Multi-morbidity: n/a
Health literacy: n/a

Interventions Theoretical framework: n/a

Focus: both clinician and patient

Type of intervention: Staff training

Clinicians involved: Mental health providers (usual)

Tools: Clinicians received training in person-centred planning via video conferencing, followed by further coaching and monitoring during monthly meetings. Person-centred planning provides a blueprint to identify life goals that can be translated into action steps to inform the collaboration between the provider and the client. The process consisted of identifying life goals, assessing behavioural health problems, developing service plans to integrate life goals and behavioural health goals, and keeping a focus on life goals during the therapeutic sessions. Providers are also trained to focus on client engagement, following up at the next appointment to discuss missed appointments and problem-solve how to avoid them. Collaborative documentation consists of re-orienting assessment, planning, and evaluation documentation to identify and integrate personal goals with more traditional mental health goals and completing all documentation during face-to-face sessions with the client.

Stages completed: Limited - B, C, D, F

Usual provider aware of patient's goals and action plans: Yes

Standardisation of clinician input: Strong (training + coaching and monthly monitoring)

Fidelity: not reported **Attrition:** not reported

Comparison: Usual care + centralised scheduling and management of no-shows

Outcomes **Health status:** n/a

Self-management capabilities: n/a

Health behaviours: medication adherence

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported



Stanh	ope	2013	(Continued))
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Length of follow-up: monthly for 11 months

Notes Author contacted and supplied additional data. No power calculation reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Cluster-randomised trial, 10 CMHCs, 5 randomly allocated to intervention - no further details provided.
Allocation concealment (selection bias)	Unclear risk	No details provided, but concurrent intervention with both groups may have helped to conceal allocation.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Not possible to blind participants.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Study relied on clinicians' reports of medication adherence and no-shows.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Hard to work out from data provided - odds ratios for medication compliance over time (11 months).
Selective reporting (reporting bias)	Unclear risk	No published protocol. Each of the main outcomes is reported.
Other bias	Unclear risk	Insufficient baseline data to determine whether selective recruitment by cluster occurred or not. Client-level analyses were conducted separately for CMHCs in the experimental and control groups to examine whether the odds of medication adherence changed over time. Given that the data included a monthly binary adherence measure for each client, random-effects logistic models were used to examine adherence (dependent variable) as a function of month (independent variable), including random effects for CMHCs and participants nested within CMHCs. The effect of time across the intervention groups was compared by including an intervention-by-time interaction term in a model containing both experimental and control sites. The results of the models were stratified by relevant participant and CMHC characteristics, and a 3-way interaction between the characteristic, the intervention, and time was calculated to determine whether any of these key factors moderated medication adherence. Logisitic regression models, including a random effect for site, were run to calculate the effect of the intervention on the odds of an appointment no-show. The models used data received from each CMHC on the total number of appointment no-shows and the total number of appointments (pp. 77-8). Clinician-recorded adherence was compared with participants' own reports and corroborated these (p. 79).

Thom 2013

Methods Study design: RCT

Unit of randomisation: patient

Unit of analysis: patient



Thom 2013 (Continued)

Funding sources: American Academy of Family Physicians

Conflicting interests: not stated

Participants Country: USA

Setting: Primary care

Conditions/numbers: 299 diabetes patients (148 intervention, 151 control)

Multi-morbidity: n/a

Health literacy: 36% less than high school education, 46% primary language not English, 61% income

below USD 10,000

Interventions Theoretical framework: n/a

Focus: patient

Type of intervention: training for peer coaches

Clinicians involved: peer coaches (additional)

Tools: Potential peer coaches attended 36 hours of training over 8 weeks in either English or Spanish. They were trained in active listening and non-judgemental communication, helping with diabetes self-management skills, providing social and emotional support, assisting with lifestyle change, facilitating medication understanding and adherence, navigating the clinic, and accessing community resources. Trainees who passed both a written and an oral examination became peer coaches in the study. Peer coaches interacted in person with the participants they coached at the discretion of the coach and participant, either outside the clinica by telephone or during a clinic visit. Target goals for coaching sessions were telephone contact at least twice a month and 2 or more in-person contacts over 6 months. Coaches helped participants design action plans to achieve goals chosen by the participant.

Stages completed: Limited - B, C, F

Usual provider aware of patient's goals and action plans: Not stated

Standardisation of clinician input: Strong - peer coaches had 36 hours training over 8 weeks + written

and oral examination

Fidelity: not reported

Attrition: 8% dropped out

Comparison: Usual care included access to a nutritionist and diabetes educator through referral from

primary care clinician

Outcomes Health status: physical: blood glucose (HbA1c)*, cholesterol (LDL-C), systolic blood pressure (SBP),

body mass index (BMI)

Self-management capabilities: n/a

Health behaviours: n/a

Achievement of personal goals: n/a

Service use: n/a

Notes

Adverse events: none reported

Length of follow-up: baseline, 6 months

*Primary outcome. Power calculation - 400 participants required to detect clinically significant differ-

ence in HbA1c, so under-powered.



Thom 2013 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients who enrolled and completed baseline data collection were paid USD 10 and assigned to the usual care or peer-coaching arm using randomly ordered opaque envelopes (p. 139).
Allocation concealment (selection bias)	Low risk	Opaque envelopes.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Not possible to blind participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information about blinding of assessors.
Incomplete outcome data (attrition bias) All outcomes	Low risk	24 (8%) participants did not complete 6-month data and were considered to have dropped out. These participants were likely to be younger, more likely to smoke, less likely to report having hyperlipidaemia, but otherwise did not vary significantly from remaining participants (p. 141)
Selective reporting (reporting bias)	Unclear risk	No published protocol. All outcomes, attritions and exclusions reported, missing data treated as missing, not imputed.
Other bias	Low risk	

Tsay 2004

Methods	Study design: RCT
	Unit of randomisation: patient
	Unit of analysis: patient
	Funding sources: National Science Council of Taiwan
	Conflicting interests: not stated
Participants	Country: Taiwan
	Setting: Dialysis centres in 2 hospitals
	Conditions/numbers: 50 patients with end-stage renal disease (ESRD) (25 intervention, 25 control)
	Multi-morbidity: n/a
	Health literacy: n/a
Interventions	Theoretical framework: n/a
	Focus: patient
	Type of intervention: Structured, face-to-face self-management support
	Clinicians involved: Nurse (additional)



Tsay 2004 (Continued)

Tools: The programme focused on helping participants develop skills and self awareness in goal-setting, problem-solving, stress management, coping, social support and motivation. It included participant identification of problem areas for self management of ESRD, the exploration of emotions associated with these problems, the development of a set of goals and strategies to overcome these problems and for achieving the goals, making a behavioural change plan, and initiating self-care behaviours and stress management. Participants received an information package + individual consulting sessions 3 times a week for 4 weeks (p. 61).

Stages completed: Limited - B, C, F

Usual provider aware of patient's goals and action plans: Not stated

Standardisation of clinician input: Strong - single clinical nurse specialist provided coaching (p. 61)

Fidelity: not reported **Attrition:** no drop-outs

Comparison: Information package + usual care

Outcomes

Health status: psychological: Beck Depression Inventory

Self-management capabilities: Empowerment scale, Strategies used by People to Promote Health

(SUPPH)

Health behaviours: n/a

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: baseline, 6 weeks

Notes

No primary outcome. Power calculation performed and number of participants reported as adequate but few details provided.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were assigned to experimental or control group based on SPSS statistical randomisation software (p. 60)
Allocation concealment (selection bias)	Unclear risk	Researcher and nurse were aware of which treatments participants were receiving, but data collector was not.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Participants' usual caregivers (physicians, nurses, dieticians, and/or social workers) were uninformed about treatment group (p. 61), but not possible to blind participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The data collector was a trained research assistant who was unaware of the participant's status to maintain double-blind accuracy. (p. 61)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs in either group.



Tsay 2004 (Continued)

Selective reporting (reporting bias)

Unclear risk

No published protocol. Results reported for all outcome measures.

Other bias

Low risk

Van der Wulp 2012

Methods Study design: RCT

Unit of randomisation: patient

Unit of analysis: patient

Funding sources: Dutch Diabetes Research Foundation

Conflicting interests: none declared

Participants Country: Netherlands

Setting: Primary care

Conditions/numbers: 119 diabetes patients (type 2) (59 intervention, 60 control)

Multi-morbidity: n/a
Health literacy: n/a

Interventions

Theoretical framework: Bandura's Social Cognitive Theory

Focus: peer coach

Type of intervention: Training for peer coaches **Clinicians involved:** Peer coaches (additional)

Tools: A peer-led self-management programme was developed with input from patients, GPs and dieticians. The primary objective was to increase self efficacy in patients with Type 2 diabetes. Secondary objectives were to improve physical activity and dietary habits. Five expert patients with diabetes were recruited through advertisements. They received 3 training sessions, each lasting $3\frac{1}{2}$ hours. They learnt the basic principles of motivational interviewing (how to support self efficacy, coping with resistance, showing empathy, exploring discrepancies). A script was developed for use by expert patients (peer coaches) who carried out 3 monthly 1-hour home visits to discuss participant's priorities, goals and action plans, with subsequent follow-up calls. During the first visit, areas for lifestyle change were explored. In the second visit, participants discussed the feasibility of lifestyle changes and set goals to work on over the next month. Progress towards the goals was evaluated in the third visit. Home visits lasted 1 hour on average. Within 2 weeks after each visit the expert patients contacted their participants by phone to evaluate the previous visit and answer any questions. Between visits participants could contact their expert patient by phone or email as often as they liked.

Stages completed: Limited - B, C, F

Usual provider aware of patient's goals and action plans: not stated

Standardisation of clinician input: Strong - 5 expert patients received 3 x 3½-hour training sessions in motivational interviewing + follow-up meetings and supervision (p. 391).

Fidelity: not reported

Attrition: 13 participants dropped out (11%) and 23 did not return questionnaires (19%)



V	an d	ler W	ul	p 201	12 (Continued)
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Comparison: Usual care

Outcomes

 $\textbf{Health status:}\ psychological: \textbf{Center for Epidemiologic Studies Depression Scale (CES-D)}; subjective:$

WHO Well-Being Index; Problem Areas in Diabetes (PAID-2)

Self-management capabilities: Diabetes Self-Efficacy*, Diabetes Coping;

Health behaviours: Physical Activity Scale for the Elderly, Fatlist

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: baseline, 3 months, 6 months

Notes

* Primary outcome measure. Power calculation - 80 participants required to demonstrate difference

between groups in relation to self efficacy

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computerised randomisation model allocated participants to intervention or control (p. 396)
Allocation concealment (selection bias)	Low risk	Randomisation conducted by person not familiar with study or researchers.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Not possible to blind participants or peer coaches.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Nothing reported re blinding of assessors.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data patterns were analysed and revealed that data were missing completely at random, so missing values were imputed by means of regression analysis. Attrition accounted for in detail (p. 392)
Selective reporting (reporting bias)	Unclear risk	No published protocol. All outcome measures reported.
Other bias	Low risk	Intervention took place in participants' homes with peer coaches. Contamination unlikely.

Wilson 2010

Methods

Study design: 3-arm RCT (only shared decision-making arm (SDM) and usual care included in review)

Unit of randomisation: patient

Unit of analysis: patient

Funding sources: National Institutes of Health



Wilson 2010 (Continued)

Conflicting interests: fees/grants from Asthmatix, GlaxoSmithKline, AstraZeneca, Merck, Sepracor, Schering Plough, Pfizer, Palo Alto Medical Foundation Research Institute, Novartis, Bohringer Ingelheim, Vanguard Health Care, Kaiser Permanante

Participants Country: USA

Setting: Primary care

Conditions/numbers: 408 asthma patients (asthma poorly controlled at baseline) (204 SDM interven-

tion, 204 usual care)

Multi-morbidity: n/a

Health literacy: n/a

Interventions Theoretical framework: n/a

Focus: both patient and clinician

Type of intervention: Information + shared decision-making + follow-up phone calls + staff training

Clinicians involved: Care managers (usual)

Tools: Better Outcomes of Asthma Treatment (BOAT). Scripts were provided for use by specially trained care managers, together with visual aids and worksheets for participants. These were based on a shared decision-making process, involving stage-setting, gathering information from the participant (symptoms, perceptions of control, medication use, alternative treatments, environmental triggers, participant's goals and preferences), providing information (current understanding of asthma, review information and comprehension), negotiation (summarising goals and preferences, discussing options, negotiating decisions), wrapping-up (prescribe, give action plan, teach inhaler technique, give asthma diary), and 3 follow-up phone calls. At the end of session 1 a written asthma management and action plan was created, and potential barriers to medication adherence were elicited and addressed using motivational interviewing techniques. Care managers documented each encounter in the participant's chart, shared this with clinicians and discussed their recommendations.

Stages completed: Limited - A, B, C, F

Usual provider aware of patient's goals and action plans: yes

Standardisation of clinician input: Strong - training for care managers + scripts + supervised tape-recorded practice sessions with feedback + monthly conference calls + ongoing quality control - 10% of sessions audiotaped + participants' reports

Fidelity: Good. Adherence to protocol formally assessed as high (online supplement p. 16)

Attrition: 11% intervention, 7% usual care lost to follow-up

Comparison: usual care

Outcomes

Health status: physical: Asthma Therapy Assessment Questionnaire (ATAQ)*, lung function - FEV1; subjective: Juniper Mini Asthma Quality of Life questionnaire*

Self-management capabilities: n/a

Health behaviours: medication adherence

Achievement of personal goals: n/a

Service use: asthma health care utilisation*

Adverse events: none reported

Length of follow-up: baseline, 12 months



Wilson 2010 (Continued)

Notes

* Primary outcomes. Author contacted and supplied additional data. No power calculation reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computer-based adaptive randomisation algorithm was used (p. 567).
Allocation concealment (selection bias)	Low risk	Computer randomisation ensured concealment from staff. Randomisation was implemented by having a designated, non-blinded research staff member at the site enter the relevant participant descriptors into the randomisation module on the BOAT website, which immediately performed the randomisation, stored the result, and returned the participant's study assignment for implementation of the experimental assignment as indicated. All other study personnel, with the exception of the care managers, were blinded to participant's study assignment (online suppl. p. 3)
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	There was no intent that the participant's physicians be fully blinded to intervention assignment, nor obviously could the care manager be blinded to both the participation and study assignments of other participants, but they were not informed about this.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All study personnel apart from care managers were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data were not imputed: baseline and follow-up analyses were restricted to those participants with complete data for the analytic model variables at both time points (numbers on p. 570).
Selective reporting (reporting bias)	Unclear risk	No published protocol. All outcomes reported.
Other bias	Low risk	

Wolever 2010

Methods	Study design: RCT		
	Unit of randomisation: patient		
	Unit of analysis: patient		
	Funding sources: GlaxoSmithKline		
	Conflicting interests: none declared		
Participants	Country: USA		
	Setting: Community		
	Conditions/numbers: 56 diabetes patients (30 intervention, 26 control)		
	Multi-morbidity: n/a		
	Health literacy: n/a		



Wolever 2010 (Continued)

Interventions

Theoretical framework: n/a

Focus: patient

Type of intervention: Information + structured coaching (phone)

Clinicians involved: Health coaches (additional)

Tools: Integrative Health coaching. The intervention group received a binder of educational materials at the initial visit. An initial telephone call then offered participants 30-minute coaching sessions by telephone (8 weekly calls, 4 bi-weekly calls and 1 final call a month later). In the initial call participants were asked what was important to them in terms of diabetes care, how well they were managing their health, and what challenges they faced. The Wheel of Health (taking medicines as prescribed, stress reduction and self care, exercise, communication and relationships, nutrition, personal development) was used to guide the discussion. Priorities and goals were those of the participants. Goals were broken down into small, realistic action steps. Participants could select any goal for coaching support. Each participant received USD 75

Stages completed: Limited - A, B, C, F

Usual provider aware of patient's goals and action plans: not stated

Standardisation of clinician input: Strong - 2 experienced health coaches

Fidelity: not reported

Attrition: 7 withdrawals (12.5%), 3 coaching, 4 control

Comparison: usual care

Outcomes

Health status: physical: blood glucose (HbA1c); psychological: Perceived Stress Scale (PSS-4), subjective: Medical Outcomes Study short form (SF-12)

Self-management capabilities: Patient Activation Measure (PAM-13), Appraisal of Diabetes Scale (illness perception), Interpersonal Support Evaluation List (ISEL-12) (perceived social support), Benefit-Finding Scale (perceived benefits of the condition)

Health behaviours: Adherence - ASK-20, Morisky Adherence Scale, exercise frequency

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: baseline, 6 months

Notes

No primary outcome. No power calculation reported.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details given
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of participants and personnel (perfor- mance bias)	High risk	Participants and personnel not blinded and most outcomes are subjective. No primary outcome reported.



Wolever 2010 (Continued)

All outcomes				
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Pre-assessments and post-assessments were administered by blinded study staff but most outcomes are self-reported.		
Incomplete outcome data (attrition bias)	Low risk	Loss to follow-up - 3/30 (10%) in the intervention group and 4/26 (15%) in the control group. Reasons for withdrawal reported.		

All outcomes		out of groups received a market and reported.
Selective reporting (reporting bias)	Unclear risk	No published protocol, but results reported for all outcomes.
Other bias	Low risk	

Zoffmann 2006

Methods	Study design: RCT		
	Unit of randomisation: patient		
	Unit of analysis: patient		
	Funding sources: Danish Health Insurance Foundation; Novo Nordisk; Ely Lilly; Research Initiative in Aarhus; Danish Nurses' Organization; Aarhus University Hospital		
	Conflicting interests: not stated		
Participants	Country: Denmark		

Setting: Hospital outpatients

Conditions/numbers: 61 diabetes patients (type 1) (36 intervention, 25 control)

Multi-morbidity: n/a Health literacy: n/a

Interventions Theoretical framework: Prochaska's Stages of Change

Focus: patient

Type of intervention: Group visit + structured face-to-face coaching + staff training

Clinicians involved: Nurses (additional)

Tools: Guided Self-Determination (GSD) aimed at increasing patients' life skills. Participants received group training + semi-structured worksheets + follow-up appointments either individually or in a group. Participants were prompted to systematically explore and express their personal difficulties through words and drawings. Reflections are recorded on worksheets designed to increase patients' ability to express their views and prepare them for active participation in the care process. Groups of about 10 members met over 8 weeks for 2-hour sessions. A researcher introduced the sessions and worked together with GSD-trained nurses as coaches in smaller groups, supporting and challenging participants to develop their problem-solving skills. Participants set their own goals for future diabetes care. Three central worksheets comprising person-specific knowledge and agreements on strategies for problem-solving were saved in a folder in the participant's medical record for follow-up at outpatient appointments. Appointments between nurse and participant during 1-year follow-up were arranged either individually or on a group basis according to participant's preferences.

Stages completed: Extended - A, B, C, D, F



Zoffmann 2006 (Continued)

Usual provider aware of patient's goals and action plans: not stated

Standardisation of clinician input: Strong - 7 training lectures + supervision

Fidelity: participants' reports indicated that GSD-GT-initiated autonomy support had taken place as in-

tended (p. 84)

Attrition: 11 drop-outs (18%)

Comparison: usual care

Outcomes Health status: physical: HbA1c; subjective: Problem Areas in Diabetes (PAID-2)

Self-management capabilities: Treatment Self-Regulation Questionnaire (TSRQ), Perceived Compe-

tence in Diabetes scale (PCD),

Health behaviours: Self-Measured Blood Glucose (SMBG) frequency (NV)

Achievement of personal goals: n/a

Service use: n/a

Adverse events: none reported

Length of follow-up: baseline, 1 year

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation took place at the 2 diabetes clinics. Written assignments were placed in sealed opaque envelopes, numbered and stacked randomly (p. 80).
Allocation concealment (selection bias)	Unclear risk	If 2 participants were closely acquainted they were assigned to the same group. Can see why they did this but it means allocation was not completely concealed and not completely random (p. 80).
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	No blinding of participants and personnel possible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Rate of attrition reported and all outcome measures given.
Selective reporting (reporting bias)	Unclear risk	No published protocol. All outcome measures reported.
Other bias	Low risk	

NV: not validated



Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion	
Alamo 2002	Not collaborative - clinicians decide on care plan.	
Anderson 2005	Patient education only.	
Bieber 2006	Collaborative goal-setting element is insufficient. More akin to a decision aid trial.	
Brown 2005	Collaborative goal-setting element is insufficient, only self-management support.	
Chambers 2008	Intervention involves decision counselling and problem-solving without collaborative action-planning and goal-setting.	
Chin 2007	There is no action-planning and the way participants are involved is unclear.	
Coleman 2006	No collaboration. Patient information/education and personal health record only. Goal and plans restricted to medicines only.	
Cooper 2011	Intervention is aimed specifically at overcoming barriers without collaborative action-planning or goal-setting.	
Cooper 2013	Participants are involved, but not in action-planning or goal-setting process.	
Deen 2011	Intervention lacks collaborative care planning.	
Druss 2010	Educational intervention where participants are taught to create a care plan, rather than making one in collaboration.	
Eakin 2007	Goals predetermined and constrained - diet and exercise only.	
Estabrooks 2005	Initial goals are set using a computer programme, not in collaboration.	
Glasgow 2010	No real engagement between patient and professional.	
Halpern 2004	Goals and actions planned restricted to medication or psychotherapy.	
Hamann 2006	Intervention lacks collaborative goal-setting and action-planning.	
Harris 2009	Intervention lacks collaborative goal-setting and action-planning.	
Heisler 2013	Intervention lacks collaborative goal-setting and action-planning. Collaborative discussion with nurse is optional.	
Joosten 2011	No action-planning and predetermined limited goals only.	
Kilbourne 2013	Patient education only.	
Koelewijn-van Loon 2010	Most participants do not have long-term conditions.	
Lin 2006	Restricted options and most decisions made by nurse and other clinicians.	
Maindal 2011	Little evidence of collaborative planning.	
McKay 2002	Care planning is limited to dietary changes only.	



Study	Reason for exclusion			
Patja 2012	Little evidence of collaborative planning.			
Redfern 2010	Predetermined options and plans, Little opportunity for patients to influence.			
Richardson 2010	Little evidence of collaborative planning.			
Riley 2001	Goals predetermined and constrained - exercise, diet, smoking only.			
Ruggiero 2010	Patient education only. Goals based on provider recommendations.			
Ruland 2003	Not collaborative.			
Sciamanna 2011	Not collaborative.			
Simon 2002	Little evidence of collaborative goal setting or planning.			
Simon 2011	Little evidence of collaborative planning.			
Smeulders 2009	Patient education only.			
Smith 2008	Patient information only.			
Sobell 2000	Collaboration between patient and spouse, not clinician.			
Sol 2008	Action plans developed by nurse, not collaboratively.			
Street 2010	Focused on communication only, not action-planning/			
Stringer 2011	Goals determined by professional team.			
Van GestelTimmermans 2012	Patient education only.			
Vestala 2013	Participation in documentation only, no collaborative goal setting or action-planning.			
Von Korff 2003	Prescriptive. Very little collaboration involved.			
Walker 2005	Information only.			
Wennberg 2010	Not possible to isolate those patients with long-term conditions.			
Woltmann 2011	Very little collaboration involved - client and case manager complete electronic plans individually.			
Wright 2003	No evidence of collaborative goal setting or action-planning.			

Characteristics of ongoing studies [ordered by study ID]

Altiner 2012

Trial name or title	MultiCare AGENDA		
Methods	2-arm cluster-RCT		
Participants	Patients aged 65 - 84 with at least 3 chronic conditions		



Altiner 2012 (Continued)				
Interventions	Clinician-focused. Training for GPs in planned, structured collaborative consultations and narrative-based medicine			
Outcomes	EQ-5D, Health Care Empowerment questionnaire, medication use, Leipzig Supply and Cost			
Starting date	Not stated			
Contact information	in.schaefer@uke.de			
Notes	ISRCTN46272088			

Bachman-Mettler 2011

Trial name or title	Case management in oncology rehabilitation (CAMON)			
Methods	Multi-centre, 2-arm RCT			
Participants	Patients aged 18 and over with any type of cancer			
Interventions	Clinician-focused. Training for case managers (rehabilitation coaches) on how to provide self-management support, including goal-setting, action-planning and review			
Outcomes	FACT-G quality of life, activity restrictions, Jerusalem & Schwarzer questionnaire (self management and perceived self efficacy), PACIC-5A			
Starting date	May 2010			
Contact information	irene.bachmann@usz.ch			
Notes	ISRCTN41474586			

Battersby 2010

Trial name or title	Flinders Program		
Methods	Practice-based RCT		
Participants	Patients aged over 45 with COPD, CAD, cerebrovascular disease, chronic heart failure, diabetes, musculoskeletal disorders		
Interventions	Focused both on patients and clinicians. Set of tools to enable health workers and patients to collaboratively identify problems, set goals, and develop individual care plans covering self care, me ical, psychosocial and carer issues		
Outcomes	SF-12, Partners in Health scale, Stanford measures		
Starting date	Sept 2009		
Contact information	melanie.harris@flinders.edu.au		
Notes			



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Trial name or title	Collaborative Interventions for Circulation and Depression (COINCIDE)			
Methods	Pragmatic cluster-RCT			
Participants	Patients aged 18 and over with diabetes and/or coronary heart disease plus depression			
Interventions	Clinician-focused. Training + supervision in collaborative goal-setting and action-planning for psychological well-being practitioners			
Outcomes	EQ-5D, WHOQoL-BREF, Diabetes Quality of Life, Seattle Angina Questionnaire, Generalized Anxiety Disorder (GAD-7), Sheehan Disability Scale, Relationship Scales Questionnaire (RSQ), Stanford Self-Efficacy scale, Health Education Impact Questionnaire (heiQ), PACIC-5A, ENRICHD Social Support Instrument (ESSI), Patient Service Utilization Questionnaire			
Starting date	Not stated			
Contact information	peter.a.coventry@manchester.ac.uk			
Notes	ISRCTN80309252			

Reed 2011

Trial name or title	Flinders Program (2)			
Methods	RCT			
Participants	Patients aged 60 and over with 2 or more chronic conditions			
Interventions	Focused both on patients and clinicians. Set of tools to enable health workers and patients to collaboratively identify problems, set goals, and develop individual care plans covering self-care, medical, psychosocial and carer issues			
Outcomes	Stanford scales for fatigue, pain, health distress, energy, illness intrusiveness, PHQ-9, self efficacy, heiQ, Flinders scales, exercise, medication adherence, GP visits, ED visits, hospital admissions			
Starting date	Not stated			
Contact information	richard.reed@flinders.edu.au			
Notes				

Tylee 2012

Trial name or title	UPBEAT-UK		
Methods	Pilot RCT		
Participants	Patients aged 18 and over with CHD and depression		



Tylee 2012 (Continued)			
Interventions	Patient-focused. Case managers working with patients on a collaborative basis to develop a personalised care plan		
Outcomes	HADS depression sub-scale, PHQ-9, Modified Rose Angina questionnaire, specific activity schedule, Guy's hospital chest pain questionnaire, EQ-5D, SF-12, Warwick-Edinburgh Mental Well-Being scale, Brief Illness Perceptions Questionnaire, Psychlops, adapted Morisky adherence questionnaire, Client Service Receipt Inventory (CSRI)		
Starting date	2011		
Contact information	a.tylee@iop.kcl.ac.uk		
Notes	ISRCTN21615909		

Van der Voort 2011

Trial name or title	Collaborative Care			
Methods	2-arm cluster-RCT			
Participants	Patients aged 18 - 65 with bipolar disorder			
Interventions	Focused both on patients and clinicians. Formulation of Collaborative Care team including patient and family member or friend. All decisions to be shared; development of personalised care plan; psycho education; problem-solving treatment; mood-charting.			
Outcomes	Functioning Assessment Short Test (FAST-NL-P), Clinical Global Impression for Bipolar Disorder (CGI-BP), Brief Symptom Inventory, Quick Inventory for Depressive Symptoms (QIDS-SR), Altman Self Rating Mania Scale, Life Chart Method, WHOQoL-BREF, Sense of Mastery scale, costs - TiC-P.			
Starting date	Not stated			
Contact information	n.vandervoort@ggzingeest.nl			
Notes				

DATA AND ANALYSES

Comparison 1. Physical health (personalised care planning vs usual care)

Outcome or sub- group title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 HbA1c (change)	9	1916	Mean Difference (IV, Fixed, 95% CI)	-0.24 [-0.35, -0.14]
2 SBP (change)	6	1200	Mean Difference (IV, Fixed, 95% CI)	-2.64 [-4.47, -0.82]
3 DBP (change)	4	751	Mean Difference (IV, Fixed, 95% CI)	-0.71 [-2.26, 0.84]
4 Cholesterol (change)	5	1545	Std. Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.09, 0.11]



Outcome or sub- group title	No. of studies	No. of partici- pants	Statistical method	Effect size
5 BMI (change)	4	822	Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.35, 0.13]

Analysis 1.1. Comparison 1 Physical health (personalised care planning vs usual care), Outcome 1 HbA1c (change).

Study or subgroup	Perso	nalised care	c	ontrol	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
Glasgow 2005a	379	-0.2 (1.2)	354	-0.2 (1.1)	+	41.42%	-0.02[-0.19,0.15]
Zoffmann 2006	30	-0.6 (0.4)	20	-0.2 (0.4)		20.46%	-0.41[-0.65,-0.17]
Hiss 2007	81	-0.4 (1.4)	83	-0.2 (1.5)	+	5.73%	-0.2[-0.64,0.24]
Schillinger 2009	101	-0.6 (1.8)	103	-0.5 (1.8)		4.53%	-0.1[-0.6,0.4]
Wolever 2010	27	-0.4 (1.7)	22	0.1 (1.9)		1.09%	-0.5[-1.52,0.52]
Katon 2010a	99	-0.8 (1)	95	-0.2 (1)	→	13.46%	-0.56[-0.85,-0.27]
Frosch 2011	100	-0.5 (1.7)	101	-0.6 (1.8)	-	4.86%	0.1[-0.38,0.58]
Naik 2011	44	-0.8 (1.2)	41	-0.1 (1.2)		4.26%	-0.71[-1.23,-0.19]
Thom 2013	122	-1.1 (2)	114	-0.4 (2)		4.2%	-0.69[-1.21,-0.17]
Total ***	983		933		•	100%	-0.24[-0.35,-0.14]
Heterogeneity: Tau²=0; Chi²=22.	05, df=8(P=0)	; I ² =63.73%					
Test for overall effect: Z=4.48(P<	(0.0001)						

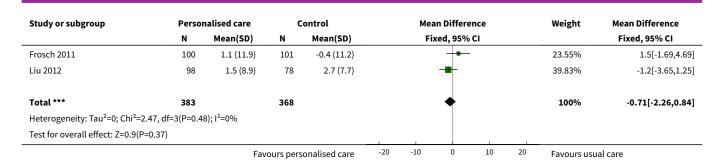
Analysis 1.2. Comparison 1 Physical health (personalised care planning vs usual care), Outcome 2 SBP (change).

Study or subgroup	Perso	nalised care	c	ontrol	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
Hiss 2007	79	-7.3 (21.3)	82	4.1 (19.9)		8.21%	-11.4[-17.78,-5.02]
Schillinger 2009	107	0 (19.1)	108	3.2 (19.1)	-+	12.85%	-3.2[-8.3,1.9]
Katon 2010a	105	-4.7 (13)	106	-1.3 (13)		27.29%	-3.4[-6.9,0.1]
Frosch 2011	100	1.5 (18.2)	101	0.5 (18.1)		13.25%	1[-4.02,6.02]
Liu 2012	98	1.5 (12)	78	5.2 (12.3)		25.38%	-3.72[-7.35,-0.09]
Thom 2013	122	1.4 (19.9)	114	-2 (19.9)	+	13%	3.4[-1.67,8.47]
Total ***	611		589		•	100%	-2.64[-4.47,-0.82]
Heterogeneity: Tau ² =0; Chi ² =1	15.28, df=5(P=0.	01); I ² =67.27%					
Test for overall effect: Z=2.84(P=0)						
Test for overall effect: Z=2.84(P=0)	Fav	ours pers	onalised care	-20 -10 0 10	20 Favours us	_ sı

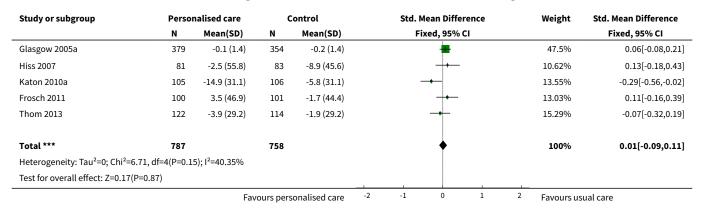
Analysis 1.3. Comparison 1 Physical health (personalised care planning vs usual care), Outcome 3 DBP (change).

Study or subgroup	Person	nalised care	ed care Control			Mean Difference				Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI					Fixed, 95% CI	
Hiss 2007	78	-1 (11.5)	81	0.7 (12.6)		-	+			17.08%	-1.61[-5.35,2.13]
Schillinger 2009	107	0.4 (13.1)	108	2 (13.1)			-+-			19.55%	-1.6[-5.1,1.9]
		Fav	Favours personalised care			-10	0	10	20	Favours usua	l care





Analysis 1.4. Comparison 1 Physical health (personalised care planning vs usual care), Outcome 4 Cholesterol (change).



Analysis 1.5. Comparison 1 Physical health (personalised care planning vs usual care), Outcome 5 BMI (change).

Study or subgroup	Person	alised care	c	ontrol	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
Frosch 2011	100	0.1 (7.8)	101	0.1 (7.5)		1.29%	0[-2.11,2.11]
Liu 2012	98	0.1 (1.1)	78	0.3 (1.3)	-	44.64%	-0.22[-0.58,0.14]
Schillinger 2009	104	0.4 (1.8)	105	0.3 (1.8)	-	23.06%	0.1[-0.4,0.6]
Thom 2013	122	-0.1 (1.7)	114	0 (1.7)	-	31.01%	-0.1[-0.53,0.33]
Total ***	424		398		•	100%	-0.11[-0.35,0.13]
Heterogeneity: Tau ² =0; Chi ² =	1.05, df=3(P=0.79	9); I ² =0%					
Test for overall effect: Z=0.87	(P=0.39)						
		Fav	ours pers	onalised care	-2 -1 0 1 2	Favours usu	ıal care

Comparison 2. Psychological health (personalised care planning vs usual care)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size	
1 Depression	5	599	Std. Mean Difference (IV, Fixed, 95% CI)	-0.36 [-0.52, -0.20]	



Analysis 2.1. Comparison 2 Psychological health (personalised care planning vs usual care), Outcome 1 Depression.

Study or subgroup	Persor	nalised care	c	ontrol	Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
Tsay 2004	25	-0.6 (0.9)	25	0 (0.9)		8.14%	-0.69[-1.27,-0.12]
Ludman 2007	20	-0.4 (0.6)	23	-0.5 (0.6)	+	7.42%	0.08[-0.52,0.68]
Katon 2010a	105	-0.9 (0.6)	106	-0.5 (0.6)	-	34.26%	-0.74[-1.01,-0.46]
Liu 2012	98	4.5 (5)	78	3.9 (5)	-	30.1%	0.11[-0.18,0.41]
Van der Wulp 2012	59	-2.5 (8.5)	60	1.6 (8.9)	-	20.08%	-0.47[-0.83,-0.1]
Total ***	307		292		•	100%	-0.36[-0.52,-0.2]
Heterogeneity: Tau ² =0; Chi ² =	20.4, df=4(P=0);	²=80.39%					
Test for overall effect: Z=4.34	(P<0.0001)						
		Fav	ours pers	onalised care	-2 -1 0 1 2	Favours us	sual care

Comparison 3. Subjective health status (personalised care planning vs usual care)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Generic health status (physical)	3	345	Std. Mean Difference (IV, Fixed, 95% CI)	0.16 [-0.05, 0.38]
2 Generic health status (mental)	3	345	Std. Mean Difference (IV, Fixed, 95% CI)	0.07 [-0.15, 0.28]
3 Condition-specific health status	4	1330	Std. Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.11, 0.10]

Analysis 3.1. Comparison 3 Subjective health status (personalised care planning vs usual care), Outcome 1 Generic health status (physical).

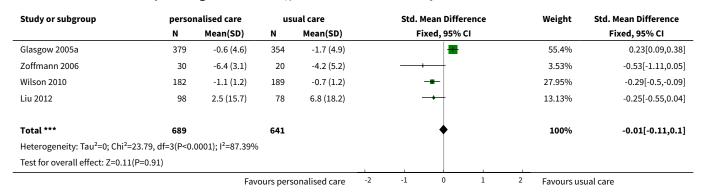
Study or subgroup	perso	personalised care		ual care	:	Std. Mea	an Difference		Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)		Fixe	d, 95% CI			Fixed, 95% CI
Shearer 2007	34	2.9 (10)	34	2.3 (9.3)		-	-		20.42%	0.06[-0.42,0.53]
Battersby 2007	49	2.5 (8.2)	22	-1.4 (8.2)			-		17.8%	0.47[-0.04,0.98]
Schillinger 2009	101	8.9 (24.5)	105	6.2 (24.5)			-		61.78%	0.11[-0.16,0.38]
Total ***	184		161				•		100%	0.16[-0.05,0.38]
Heterogeneity: Tau ² =0; Chi ² =	1.73, df=2(P=0.4	2); I ² =0%								
Test for overall effect: Z=1.49	(P=0.14)									
			Favo	urs usual care	-2	-1	0 1	2	Favours Pe	rsonalised care



Analysis 3.2. Comparison 3 Subjective health status (personalised care planning vs usual care), Outcome 2 Generic health status (mental).

Study or subgroup	perso	personalised care		usual care		Std. Mea	n Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)		Fixed	d, 95% CI		Fixed, 95% CI
Shearer 2007	34	4.4 (12.1)	34	3.8 (11.8)		-	+	20.4%	0.06[-0.42,0.53]
Battersby 2007	49	-1.9 (12.2)	22	1.7 (12.2)		_	•—	18.06%	-0.29[-0.79,0.22]
Schillinger 2009	101	9.8 (20.9)	105	6.1 (20.9)			-	61.55%	0.18[-0.1,0.45]
Total ***	184		161				•	100%	0.07[-0.15,0.28]
Heterogeneity: Tau ² =0; Chi ² =	2.51, df=2(P=0.2	9); I ² =20.32%							
Test for overall effect: Z=0.62	(P=0.53)								
			Favoi	urs usual care	-2	-1	0 1 2	Favours Pe	ersonalised Care

Analysis 3.3. Comparison 3 Subjective health status (personalised care planning vs usual care), Outcome 3 Condition-specific health status.



Comparison 4. Self-management capabilities (personalised care planning vs usual care)

Outcome or subgroup ti- tle	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Self efficacy	5	471	Std. Mean Difference (IV, Fixed, 95% CI)	0.25 [0.07, 0.43]

Analysis 4.1. Comparison 4 Self-management capabilities (personalised care planning vs usual care), Outcome 1 Self efficacy.

Study or subgroup	persor	nalised care	us	ual care	Std. Mean Difference	Weight	Std. Mean Difference
	N Mean(SD)		N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
Tsay 2004	25	6 (8.3)	25	-1.6 (8.3)		9.83%	0.91[0.33,1.49]
Zoffmann 2006	30	0.5 (2.8)	20	1.5 (5.3)		10.41%	-0.25[-0.81,0.32]
Naik 2011	42	-0 (1.9)	34	-0.2 (2.1)		16.41%	0.1[-0.35,0.56]
Van der Wulp 2012	59	5 (12.9)	60	3.1 (15)		25.96%	0.14[-0.22,0.5]
Liu 2012	98	0.2 (2)	78	-0.5 (2)	_ 	37.39%	0.36[0.06,0.65]
			Favo	urs usual care	-1 -0.5 0 0.5 1	Favours pe	ersonalised care

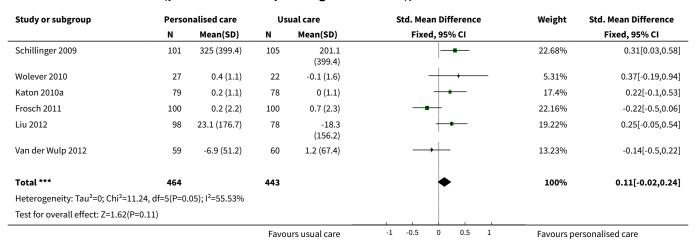


Study or subgroup	person	personalised care		usual care		Std. Mean Difference			Std. Mean Difference	
	N	Mean(SD)	N	Mean(SD)		Fixed,	95% CI		Fixed, 95% CI	
Total ***	254		217	_			•	100%	0.25[0.07,0.43]	
Heterogeneity: Tau ² =0; Chi ² =	9.09, df=4(P=0.06); I ² =56%								
Test for overall effect: Z=2.66	6(P=0.01)									
			Favou	ırs usual care	-1	-0.5	0 0.5 1	Favours ne	ersonalised care	

Comparison 5. Health-related behaviours (personalised care planning vs usual care)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size	
1 Exercise	6	907	Std. Mean Difference (IV, Fixed, 95% CI)	0.11 [-0.02, 0.24]	

Analysis 5.1. Comparison 5 Health-related behaviours (personalised care planning vs usual care), Outcome 1 Exercise.



Comparison 6. Self-care activities (personalised care planning vs usual care)

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Self care (days per week)	4	520	Std. Mean Difference (IV, Fixed, 95% CI)	0.35 [0.17, 0.52]



Analysis 6.1. Comparison 6 Self-care activities (personalised care planning vs usual care), Outcome 1 Self care (days per week).

Study or subgroup	Perso	Personalised care		ual care	Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
Zoffmann 2006	30	12 (15.2)	20	1.5 (18.4)		9.09%	0.62[0.04,1.2]
Shearer 2007	33	3.2 (2.3)	31	1 (2.9)		11.65%	0.83[0.32,1.34]
Schillinger 2009	101	0.7 (1.1)	105	0.1 (1.1)		39.48%	0.54[0.27,0.82]
Frosch 2011	100	0.4 (2.7)	100	0.5 (2.7)	-	39.78%	-0.05[-0.33,0.23]
Total ***	264		256		•	100%	0.35[0.17,0.52]
Heterogeneity: Tau ² =0; Chi ² =	:14.02, df=3(P=0)	; I ² =78.61%					
Test for overall effect: Z=3.92	(P<0.0001)						
			Favo	urs usual care	-1 -0.5 0 0.5 1	Favours pe	ersonalised are

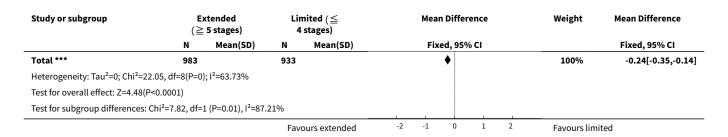
Comparison 7. Type of intervention (HbA1c) (extended vs limited)

Outcome or sub- group title	No. of studies No. of participants		Statistical method	Effect size		
1 HbA1c (change)	9	1916	Mean Difference (IV, Fixed, 95% CI)	-0.24 [-0.35, -0.14]		
1.1 Extended	3	408	Mean Difference (IV, Fixed, 95% CI)	-0.43 [-0.60, -0.26]		
1.2 Limited	6	1508	Mean Difference (IV, Fixed, 95% CI)	-0.12 [-0.26, 0.02]		

Analysis 7.1. Comparison 7 Type of intervention (HbA1c) (extended vs limited), Outcome 1 HbA1c (change).

Study or subgroup		Extended $(\geqq 5 \text{ stages})$		nited (\leqq stages)	Mean Difference	Weight	Mean Difference	
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI	
7.1.1 Extended								
Zoffmann 2006	30	-0.6 (0.4)	20	-0.2 (0.4)	-	20.46%	-0.41[-0.65,-0.17]	
Hiss 2007	81	-0.4 (1.4)	83	-0.2 (1.5)	-+	5.73%	-0.2[-0.64,0.24]	
Katon 2010a	99	-0.8 (1)	95	-0.2 (1)	-	13.46%	-0.56[-0.85,-0.27]	
Subtotal ***	210		198		◆	39.64%	-0.43[-0.6,-0.26]	
Heterogeneity: Tau ² =0; Chi ² =	1.83, df=2(P=0.4); I ² =0%						
Test for overall effect: Z=4.99((P<0.0001)							
7.1.2 Limited								
Glasgow 2005a	379	-0.2 (1.2)	354	-0.2 (1.1)	•	41.42%	-0.02[-0.19,0.15]	
Schillinger 2009	101	-0.6 (1.8)	103	-0.5 (1.8)		4.53%	-0.1[-0.6,0.4]	
Wolever 2010	27	-0.4 (1.7)	22	0.1 (1.9)		1.09%	-0.5[-1.52,0.52]	
Frosch 2011	100	-0.5 (1.7)	101	-0.6 (1.8)	-+-	4.86%	0.1[-0.38,0.58]	
Naik 2011	44	-0.8 (1.2)	41	-0.1 (1.2)		4.26%	-0.71[-1.23,-0.19]	
Thom 2013	122	-1.1 (2)	114	-0.4 (2)		4.2%	-0.69[-1.21,-0.17]	
Subtotal ***	773		735		•	60.36%	-0.12[-0.26,0.02]	
Heterogeneity: Tau ² =0; Chi ² =:	12.41, df=5(P=0.	03); I ² =59.7%						
Test for overall effect: Z=1.72	(P=0.09)							
			Favo	ours extended	-2 -1 0 1	2 Favours lim	ited	





Comparison 8. Type of intervention (HbA1c) (high intensity vs low intensity)

Outcome or sub- group title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 HbA1c (change)	9	1916	Mean Difference (IV, Fixed, 95% CI)	-0.24 [-0.35, -0.14]
1.1 High	5	847	Mean Difference (IV, Fixed, 95% CI)	-0.43 [-0.63, -0.24]
1.2 Low	4	1069	Mean Difference (IV, Fixed, 95% CI)	-0.17 [-0.29, -0.04]

Analysis 8.1. Comparison 8 Type of intervention (HbA1c) (high intensity vs low intensity), Outcome 1 HbA1c (change).

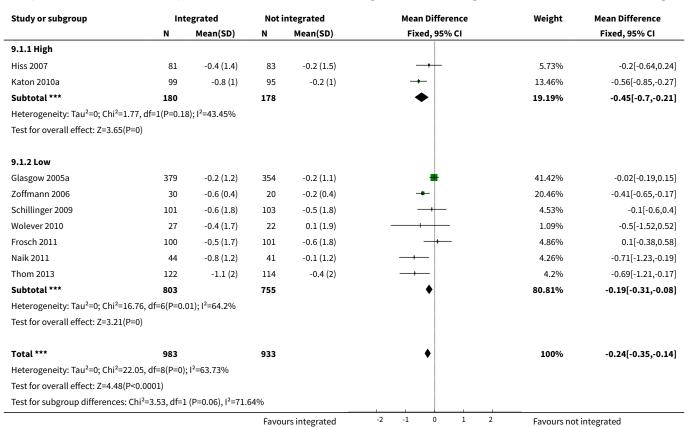
Study or subgroup	High	intensity	Low	intensity	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
8.1.1 High							
Hiss 2007	81	-0.4 (1.4)	83	-0.2 (1.5)	-+	5.73%	-0.2[-0.64,0.24]
Schillinger 2009	101	-0.6 (1.8)	103	-0.5 (1.8)		4.53%	-0.1[-0.6,0.4]
Katon 2010a	99	-0.8 (1)	95	-0.2 (1)	→	13.46%	-0.56[-0.85,-0.27]
Wolever 2010	27	-0.4 (1.7)	22	0.1 (1.9)		1.09%	-0.5[-1.52,0.52]
Thom 2013	122	-1.1 (2)	114	-0.4 (2)		4.2%	-0.69[-1.21,-0.17]
Subtotal ***	430		417		◆	29%	-0.43[-0.63,-0.24]
Heterogeneity: Tau ² =0; Chi ² =	4.45, df=4(P=0.3	5); I ² =10.2%					
Test for overall effect: Z=4.3(I	P<0.0001)						
8.1.2 Low							
Glasgow 2005a	379	-0.2 (1.2)	354	-0.2 (1.1)	+	41.42%	-0.02[-0.19,0.15]
Zoffmann 2006	30	-0.6 (0.4)	20	-0.2 (0.4)		20.46%	-0.41[-0.65,-0.17]
Naik 2011	44	-0.8 (1.2)	41	-0.1 (1.2)		4.26%	-0.71[-1.23,-0.19]
Frosch 2011	100	-0.5 (1.7)	101	-0.6 (1.8)	+	4.86%	0.1[-0.38,0.58]
Subtotal ***	553		516		♦	71%	-0.17[-0.29,-0.04]
Heterogeneity: Tau ² =0; Chi ² =	12.58, df=3(P=0.	01); I ² =76.15%					
Test for overall effect: Z=2.57	(P=0.01)						
Total ***	983		933		•	100%	-0.24[-0.35,-0.14]
Heterogeneity: Tau ² =0; Chi ² =	22.05, df=8(P=0)	; I ² =63.73%					
Test for overall effect: Z=4.48	(P<0.0001)						
Test for subgroup differences	s: Chi ² =5.02, df=1	L (P=0.03), I ² =80.	09%				
			Favours	high intensity	-2 -1 0 1 2	Favours low	, intensity



Comparison 9. Type of intervention (HbA1c) (integrated vs not integrated)

Outcome or sub- group title	No. of studies	No. of partici- pants	Statistical method	Effect size		
1 HbA1c (change)	9	1916	Mean Difference (IV, Fixed, 95% CI)	-0.24 [-0.35, -0.14]		
1.1 High	2	358	Mean Difference (IV, Fixed, 95% CI)	-0.45 [-0.70, -0.21]		
1.2 Low	7	1558	Mean Difference (IV, Fixed, 95% CI)	-0.19 [-0.31, -0.08]		

Analysis 9.1. Comparison 9 Type of intervention (HbA1c) (integrated vs not integrated), Outcome 1 HbA1c (change).



ADDITIONAL TABLES

Table 1. Included studies and interventions

Study ID	Study ID Type of Country study		Setting	Condi- tion(s)	No. of par- ticipants	Main focus of interven- tion	Clinicians involved (usual/additional)	Tools/techniques	
Battersby 2007	RCT	Australia	Primary care	Cardiac, respiratory, somatisation, aged care	1703	Both pa- tients and clinicians	Service co-ordinators (additional) and GPs (usual)	Problem & goals statements, care plan generator, face-to-face contact	
Frosch 2011	RCT	USA	Primary care	Diabetes	Diabetes 201 Patients Health coach (addition al)		Health coach (addition- al)	DVD + booklet, phone contact	
Glasgow 2005a	Cluster RCT	USA	Primary care	Diabetes	• • • • • • • • • • • • • • • • • • • •		CD-Rom care enhancement programme, phone contact		
Hart 1978	RCT	USA	Community clinic	Mental health	32	Patients	Clinician 'scaler' (addi- tional) and psychothera- pist (usual)	Behavioural monitoring process record, face-to-face contact	
Hiss 2007	RCT	USA	Primary care	Diabetes	197	Patients	Nurse care manager (additional) and primary care physician (usual)	Structured collaboration, face-to- face contact	
Katon 2010a	RCT	USA	Primary care	Depression + diabetes and/or CHD	214	Patients	Nurses (additional), pri- mary care physicians (usual)	DVD, booklet, self-monitoring devices, face-to-face contact	
Kennedy 2013	Cluster RCT	UK	Primary care	Diabetes, COPD, irrita- ble bowel	5599	Both pa- tients and clinicians	Nurses (usual), GPs (usual)	PRISMS tool, booklets, face-to- face contact	
Liu 2012	RCT	China	Primary care	Diabetes	208	Patients	Nurse (usual), GP (usual), preventive doctor (usual)	Group education + face-to-face contact	
Ludman 2007	RCT	USA	Primary care	Depression	52	Patients	Care manager (additional)	Computerised decision support, phone contact	
Naik 2011	RCT	USA	Primary care	Diabetes	87	Patients	Physicians (additional)	Group education + face-to-face contact	



Table 1. Included studies and interventions (Continued)

Schillinger 2009	RCT	USA	Primary care	Diabetes	226	Patients Care manager (additional)		Automated telephone + phone follow-up
Shearer 2007	RCT	USA	Hospital clinic	Heart failure	90	Patients	Nurses (additional)	Structured collaboration, face-to- face contact
Stanhope 2013	Cluster RCT	USA	Community clinic	Mental health	·		Structured collaboration, face-to- face contact	
Thom 2013	RCT	USA	Primary care	Diabetes	299	Patients	Peer coaches (additional)	Structured collaboration, face-to- face contact
Tsay 2004	RCT	Taiwan	Hospital clinic	End-stage renal dis- ease	50	Patients	Nurse (additional)	Information + structured collaboration, face-to-face contact
Van der Wulp 2012	RCT	Netherlands	Primary care	Diabetes	119	Patients	Peer coaches (additional)	Structured collaboration, face-to- face contact
Wilson 2010	RCT	USA	Primary care	Asthma	408	Both pa- tients and clinicians	Care managers (usual)	Information + structured collaboration, face-to-face contact
Wolever 2010	RCT	USA	Community clinic	Diabetes	56	Patients	Health coaches (addi- tional)	Information + Wheel of Health, face-to-face contact
Zoffmann 2006	RCT	Denmark	Hospital clinic	Diabetes	61	Patients	Nurses (additional)	Group visits + face-to-face contact

CHD: coronary heart disease; COPD: chronic obstructive pulmonary disease

Table 2. Care planning cycle: stages completed

	,							
Study ID	Intervention type	A. Prepara- tion	B. goal set- ting	C. Ac- tion-plan- ning	D. Docu- menting	E. Co-ordi- nating	F. Support- ing	G. Review- ing
Battersby 2007	Extended	Х	Х	Х	Х	X	Х	Х
Frosch 2011	Limited	,	X	Х			Х	

Table 2.	Care planning cycle: stages completed (Continued)	
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Glasgow 2005a	Limited		Χ	X	X		X	
Hart 1978	Limited		Х	Х	Х		Х	
Hiss 2007	Extended	Х	Х	Х		Х	Х	
Katon 2010a	Extended	Х	Х	Х	Х	Х	Х	Х
Kennedy 2013	Limited		Х	Х		Х	Х	
Liu 2012	Limited		Х	Х			Х	
Ludman 2007	Extended		Х	Х	Х	Х	Х	
Naik 2011	Limited		Х	Х			Х	X
Schillinger 2009	Limited		Х	Х			Х	
Shearer 2007	Limited		Х	Х			Х	
Stanhope 2013	Limited		Х	Х	X		Х	
Thom 2013	Limited		Х	Х			Х	
Tsay 2004	Limited		Х	Х			Х	
Van der Wulp 2012	Limited		Х	Х			Х	
Wilson 2010	Limited		Х	Х			Х	
Wolever 2010	Limited	Х	Х	Х			Х	
Zoffmann 2006	Extended	Х	Х	Х	Х		Х	



Table 3. Degree of intensity and integration of the care planning intervention

Study ID	Duration of inter- vention	Number of contacts between	Intensity (1 or more	Usual care clinician	Usual-care clinician	Integra- tion (usu-
		clinician (care manager or	contacts per month for more than	involved in care-plan-	informed about pa- tient's	al clinician both
		peer coach) and participant	3 months = high)	ning inter- vention	goals and plans	involved and in- formed = high)
Battersby 2007	12 months	8 to 12	High	Yes	Yes	Yes
Frosch 2011	6 months	Up to 5	Low	No	No	No
Glasgow 2005a	6 months	2 to 4	Low	No	Yes	No
Hart 1978	3 months	3	Low	Yes	Yes	Yes
Hiss 2007	6 months	mean = 7	High	Yes	Yes	Yes
Katon 2010a	12 months	16 to 24	High	Yes	Yes	Yes
Kennedy 2013	12 months	Not reported	Low	Yes	Yes	Yes
Liu 2012	12 months	12	High	Yes	Yes	Yes
Ludman 2007	12 months	3 or more	Low	No	Yes	No
Naik 2011	3 months	4	Low	No	Yes	No
Schillinger 2009	9 months	39 or more	High	No	Yes	No
Shearer 2007	3 months	6	Low	No	No	No
Stanhope 2013	11 months	Not reported	Low	Yes	Yes	Yes
Thom 2013	6 months	14+	High	No	No	No
Tsay 2004	1 month	12	Low	No	No	No
Van der Wulp 2012	3 months	3+	High	No	No	No
Wilson 2010	9 months	4	Low	Yes	Yes	Yes
Wolever 2010	6 months	14	High	No	No	No
Zoffmann 2006	12 months	8+	Low	No	No	No

Table 4. Physical health

Study	Condition	No. of partici-	Timing of outcome	HbA1c	SBP	DBP	LDL-C	ВМІ	Other	Effects of interven- tion
		pants	measure- ment							as reported
Frosch 2011	Diabetes	201	6 months	Х	Х	Х	Х	Х		No significant effects
Glasgow 2005a	Diabetes	886	12 months	Х			Х			No significant effects
Hiss 2007	Diabetes	197	6 months	Х	Χ	Х	Х			HbA1c improved
										SBP improved
Katon 2010a	Depression	214	12 months	Х	Х		Х			HbA1c improved
	+									SBP improved
	dia- betes/CHD									LDL-C improved
Liu 2012	Diabetes	208	12 months		Х	Х		Х		SBP improved
Naik 2011	Diabetes	87	12 months	X				,		HbA1c improved
Schillinger 2009	Diabetes	226	12 months	Х	Х	Х		Х		No significant effects
Thom 2013	Diabetes	299	6 months	Х	Х		Х	Х		HbA1c improved
Wilson 2010	Asthma	408	12 months						FEV1,	FEV1 improved
									ATAQ	ATAQ improved
Wolever 2010	Diabetes	56	6 months	X						HbA1c improved
Zoffmann 2006	Diabetes	61	12 months	Х						HbA1c improved

ATAQ: Asthma Therapy Assessment Questionnaire; BMI: body mass index; DBP: diastolic blood pressure; FEV1: lung function; HbA1c: glycated haemoglobin; LDL-C: cholesterol; SBP: systolic blood pressure



Table 5. Psychological health

Study	Condition	No. of par- ticipants	Timing of outcome	Outcomes included	Outcomes not includ- ed	Results as reported
			measure- ment	in meta- analysis	in meta- analysis	
Glasgow 2005a	Diabetes	886	12 months	PHQ-9		No significant effects
Katon 2010a	Depression + diabetes/CHD	214	12 months	SCL-20	PGI	Depression improved
Liu 2012	Diabetes	208	12 months	PHQ-9		No significant effects
Ludman 2007	Depression	52	12 months	SCL-20	PGI, SCID	No significant effects
Tsay 2004	End-stage renal disease	50	6 weeks	Beck Depression		Depression improved
Van der Wulp 2012	Diabetes	119	6 months	CES-D		No significant effects
Wolever 2010	Diabetes	56	6 months		PSS-4, Ben- efit Finding	Stress improved Benefit finding improved

CES-D: Center for Epidemiologic Studies Depression scale; CHD: coronary heart disease; PGI: Patient Global rating for Improvement; PHQ-9: Patient Health Questionnaire; PSS-4: Perceived Stress Scale; SCID: Structured Clinical Interview for DSM-IV Depression; SCL-20: Symptom Checklist 20

Table 6.

Subjective health status		-					
Condition	No. of partic- ipants	Timing of out- come measurement	Generic health status	Other generic measures not included in meta-analysis	Condi- tion-specific health status	Results as reported	Cochra
							■ . <u>)</u> w

Study	Condition	No. of partic- ipants	Timing of out- come	Generic health status	Other generic mea- sures not	Condi- tion-specific	Results as reported
			measurement		included in meta- analysis	health status	
Battersby 2007	Various	1703 (124 in- cluded	12 months	SF-36 (PCS, MCS)	WSAS		No significant effects
		in meta- analysis)					
Glasgow 2005a	Diabetes	886	12 months			PAID-2	No significant effects
Katon 2010a	Depression +	214	12 months		WHODAS-2, Sheehan		Sheehan improved
	diabetes/CHD				disability scale, glob- al rating		Global rating improved
					score		
Kennedy 2013	Diabetes,	5599	12 months		Selected subscales		No significant effects
	COPD, IBS				of SF-36, EQ-5D		
Liu 2012	Diabetes	208	12 months			Stanford Ill-	Illness intrusiveness
						ness Intrusiveness	improved
Schillinger 2009	Diabetes	226	12 months	SF-12 (PCS, MCS)			No significant effects
Shearer 2007	Heart failure	90	3 months	SF-36 (PCS, MCS)			No significant effects
Wilson 2010	Asthma	408	12 months			AQLQ	AQLQ improved
Wolever 2010	Diabetes	56	6 months		SF-12 (single score)		No significant effects
Zoffmann 2006	Diabetes	61	12 months			PAID-2	No significant effects

AQLQ: Asthma Quality of Life Questionnaire; CHD: coronary heart disease; COPD: chronic obstructive pulmonary disease; EQ-5D: Euro-Qol; IBS: irritable bowel syndrome; PAID-2: Problem Areas in Diabetes scale; SF-36, SF-12 (PCS, MCS): Health survey (physical component score, mental component score);



Table 7. Self-management capabilities

Study	Condition	No. of par- ticipants	Timing of outcome	Self effica- cy	Other mea- sures not	Results as reported
			measure- ment		included in meta-analysis	
Frosch 2011	Diabetes	201	6 months		Michigan Dia- betes	No significant effects
					Knowledge	
Katon 2010a	Depression +	214	12 months		4 items from	2 PAM items
	diabetes/CHD				PAM-13	improved
Kennedy	Diabetes,	5599	12 months	Stanford	PEI	No significant effects
2013	COPD, IBS			self efficacy		
Liu 2012	Diabetes	208	12 months	Stanford		Self efficacy
				self efficacy		improved
Naik 2011	Diabetes	87	12 months	Stanford		Self efficacy
				self efficacy		improved
Shearer 2007	Heart failure	90	3 months		PKPCT	No significant effects
Tsay 2004	End-stage	50	6 weeks	SUPPH	Diabetes Em-	Self efficacy and
	Renal Disease				powerment Scale (DES)	empowerment improved
vt	D: 1 .		C 11	D: 1 -	Scale (DES)	N : :::
Van der Wulp 2012	Diabetes	119	6 months	Diabetes self efficacy		No significant effects
				Sell efficacy		_
Wolever 2010	Diabetes	56	6 months		ADS, ISEL-12, PAM-13	ISEL-12 and PAM-13
						improved
Zoffmann 2006	Diabetes	61	12 months	PCDS		PCDS improved

ADS: Appraisal of Diabetes Scale; CHD: coronary heart disease; CPOD: chronic obstructive pulmonary disease; IBS: irritable bowel syndrome; ISEL-12: Interpersonal Support Evaluation List; PAM-13: Patient Activation Measure; PCDS: Perceived Competence in Diabetes Scale; PEI: Patient Enablement Instrument; PKPCT: Power as Knowing Participation in Change Tool; SUPPH: Strategies Used by People to Promote Health

Cochrane

Table 8. Health behaviours

Study	Condition	No. of par- ticipants	Timing of outcome	Exercise	Diet	Medication ad- herence	Self-care activities	Results as reported
			measure- ment					
Frosch 2011	Diabetes	201	6 months	At least 30 mins, d/wk	General di- et,	Self report (SDSCA)	Blood glucose test- ing,	Exercise improved
				illiis, u/wk	d/wk		foot care (SDSCA days/wk)	
Katon 2010a	Depression +	214	12 months	At least 30 mins, d/wk	General di- et,	CMA pharmacy refill	Blood glucose test- ing	Self care improved
	dia- betes/CHD			IIIIIS, u/wk	d/wk		and BP monitoring (days/wk)*	
Liu 2012	Diabetes	208	12 months	Aerobic exer- cise	Specific questions,			Exercise improved
				mins/wk	no summary			
Schillinger 2009	Diabetes	226	12 months	Moderate activ- ity,			Self management	Exercise improved
				mins/wk			days/wk	Self care improved
Shearer 2007	Heart failure	90	3 months				Self management (SMHF - experience)	Self care improved
Stanhope 2013	Mental health	367	11 months			Clinician report		Medication adherence improved
Van der Wulp 2012	Diabetes	119	6 months	Specific activities, hrs/d (PASE)	Saturated fat intake (Fatlist)			No significant effects
Wilson 2010	Asthma	408	24 months			CMA pharmacy refill,		Medication adherence improved
						other adher- ence		
						measures		

Table 8. H	eattii benaviot	ITS (Continued	a)					
Wolever 2010	Diabetes	56	6 months	At least 15 mins, d/mth	Self report (Morisky), ASK-20		Medication adherence (ASK-20) improved	
Zoffmann 2006	Diabetes	61	12 months			Blood glucose test- ing (frequency)	No significant effects	

^{*} Excluded from meta-analysis because published data were incompletely reported ASK-20: Adherence barrier questionnaire; CHD: coronary heart disease; CMA: continuous medication acquisition; PASE: Physical Activity Scale for the Elderly; SMHF: Self-Management of Heart Failure



Table 9. Resource use and costs

Study	Condition	No. of partici- pants	Timing of outcome	Resource use	Results as reported
			measure- ment		
Battersby 2007	Various	1703*	12 months	Primary care, med- ications,	No reduction in service use, no cost savings
				hospital admissions	
Katon 2010a	Depression +	214	24 months	Health plan	0.335 additional QALYs for interven-
	diabetes/CHD			accounting records,	tion group and
				QALYs	lower outpatient costs
Wilson 2010	Asthma	408	12 months	Medications	Significant changes in medication use; no assessment of cost effectiveness

^{*} This figure includes 8 sub-regional studies, 4 of which used geographic controls and were not randomised. CHD: coronary heart disease; QALY: quality-adjusted life year

APPENDICES

Appendix 1. Search strategy

The cumulative search of electronic databases was as follows:

- Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library) (July 2013 Issue 7)
- Dissertations & Theses (Proquest) (1743 July 2013)
- Embase (Ovid) (1974 to July 2013)
- Medline & Medline In-process (Ovid) (1946 to July 2013)
- PsycINFO (Ovid) (1967 to July 2013)
- Clinicaltrials.gov (21st June 2013)

Search results

Database:	Interface:	Coverage:	Dates:	Hits:
Cochrane Central Register of Controlled Trials	Cochrane Library, Wiley		31/07/2013	2351
Dissertations & Theses	Proquest	1743 – present	31/07/2013	657
Embase	OvidSP	1974 - present	31/07/2013	6811
Medline & Medline In-process	OvidSP	1946 - present	31/07/2013	4806
PsycINFO	OvidSP	1967 - present	31/07/2013	1526
Final:				16151



(Continued)

Duplicates:	6273
Final total:	9878

CENTRAL:

- #1 (chronic*):ti,ab,kw (Word variations have been searched)
- #2 ((persistent or long* term or ongoing or degenerative) near/3 (disease* or ill* or condition* or insufficienc* or disorder*)):ti,ab,kw (Word variations have been searched)
- #3 ((longterm or long-term or "long term") next care):ti,ab,kw (Word variations have been searched)
- #4 MeSH descriptor: [Cardiovascular Diseases] explode all trees
- #5 "heart disease*" or "heart failure" or "myocardial ischemia" or "coronary disease" * or "coronary artery disease*" or "myocardial infarct*" or hypertension or "high blood pressure":ti,ab,kw (Word variations have been searched)
- #6 ("cardiovascular disease*" or cvd):ti,ab,kw (Word variations have been searched)
- #7 "sickle cell":ti,ab,kw (Word variations have been searched)
- #8 MeSH descriptor: [Lung Diseases, Obstructive] explode all trees
- #9 "obstructive lung disease*" or "obstructive pulmonary disease*" or copd or asthma or bronchitis:ti,ab,kw (Word variations have been searched)
- #10 emphysema:ti,ab,kw (Word variations have been searched)
- #11 "cystic fibrosis" or "respiratory distress":ti,ab,kw (Word variations have been searched)
- #12 MeSH descriptor: [Nervous System Diseases] explode all trees
- #13 (brain next (disease* or damage* or injur*)):ti,ab,kw (Word variations have been searched)
- #14 cerebrovascular or "brain isch?emia" or "cerebral infarc*" or "carotid artery disease*" or stroke or epilep* or seizure*:ti,ab,kw (Word variations have been searched)
- #15 neurodegenerative or Huntington* or Parkinson* or "amyotrophic lateral sclerosis" or "multiple sclerosis" or "motor neuron disease":ti,ab,kw (Word variations have been searched)
- #16 paralys* or quadriplegi* or tetraplegi* or paraplegi* or "locked-in syndrome":ti,ab,kw (Word variations have been searched)
- #17 ((communication or learning or consciousness or perceptual or speech or voice or vision or hearing or psychomotor) next disorder*):ti,ab,kw (Word variations have been searched)
- #18 "hearing loss" or "hearing aid*" or deaf* or blind* or stutter*:ti,ab,kw (Word variations have been searched)
- #19 "down* syndrome" or "cerebral palsy":ti,ab,kw (Word variations have been searched)
- #20 MeSH descriptor: [Gastrointestinal Diseases] explode all trees
- #21 gastroenter* or intestinal or bowel or colonic:ti,ab,kw (Word variations have been searched)
- #22 ((renal or kidney) next (failure* or insufficienc*)):ti,ab,kw (Word variations have been searched)
- #23 (diabetes or diabetic*):ti,ab,kw (Word variations have been searched)
- #24 MeSH descriptor: [Nutrition Disorders] explode all trees
- #25 underweight or malnutrition or malnourished or overweight or obes*:ti,ab,kw (Word variations have been searched)
- #26 arthritis or osteoarthritis or rheumati* or fibromyalgia:ti,ab,kw (Word variations have been searched)



#27 ((back or neck) adj pain):ti,ab,kw (Word variations have been searched)

#28 MeSH descriptor: [Thyroid Diseases] explode all trees

#29 thyroid:ti,ab,kw (Word variations have been searched)

#30 MeSH descriptor: [Hypersensitivity] explode all trees

#31 allerg* or hypersensitivit* or tierg* or intolerance or anaphyla*:ti,ab,kw (Word variations have been searched)

#32 MeSH descriptor: [Neoplasms] explode all trees

#33 cancer* or oncolog* or neoplasm* or carcinom* or tumo?r* or malignan* or leuk?emia:ti,ab,kw (Word variations have been searched)

#34 MeSH descriptor: [HIV Infections] explode all trees

#35 ("hiv infect*" or "hiv disease*"):ti,ab,kw (Word variations have been searched)

#36 MeSH descriptor: [Mental Disorders] explode all trees

#37 MeSH descriptor: [Behavioral Symptoms] explode all trees

#38 ((mental* or psychiatr* or psychological* or behavio*) next (ill* or disorder* or disease* or distress* or disab* or problem* or health* or patient* or treatment)):ti,ab,kw (Word variations have been searched)

#39 (psychosis or psychoses or psychotic* or paranoi* or schizo* or neurosis or neuroses or neurotic* or delusion* or depression or depressive or bipolar or mania or manic or obsessi* or compulsi* or panic or phobic or phobia or anorexia or bulimia or neurastheni* or dissociative or autis* or Asperger* or Tourette or dyslex* or affective or borderline or narcissis* or suicid* or self injur* or self harm or adhd):ti,ab,kw (Word variations have been searched)

#40 ((personality or mood or dysthymic or cognit* or anxiety or stress or eating or adjustment or reactive or somatoform or conversion or behavior or perception or psycho* or "impulse control" or development* or "attention deficit" or hyperactivity or conduct or "motor skills" or movement or tic or "substance related") next disorder*):ti,ab,kw (Word variations have been searched)

#41 (((substance or drug or alcohol) next abuse) or "substance use" or "illegal drug use" or addict* or alcoholism or (problem* near/1 drinking)):ti,ab,kw (Word variations have been searched)

#42 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41

#43 MeSH descriptor: [Patient Care Planning] this term only

#44 ((care or action or treatment) next plan*):ti,ab,kw (Word variations have been searched)

#45 MeSH descriptor: [Decision Making] this term only

#46 MeSH descriptor: [Choice Behavior] this term only

#47 (patient* near/7 (decision* or choice*)):ti,ab,kw (Word variations have been searched)

#48 (patient* near/3 (preference* or priorit* or value*)):ti,ab,kw (Word variations have been searched)

#49 MeSH descriptor: [Patient Preference] explode all trees

#50 (treatment next (option* or choice*)):ti,ab,kw (Word variations have been searched)

#51 MeSH descriptor: [Goals] explode all trees

#52 (goal* adj2 (set* or plan*)):ti,ab,kw (Word variations have been searched)

#53 MeSH descriptor: [Patient-Centered Care] explode all trees

#54 (patient next (cent*red or focus*ed or oriented)):ti,ab,kw (Word variations have been searched)

#55 MeSH descriptor: [Individualized Medicine] explode all trees

#56 (individualise? or individualize? or individualising or individualizing or personalise? or personalize? or personalising or personalizing or tailor or tailored or tailoring):ti,ab,kw (Word variations have been searched)



#57 #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56

#58 (patient* near/3 (participat* or involv*)):ti,ab,kw (Word variations have been searched)

#59 (negotiat* or agreement or concordan* or cooperat* or co-operat* or collaborat* or partnership):ti,ab,kw (Word variations have been searched)

#60 #58 or #59

#61 #57 and #60

#62 MeSH descriptor: [Patient Participation] explode all trees

#63 (patient* near/2 (empower* or activat*)):ti,ab,kw (Word variations have been searched)

#64 ((shared or joint or informed or collaborative) near/2 decision making):ti,ab,kw (Word variations have been searched)

#65 ((involv* or participat*) near/3 (choice* or decision*)):ti,ab,kw (Word variations have been searched)

#66 (decision next (aid* or support or tool*)):ti,ab,kw (Word variations have been searched)

#67 ("patient provider agreement*" or "decisional self efficacy" or "personal budget*" or "direct payment*" or "record access" or "patient held record*"):ti,ab,kw (Word variations have been searched)

#68 (("self management" or "self care") near/2 support*):ti,ab,kw (Word variations have been searched)

#69 #61 or #62 or #63 or #64 or #65 or #66 or #67 or #68

#70 #42 and #69

Dissertations & Theses:

(((all((chronic NEAR/3 (disease* OR ill* OR condition* OR insufficienc* OR disorder*))) OR all((longterm NEAR/3 (disease* OR ill* OR condition* OR insufficienc* OR disorder*))) OR all((long-term NEAR/3 (disease* OR ill* OR condition* OR insufficienc* OR disorder*))) OR all((persistent NEAR/3 (disease* OR ill* OR condition* OR insufficienc* OR disorder*))) OR all((ongoing NEAR/3 (disease* OR ill* OR condition* OR insufficienc* OR disorder*))) OR all((chronic NEAR/3 (disease* OR ill* OR condition* OR insufficienc* OR disorder*)))) OR All(cardiovascular disease* or heart disease* or heart failure or myocardial ischemia or coronary disease* or coronary artery disease* or myocardial infarction or hypertension or high blood pressure) OR All(obstructive lung disease* or obstructive pulmonary disease* or copd or asthma or bronchitis or emphysema or "cystic fibrosis" or respiratory distress) OR All(brain disease* or brain damage* or brain injur*) OR All(cerebrovascular or brain ischemia or cerebral infarction or carotid artery disease* or stroke or epilep* or seizure or Huntington* or Parkinson* or amyotrophic lateral sclerosis or multiple sclerosis or motor neuron disease or paralys* or quadriplegi* or tetraplegi* or paraplegi* or locked-in syndrome) OR All((disorder NEAR1 (communication or learning or consciousness or perceptual or speech or voice or vision or hearing or psychomotor))) OR All(hearing loss or hearing aid* or deaf* or blind* or stutter*) OR All(down* syndrome or cerebral palsy) OR All(gastroenter* or intestinal or bowel or colonic) OR All(gastroenter* or intestinal or bowel or colonic) OR All(diabetes or diabetic*) OR All(underweight or malnutrition or malnourished or overweight or obes*) OR All(arthritis or osteoarthritis or rheumati* or fibromyalgia or back pain or neck pain) OR All(thyroid*) OR All(hypersensitivit* or allerg* or intolerance or anaphyla*) OR All(cancer* or oncolog* or neoplasm* or carcinom* or tumo?r* or malignan* or leuk?emia) OR All(hiv infect* or hiv disease*) OR All("mental illness" OR "mentally ill" OR "mental disorder*" OR "mental disease* OR "mental distress" OR "mental disab*" OR "mentally disabled" OR "mental problem*" OR "mental health" OR "mental patient*" OR "mental treatment") OR All("psychiatric illness" OR "psychiatrically ill" OR "psychiatric disorder*" OR "psychiatric disease* OR "psychiatric distress" OR "psychiatric disab*" OR "psychiatric disabled" OR "psychiatric problem*" OR "psychiatric health" OR "psychiatric patient*" OR "psychiatric treatment") OR All(personality disorder* or mood disorder* or dysthymic disorder* or cognit* disorder* or anxiety disorder* or stress disorder* or eating disorder* or adjustment disorder* or reactive disorder* or somatoform disorder* conversion disorder* or behaviour* disorder* or perception disorder* or psycho* disorder* or impulse control disorder* or development* disorder* or attention deficit disorder* or hyperactivity disorder* or conduct disorder* or motor skills or movement disorder* $or\ tic\ disorder^*\ or\ substance\ related)\ OR\ All(psychosis\ or\ psychotic^*\ or\ paranoi^*\ or\ schizo^*\ or\ neuros\#s\ or\ neurotic^*\ or\ delusion^*\ or\ delusion^*\$ depression or depressive or bipolar or mania or manic or obsessi* or compulsi* or panic or phobic or phobia or anorexia or bulimia or neurastheni* or dissociative or autis* or Asperger* or Tourette or dyslex* or affective or borderline or narcissis* or suicid* or self injur* or self harm or adhd or psychoses) OR All(substance abuse or drug abuse or alcohol abuse or "substance use" or "illegal drug use" or addict* or alcoholism or problem drinking)) AND (((All((plan* NEAR/1 (care or action or treatment))) OR All((patient* NEAR/7 (decision* or choice*))) OR All((patient* NEAR/3 (preference* or priorit* or value*))) OR All((treatment NEAR/1 (option* or choice*))) OR All((goal* NEAR/2 (set* or plan*))) OR All((patient NEAR/1 (cent*red or focus*ed or oriented))) OR All(individuali#e? or individuali#ing



or personali#e? or personali#ing or tailor or tailored or tailoring)) AND (All((patient* NEAR/3 (participat* or involv*))) OR All(negotiat* or agreement or concordan* or cooperat* or co-operat* or collaborat* or partnership))) OR All((patient* NEAR/2 (empower* or activat*))) OR All((decision making NEAR/2 (shared or joint or informed or collaborative))) OR (All((involv* NEAR/3 (choice* or decision*)))) or All((participat* NEAR/3 (choice* or decision*)))) OR All((decision aid* or decision support or decision tool*) OR All(patient provider agreement* or decisional self efficacy or personal budget* or direct payment* or record access or patient held record*) OR All((support AND (self management or self care))))) AND (ti((random* OR placebo* OR double blind*)) OR ab((random* OR placebo* OR double blind*)))

Medline:

- 1. chronic*.mp.
- 2. ((persistent or long* term or ongoing or degenerative) adj3 (disease* or ill* or condition* or insufficienc* or disorder*)).tw.
- 3. long term care/
- 4. long* term care.tw.
- 5. exp cardiovascular diseases/
- 6. (heart disease* or heart failure or myocardial ischemia or coronary disease* or coronary artery disease* or myocardial infarction or hypertension or high blood pressure).tw.
- 7. sickle cell.mp.
- 8. exp lung diseases obstructive/
- 9. (obstructive lung disease* or obstructive pulmonary disease* or copd or asthma or bronchitis).tw.
- 10.exp emphysema/
- 11.exp pulmonary emphysema/
- 12.emphysema.tw.
- 13.(cystic fibrosis or respiratory distress),mp.
- 14.exp nervous system diseases/
- 15.(brain adj (disease* or damage* or injur*)).tw.
- 16. (cerebrovascular or brain ischemia or cerebral infarction or carotid artery disease* or stroke or epilep* or seizure*).tw.
- 17. (neurodegenerative or Huntingdon* or Parkinson* or amyotrophic lateral sclerosis or multiple sclerosis or motor neuron disease).tw.
- 18.(paralys* or quadriplegi* or tetraplegi* or paraplegi* or locked-in syndrome).tw.
- 19. ((communication or learning or consciousness or perpetual or speech or voice or vision or hearing or psychomotor) adj disorder*).tw.
- 20.(hearing loss or hearing aid* or deaf* or blind* or stutter*).tw.
- 21.down* syndrome.tw.
- 22.cerebral palsy.tw.
- 23.exp gastrointestinal diseases/
- 24. (gatroenter* or intestinal or bowel or colonic).tw.
- 25.renal insufficiency/
- 26.((renal or kidney) adj (failure* or insufficienc*)).tw.
- 27.diabetes mellitus/
- 28.(diabetes or diabetic*).tw.
- 29.exp nutrition disorders/
- 30.(underweight or malnutrition or malnourished or overweight or obes*).tw.
- 31.exp arthritis/
- 32.exp rheumatic diseases/
- 33.(arthritis or osteoarthritis or rheumati* or fibromyalgia).tw.
- 34.((back or neck) adj pain).tw.
- 35.exp thyroid diseases/
- 36.thyroid.tw.
- 37.exp hypersensitivity/
- 38.(hypersensitivit* or allerg* or intolerance or anaphyla*).mp.
- 39.exp neoplasms/
- 40.(cancer* or oncolog* or neoplasm* or carcinom* or tumo?r* or malignan* or leuk?emia).tw.
- 41.exp hiv infections/



- 42.(hiv infect* or hiv disease*).tw.
- 43.exp mental disorders/
- 44.exp behavioral symptoms/
- 45.((mental* or psychiatr* or psychological*) adj (ill* or disorder* or disease* or distress* or disab* or problem* or health* or patient* or treatment)).tw.
- 46.((personality or mood or dysthymic or cognit* or anxiety or stress or eating or adjustment or reactive or somatoform or conversion or behavior or perception or psycho* or impulse control or development* or attention deficit or hyperactivity or conduct or motor skills or movement or tic or substance related) adj disorder*).tw.
- 47. (psychos#s or psychotic* or paranoi* or schizo* or neuros#s or neurotic* or delusion* or depression or depressive or bipolar or mania or manic or obsessi* or compulsi* or panic or phobic or phobia or anorexia or bulimia or neurastheni* or dissociative or autis* or Asperger* or Tourette or dyslex* or affective or borderline or narcissis* or suicid* or self injur* or self harm or adhd).tw.
- 48.(((substance or drug or alcohol) adj abuse) or "substance use" or "illegal drug use" or addict* or alcoholism or (problem* adj1 drinking)).tw.
- 49.or/1-48
- 50.patient care planning/
- 51.((care or action or treatment) adj plan*).tw.
- 52.decision making/
- 53.choice behavior/
- 54.(patient* adj7 (decision* or choice*)).tw.
- 55.patient preference/
- 56.(patient* adj3 (preference* or priorit* or value*)).tw.
- 57.(treatment adj (option* or choice*)).tw.
- 58.goals/
- 59.(goal* adj2 (set* or plan*)).tw.
- 60.patient centered care/
- 61.(patient adj (cent*red or focus*ed or oriented)).tw.
- 62.individualised medicine/
- 63.(individuali#e? or individual#ing or personali#e? or personali#ing or tailor or tailored or tailoring).tw.
- 64.or/50-63
- 65.cooperative behavior/
- 66.(patient* adj3 (participat* or involv*)).tw.
- 67. (negotiat* or agreement or concordan* or cooperat* or co-operat* or collaborat* or partnership).tw.
- 68.or/65-67
- 69.64 and 68
- 70.patient participation/
- 71.(patient* adj2 (empower* or activat*)).tw.
- 72. ((shared or joint or informed or collaborative) adj2 decision making).tw.
- 73.((involv* or participat*) adj3 (choice* or decision*)).tw.
- 74.(decision adj (aid* or support or tool*)).tw.
- 75.patient provider agreement*.tw.
- 76.decisional self efficacy.tw.
- 77.(personal budget* or direct payment*).tw.
- 78. (record access or patient held record*).tw.
- 79.((self management or self care) adj2 support*).tw.
- 80.or/69-79
- 81.49 and 80
- 82.randomised controlled trial.pt.
- 83.controlled clinical trial.pt.
- 84.randomised.ab.
- 85.placebo.ab.
- 86.clinical trials as topic.sh.
- 87.randomly.ab.
- 88.trial.ti.



89.or/82-88 90.exp animals/ not humans.sh. 91.89 not 90 92.81 and 91

Embase:

1		
chronic.mp.Multimedia(41469)		
1193893		
2		
(persistent or long* term or ongoing or degenerative) adj3 (disease* or ill* or condition* or insufficienc* or disorder*)).tw.Multimeda(964)		
47182		
3		
long term care/Multimedia(791)		
86414		
4		
long* term care.tw.Multimedia(42583)		
16373		
5		
exp cardiovascular disease/Multimedia(1325)		
2892644		
6		
(heart disease* or heart failure or myocardial ischemia or coronary disease* or coronary artery disease* or myocardial infarction or hypertension or high blood pressure).tw.Multimedia(11507)		
822423		
7		
sickle cell.mp.Multimedia(745)		
28624		
8		
exp chronic obstructive lung disease/Multimedia(3138)		
68712		
9		
(obstructive lung disease* or obstructive pulmonary disease* or copd or asthma or bronchitis).tw.Multimedia(0)		
206623		
10		



lung emphysema/ or emphysema/Multimedia(4273)
26391
11
emphysema.tw.Multimedia(27099)
22105
12
(cystic fibrosis or respiratory distress).mp.Multimedia(14905)
117951
13
("degenerative disease/" and "exp cerebrovascular disease/").mp. [mp=title, abstract, subject headings, heading word, drug tradename, original title, device manufacturer, drug manufacturer, device trade name, keyword]Multimedia(1304)
0
14
(brain adj (disease* or damage* or injur*)).tw.Multimedia(69)
70039
15
(cerebrovascular or brain ischemia or cerebral infarction or carotid artery disease* or stroke or epilep* or seizure*).tw.Multimedia(13394)
417021
16
(neurodegenerative or Huntington* or Parkinson* or amyotrophic lateral sclerosis or multiple sclerosis or motor neuron disease).tw.Multimedia(1200)
216767
17
(paralys* or quadriplegi* or tetraplegi* or paraplegi* or locked-in syndrome).tw.Multimedia(1768)
63002
18
((communication or learning or consciousness or perceptual or speech or voice or vision or hearing or psychomotor) adj disorder*).tw.Multimedia(17946)
8558
19
(hearing loss or hearing aid* or deaf* or blind* or stutter*).tw.Multimedia(1599)
335955
20
down* syndrome.tw.Multimedia(32938)
20827



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21
cerebral palsy.tw.Multimedia(16626)
18883
22
exp gastrointestinal diseases/Multimedia(13895)
63741
23
(gastroenter* or intestinal or bowel or colonic).tw.Multimedia(2692)
432591
24
kidney failure/Multimedia(7815)
99730
25
((renal or kidney) adj (failure* or insufficienc*)).tw.Multimedia(12246)
121257
26
exp diabetes mellitus/Multimedia(181990)
567599
27
(diabetes or diabetic*).tw.Multimedia(5638)
535423
28
exp nutritional disorder/Multimedia(6911)
536110
29
(underweight or malnutrition or malnourished or overweight or obes*).tw.Multimedia(6437)
272692
30
exp arthritis/Multimedia(39318)
329119
31
(arthritis or osteoarthritis or rheumati* or fibromyalgia).tw.Multimedia(3378)
244558
32
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```
((back or neck) adj pain).tw.Multimedia(541500)
43381
33
exp thyroid disease/Multimedia(1618)
171643
34
thyroid.tw.Multimedia(1088)
160664
35
exp hypersensitivity/Multimedia(2033)
459735
36
(hypersensitivit* or allerg* or intolerance or anaphyla*).mp.Multimedia(1245)
415671
37
exp neoplasm/Multimedia(121)
3319359
38
(cancer* or oncolog* or neoplasm* or carcinom* or tumo?r* or malignan* or leuk?emia).tw.Multimedia(585)
2861707
39
exp Human immunodeficiency virus infection/Multimedia(3406)
296469
40
(hiv infect* or hiv disease*).tw.Multimedia(93687)
94757
41
exp mental disease/Multimedia(1043)
1504884
42
((mental* or psychiatr* or psychological*) adj (ill* or disorder* or disease* or distress* or disab* or problem* or health* or patient* or
treatment)).tw.Multimedia(13857)
218664
43
```



((personality or mood or dysthymic or cognit* or anxiety or stress or eating or adjustment or reactive or somatoform or conversion or behavior or perception or psycho* or impulse control or development* or attention deficit or hyperactivity or conduct or motor skills or movement or tic or substance related) adj disorder*).tw.Multimedia(25768)

146882

44

(psychos#s or psychotic* or paranoi* or schizo* or neuros#s or neurotic* or delusion* or depression or depressive or bipolar or mania or manic or obsessi* or compulsi* or panic or phobic or phobia or anorexia or bulimia or neurastheni* or dissociative or autis* or Asperger* or Tourette or dyslex* or affective or borderline or narcissis* or suicid* or self injur* or self harm or adhd).tw.Multimedia(99)

723209

45

(((substance or drug or alcohol) adj abuse) or "substance use" or "illegal drug use" or addict* or alcoholism or (problem* adj1 drinking)).tw.Multimedia(315)

142653

46

1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45Multimedia(108)

11136325

47

patient care planning/Multimedia(135)

26543

48

((care or action or treatment) adj plan*).tw.Multimedia(693)

61446

49

decision making/Multimedia(0)

133248

50

(patient* adj7 (decision* or choice*)).tw.Multimedia(0)

62144

51

patient preference/Multimedia(20)

3624

52

(patient* adj3 (preference* or priorit* or value*)).tw.Multimedia(0)

49062

53

(treatment adj (option* or choice*)).tw.Multimedia(89)



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73666
54
(goal* adj2 (set* or plan*)).tw.Multimedia(0)
5819
55
(patient adj (cent*red or focus*ed or oriented)).tw.Multimedia(50298)
12376
56
personalized medicine/Multimedia(12880)
6173
57
(individuali#e? or individuali#ing or personali#e? or personali#ing or tailor or tailored or tailoring).tw.Multimedia(7255)
99601
58
47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57Multimedia(3116)
488955
59
cooperation/Multimedia(13470)
28755
60
(patient* adj3 (participat* or involv*)).tw.Multimedia(219)
73668
61
(negotiat* or agreement or concordan* or cooperat* or co-operat* or collaborat* or partnership).tw.Multimedia(0)
478234
62
59 or 60 or 61Multimedia(0)
563462
63
58 and 62Multimedia(0)
31136
patient participation/Multimedia(0)
16290
```



```
65
(patient* adj2 (empower* or activat*)).tw.Multimedia(0)
7200
66
((shared or joint or informed or collaborative) adj2 decision making).tw.Multimedia(0)
67
((involv* or participat*) adj3 (choice* or decision*)).tw.Multimedia(0)
8984
68
(decision adj (aid* or support or tool*)).tw.Multimedia(0)
10090
69
patient provider agreement*.tw.Multimedia(0)
9
70
decisional self efficacy.tw.Multimedia(0)
8
71
(personal budget* or direct payment*).tw.Multimedia(0)
171
72
(record access or patient held record*).tw.Multimedia(0)
119
73
((self management or self care) adj2 support*).tw.Multimedia(0)
1035
74
or/63-73Multimedia(0)
72116
75
46 and 74Multimedia(0)
38039
76
```



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randomised controlled trial/Multimedia(0)
355130
77
controlled clinical trial/Multimedia(0)
403750
78
single blind procedure/ or double blind procedure/Multimedia(0)
136026
79
crossover procedure/Multimedia(0)
37988
80
random*.tw.Multimedia(0)
845821
81
placebo*.tw.Multimedia(0)
198596
82
((singl* or doubl*) adj (blind* or mask*)).tw.Multimedia(0)
161143
83
(crossover or cross over or factorial* or latin square).tw.Multimedia(0)
93133
84
(assign* or allocat* or volunteer*).tw.Multimedia(0)
481400
85
or/76-84Multimedia(0)
1484254
86
75 and 85Multimedia(0)
6811
```

PsycINFO:



1
chronic.mp.Multimedia(41469)
94544
2
((persistent or long* term or ongoing or degenerative) adj3 (disease* or ill* or condition* or insufficienc* or disorder*)).tw.Multimedia(964)
5920
3
long term care/Multimedia(791)
3027
4
long* term care.tw.Multimedia(42583)
4722
5
exp Cardiovascular Disorders/Multimedia(1325)
39516
6
(heart disease* or heart failure or myocardial ischemia or coronary disease* or coronary artery disease* or myocardial infarction or hypertension or high blood pressure).tw.Multimedia(11507)
21137
7
sickle cell.mp.Multimedia(745)
982
8
exp chronic obstructive pulmonary disease/Multimedia(3138)
673
9
(obstructive lung disease* or obstructive pulmonary disease* or copd or asthma or bronchitis).tw.Multimedia(4273)
6270
10
emphysema.tw.Multimedia(27099)
187
11
(cystic fibrosis or respiratory distress).mp.Multimedia(14905)



1534
12
exp nervous system disorders/Multimedia(1304)
192500
13
(brain adj (disease* or damage* or injur*)).tw.Multimedia(69)
25607
14
(cerebrovascular or brain ischemia or cerebral infarction or carotid artery disease* or stroke or epilep* or seizure*).tw.Multimedia(13394)
53354
15
(neurodegenerative or Huntington* or Parkinson* or amyotrophic lateral sclerosis or multiple sclerosis or motor neuron disease).tw.Multimedia(1200)
38227
16
(paralys* or quadriplegi* or tetraplegi* or paraplegi* or locked-in syndrome).tw.Multimedia(1768)
3518
17
((communication or learning or consciousness or perceptual or speech or voice or vision or hearing or psychomotor) adj disorder*).tw.Multimedia(17946)
5077
18
(hearing loss or hearing aid* or deaf* or blind* or stutter*).tw.Multimedia(1599)
54139
19
down* syndrome.tw.Multimedia(32938)
5746
20
cerebral palsy.tw.Multimedia(16626)
4063
21
exp Gastrointestinal Disorders/Multimedia(13895)
5340
22
(gastroenter* or intestinal or bowel or colonic).tw.Multimedia(2692)



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4580
23
kidney diseases/Multimedia(7815)
1325
24
((renal or kidney) adj (failure* or insufficienc*)).tw.Multimedia(12246)
954
25
diabetes mellitus/Multimedia(181990)
3480
26
(diabetes or diabetic*).tw.Multimedia(5638)
17556
27
(underweight or malnutrition or malnourished or overweight or obes*).mp.Multimedia(6911)
26822
28
exp arthritis/Multimedia(6437)
2959
29
(arthritis or osteoarthritis or rheumati* or fibromyalgia).tw.Multimedia(39318)
6754
30
((back or neck) adj pain).tw.Multimedia(3378)
4155
31
exp Thyroid Disorders/Multimedia(537836)
1083
32
thyroid.tw.Multimedia(1618)
3066
33
exp allergic disorders/Multimedia(1088)
722
```



34
(hypersensitivit* or allerg* or intolerance or anaphyla*).mp.Multimedia(2033)
6828
35
exp Neoplasms/Multimedia(1245)
31715
36
(cancer* or oncolog* or neoplasm* or carcinom* or tumo?r* or malignan* or leuk?emia).tw.Multimedia(121)
48707
37
exp HIV/Multimedia(585)
29689
38
(hiv infect* or hiv disease*).tw.Multimedia(3406)
11515
39
exp mental disorders/ or exp behavior disorders/Multimedia(100174)
508536
40
((mental* or psychiatr* or psychological*) adj (ill* or disorder* or disease* or distress* or disab* or problem* or health* or patient* or treatment)).tw.Multimedia(1043)
224025
41
((personality or mood or dysthymic or cognit* or anxiety or stress or eating or adjustment or reactive or somatoform or conversion or behavior or perception or psycho* or impulse control or development* or attention deficit or hyperactivity or conduct or motor skills or movement or tic or substance related) adj disorder*).tw.Multimedia(13857)
133493
42
(psychos#s or psychotic* or paranoi* or schizo* or neuros#s or neurotic* or delusion* or depression or depressive or bipolar or mania or manic or obsessi* or compulsi* or panic or phobic or phobia or anorexia or bulimia or neurastheni* or dissociative or autis* or Asperger* or Tourette or dyslex* or affective or borderline or narcissis* or suicid* or self injur* or self harm or adhd).tw.Multimedia(7953)
485242
43
$(((substance\ or\ drug\ or\ alcohol)\ adj\ abuse)\ or\ "substance\ use"\ or\ "illegal\ drug\ use"\ or\ addict^*\ or\ alcoholism\ or\ (problem^*\ adj1\ drinking)).tw.Multimedia(205)$
97963
44



1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43Multimedia(315)

1125312 45 exp treatment planning/Multimedia(108) 3766 46 ((care or action or treatment) adj plan*).tw.Multimedia(135) 10862 47 decision making/ or choice behavior/Multimedia(693) 54275 48 (patient* adj7 (decision* or choice*)).tw.Multimedia(0) 8370 49 Preferences/Multimedia(0) 13343 50 (patient* adj3 (preference* or priorit* or value*)).tw.Multimedia(20) 3968 51 (treatment adj (option* or choice*)).tw.Multimedia(0) 6524 52 goals/ or goal setting/Multimedia(89) 10517 53 (goal* adj2 (set* or plan*)).tw.Multimedia(0) 6892 54 (patient adj (cent*red or focus*ed or oriented)).tw.Multimedia(57) 2779 55 (individuali#e? or individuali#ing or personali#e? or personali#ing or tailor or tailored or tailoring).tw.Multimedia(0)



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25208
56
45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55Multimedia(0)
130577
57
client centered therapy/ or cooperation/Multimedia(0)
13168
58
(patient* adj3 (participat* or involv*)).tw.Multimedia(0)
8767
59
(negotiat* or agreement or concordan* or cooperat* or co-operat* or collaborat* or partnership).tw.Multimedia(0)
129514
60
57 or 58 or 59Multimedia(0)
140373
61
56 and 60Multimedia(0)
10549
62
client participation/Multimedia(0)
1229
63
(patient* adj2 (empower* or activat*)).tw.Multimedia(0)
1107
64
((shared or joint or informed or collaborative) adj2 decision making).tw.Multimedia(0)
1887
65
((involv* or participat*) adj3 (choice* or decision*)).tw.Multimedia(0)
7235
66
(decision adj (aid* or support or tool*)).tw.Multimedia(0)
2979
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67
patient provider agreement*.tw.Multimedia(0)
6
68
decisional self efficacy.tw.Multimedia(0)
5
69
(personal budget* or direct payment*).tw.Multimedia(0)
98
70
(record access or patient held record*).tw.Multimedia(0)
23
71
((self management or self care) adj2 support*).tw.Multimedia(0)
403
72
or/61-71Multimedia(0)
23163
73
44 and 72Multimedia(0)
7590
74
random*.ti,ab,hw,id.Multimedia(0)
117493
75
trial*.ti,ab,hw,id.Multimedia(0)
107701
76
controlled stud*.ti,ab,hw,id.Multimedia(0)
8451
77
placebo*.ti,ab,hw,id.Multimedia(0)
29001
78
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((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.Multimedia(0) 20444 79 (cross over or crossover or factorial* or latin square).ti,ab,hw,id.Multimedia(0) 19231 80 (assign* or allocat* or volunteer*).ti,ab,hw,id.Multimedia(0) 106789 81 treatment effectiveness evaluation/Multimedia(0) 14681 82 mental health program evaluation/Multimedia(0) 1823 83 exp experimental design/Multimedia(0) 45559 84 "2000".md.Multimedia(0) 24302 85 or/74-84Multimedia(0) 341836 86 73 and 85Multimedia(0) 1526

Trial registers:

Clinicaltrials.gov http://clinicaltrials.gov – 21st June 2013

Main search: De-duplicated results = 508

PCP search: results = 735

The following terms were used in the Advanced search – Intervention search box – 8 separate searches.

"personal care plan" OR "personal care planning" OR "personal treatment plan" OR "personal treatment planning"

("decision making" OR choice OR choices OR care) AND ("patient involvement" OR "patient participation" OR "patient empowerment")



"shared decision making" OR "informed decision making" OR "joint decision making" OR "collaborative decision making"

"patient provider agreement" OR "patient provider agreements" OR "decisional self efficacy" OR "personal budget" OR "direct payment" OR "direct payments" OR "record access" OR "patient held record" OR "patient held records"

("self management" OR "self care") AND support

("patient centered care" OR "patient centred care" OR "patient focused care" OR "patient oriented care") AND (participation OR involvement)

("individualised care" OR "individualized care" OR "individualised medicine" OR "individualized medicine" OR "tailored care" OR "personalized care" OR "personalised care") AND (participation OR involvement)

"decision aid" OR decision aids" OR "decision support" OR "decision tool" OR "decision tools" (This search string gives loads of results – you might want to exclude from the search)

WHO ICTRP http://apps.who.int/trialsearch/ - 21st June 2013

Main search: De-duplicated results = 106 PCP search: Deduplicated results = 104

"individualised care" OR "individualized care" OR "individualised medicine" OR "individualized medicine" OR "tailored care" OR "personalized care" OR "personalised care"

personal care plan OR personal care planning OR personal treatment plan OR personal treatment planning

shared decision making OR informed decision making OR "joint decision making" OR "collaborative decision making"

"patient provider agreement" OR "patient provider agreements" OR "decisional self efficacy" OR "personal budget" OR "direct payment" OR "direct payments" OR "record access" OR "patient held record" OR "patient held records"

"patient centered care" OR "patient centred care" OR "patient focused care" OR "patient oriented care"

self care support OR self management support

"decision aid" OR decision aids" OR "decision support" OR "decision tool" OR "decision tools"

WHAT'S NEW

Date	Event	Description
23 March 2015	Amended	minor correction to author affiliation

CONTRIBUTIONS OF AUTHORS

Angela Coulter conceived the review and drafted the protocol. Abi Eccles led the design of the search strategy and organised the consumer involvement. Sara Ryan, Abi Eccles and Angela Coulter selected studies for inclusion. Sara Ryan and Angela Coulter extracted the data. Rafael Perera led the statistical analysis. All authors contributed to the study design and analysis.

DECLARATIONS OF INTEREST

Angela Coulter: in addition to her part-time post at the University of Oxford, Angela acts as a paid consultant for the Informed Medical Decisions Foundation, a division of Healthwise, a global not-for-profit provider of health information.

Vikki Entwistle: none known

Abi Eccles: none known

Sara Ryan: none known

Sasha Shepperd: none known

Rafael Perera: none known



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· No sources of support supplied

External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Some ambiguity in our inclusion/exclusion criteria was noted in respect of one trial (Kennedy 2013). This was designed as a trial of personalised care planning and self-management support, but in the event participating clinicians did not change their practice which remained the same in both the intervention group and the usual care group (Kennedy 2014). We therefore included this study in the review, but excluded it from the meta-analysis on the grounds that it was not a fair test of personalised care planning. Future iterations of this review should explicitly state that studies will be excluded if there is evidence that no change in practice (and hence no personalised care planning) actually occurred.

We changed the method used for dealing with missing data from that outlined in the protocol because we needed to impute standard deviations of change in some cases. Also, we originally planned to use a random-effects meta-analysis, but in the event this was not appropriate because of the small number of studies, so we used fixed-effect instead.

There were too few studies to group outcomes according to length of follow-up period as originally intended, so we took the final measurement in each case. We pooled outcomes if we felt the measures used were comparable, rather than by any other criterion. We added additional subgroup analyses to explore key characteristics (intensity, integration) once we had seen what the complex interventions actually involved.

INDEX TERMS

Medical Subject Headings (MeSH)

*Patient Care Planning; Asthma [therapy]; Chronic Disease [*therapy]; Diabetes Mellitus [blood] [therapy]; Glycated Hemoglobin [analysis]; Health Status; Heart Failure [therapy]; Kidney Failure, Chronic [therapy]; Mental Disorders [therapy]; Patient Participation; Randomized Controlled Trials as Topic; Self Care

MeSH check words

Adult; Humans