III. Self-care of cardiovascular disease, diabetes and chronic respiratory disease

### **Abbreviations**

**AMSTAR** A measurement tool to assess the methodological quality of systematic reviews

BMI Body mass indexBP Blood pressure

CCTs Controlled clinical trials
CHD Coronary heart disease
CHF Chronic heart failure
CI Confidence interval

**COPD** Chronic obstructive pulmonary disease

**CV** Cardiovascular

CVD Cardiovascular diseaseDBP Diastolic blood pressureED Emergency Department

**EQ5D** EQ5D measure of quality of life

**ER** Emergency room

FEV1 Forced expiratory volume

**FVC** Forced vital capacity

**GDG** Guideline Development Group

**GP** General Practitioner

GRADE Grading quality of evidence and strength of

recommendations

HbA1c Glycosylated haemoglobinHCP Health care professionalHRQoL Health-related quality of life

**IHCAs** Interactive health communication applications

**IHD** Ischaemic heart disease

INR International normalised ratio

**IPD** Individual patient data

LMIC Low to middle income countries

**MD** Mean difference

**METS** Metabolic Equivalent of Tasks

MI Myocardial infarction

mmHg Millimetres of mercury

NCDs Non-communicable diseases

**NGOs** Non governmental organisations

**NIHR** National Institute for Health Research

NNT Number needed to treat

NS Non significant

O2 Oxygen

OR Odds ratio

**PMD** Pooled mean difference

**QoL** Quality of life

**RCT** Randomised controlled trial

**RR** Relative risk

SBP Systolic blood pressure

SE Standard error

 ${\bf SMBG} \qquad {\bf Self\text{-}monitoring \ of \ blood \ glucose}$ 

**SMD** Standardised mean difference

SMS Short messaging service

US United States

**WHO** World Health Organisation

WMD Weighted mean difference

## **Executive Summary**

"Self-care is the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a healthcare provider"

Current epidemiological evidence indicates four non-communicable diseases (NCDs) make the largest contribution to mortality in the majority of low and middle income countries (LMIC), namely: cardio-vascular disease, diabetes, cancer and chronic respiratory disease.

Self-care strategies include both self-care and self-management by the individual. Inherent in the concept is the recognition that whatever factors and processes may determine behaviour, and whether or not self-care is effective and interfaces appropriately with professional care, it is the individual person that acts (or does not act) to preserve health or respond to symptoms.

Self-care involves the entire body of health decisions that individuals make for themselves and their families to maintain physical and mental well-being. Self-care includes a variety of strategies such as staying fit and healthy, both physically and mentally, avoiding hazards such as smoking and improved management of long-term health conditions. To achieve these strategies, self-care also includes elements of self-monitoring, self-management and self-medication. In addition, self-care practices in many different societies represent a wide spectrum of options such as using body massage, religious and cultural rituals, and various ceremonies. Thus self-care also includes managing or minimising the way a chronic condition limits an individual's life.

There is growing recognition that all countries face problems with an ageing population and an increase in NCDs accounting for substantial morbidity and increased medical costs. Whilst self-care should not be used to replace the basic components of essential health care, it may offer an approach for countries to optimize management of NCDs and aid well-being. Although self-care interventions have been integrated into various disease management programs, the evidence on the effectiveness of various interventions and the mode of their implementation have not been synthesized. This guideline provides evidence based recommendations in relation to major noncommunicable diseases as highlighted in the NCD Global Action Plan endorsed by the World Health Assembly in 2008. Determining which self-care strategies are underpinned by evidence of effectiveness and gaining an understanding of the barriers to implementation will aid effective delivery of health care for NCDs.

Guidance on self-care interventions aimed at four shared risk factors – tobacco use, physical inactivity, unhealthy diets and the harmful use of alcohol are addressed in the 2008-2013 action plan for the global strategy for the prevention and control of non-communicable diseases.

To capture the various components of self-care interventions and various modes of their delivery, the Guideline Development Group (GDG) identified nine questions for the development of the self-care in NCDs recommendations. A search strategy was used to initially retrieve evidence of effectiveness from systematic reviews relevant to self-care and NCDs, and each eligible review was rated using the AMSTAR tool.. For all systematic reviews that were included, we searched for clinical trials that were specifically undertaken in LMIC.

We used the GRADE approach for assessing the quality of evidence and deciding the strength of the recommendations. The quality of the evidence presented in the reviews for critical and important outcomes was graded as: high, moderate, low or very low. The strength of a recommendation (strong, weak) takes into account the overall quality of the evidence and the uncertainly about the target population's values and preferences. It reflects the degree of confidence that the benefits outweigh the harms and and the degree to which the intervention has been tested and/or is relevant to LMIC settings in terms of feasibility and resource implications.

Many of the self-care interventions in NCDs identified in the 9 questions are enthusiastically advocated, applied and supported by policy makers, health workers, the educational system and nongovernmental organizations. Many have wide appeal to the general public and patients themselves, and will continue to be applied or demanded. However, very few of those interventions are based on high or moderate quality evidence of their effectiveness, thus strong recommendations in their favour was judged to be inappropriate. On the other hand, there is similar lack of high or moderate quality evidence of no effectiveness, accompanied by considerable uncertainty over harms outweighing benefits. Thus strong recommendations against their use were also felt to be inappropriate, given their popularity and intuitive appeal. This guideline could help re-prioritize on-going self-care interventions, favouring those with a stronger evidence base. It will hopefully spur research activities to provide more evidence on key questions.

Currently there remains the need to identify pragmatic, low cost, feasible interventions underpinned by high quality evidence, particularly in LMIC settings. There is also a requirement to identify the most cost effective and effective individual components and combinations of interventions for self-care in these settings. The guideline gives some recommendations on future research.

## Questions

# 1. In patients with non-communicable diseases do self-care strategies targeted at the community and/or support networks rather than the individual improve outcomes?

Definition: Self-care strategies for NCDs targeted at the community are designed to be delivered beyond health care institutions either by the health care system or by the local community through its members, trained or untrained, paid or unpaid. Self-care interventions delivered through community action can be complementary to conventional health care or stand-alone programmes.

# 2. In patients with non-communicable diseases do lay led self-management patient programmes improve outcomes?

Definition: Lay led self-management education programmes are highly structured programmes for people with NCDs which are primarily educational, and address self-care of the disease with the majority of course content delivered by lay individuals.

## 3. In patients with non-communicable diseases do online resources for self-care improve outcomes?

Definition: Online resources for self-care include: health information, interactive health communication applications (web based information packages that can combine health information with at least one component of support, decision support or behaviour change support).

## 4. In patients with non-communicable diseases do self-monitoring devices improve outcomes?

Definition: On-going management of NCDs often involves monitoring of a biochemical or physical measure (e.g. blood pressure, blood glucose, peak flow). Whilst these measures can be undertaken in the clinic setting they may be self-monitored in the home setting by the patient or within the community and the results communicated to a health professional for on-going management.

# 5. In patients with non-communicable diseases do mobile telephone and/or telemonitoring interventions targeted at self-care improve outcomes?

Definition: Telemonitoring involves remotely monitoring patients who are not in the same location as the health care provider. Monitoring devices will transmit information on symptoms and/or vital signs via the telephone to a remote monitoring service provider and/or to their health care provider. Telemedicine is a broader concept that includes patient consultations using telecommunications.

# 6. In patients with non-communicable diseases do self-treatment interventions improve outcomes?

Definition: Self-treatment intervention includes self-monitoring and adjustment of dosage of medicines by the individual based on a prespecified action plan agreed jointly by a health care practitioner / worker and the patient. A situation can occur in NCD management in which the patient could or will alter the doses and/or frequency of the treatment depending upon the change in the nature, severity of symptoms and/or biochemical markers of a disease under the guidance of a professional health care provider (e.g. physician) with treatment recommendation.

## 7. In patients with non-communicable diseases do self-care education/information programmes improve outcomes?

Definition: Education is the process of receiving or giving systematic instruction about a specific aspect of disease whilst information is the knowledge communicated about a particular aspect of a disease.

## 8. In patients with non-communicable diseases do self-care rehabilitation programmes improve outcomes?

Definition: Rehabilitation therapy aims to improve function that has been lost or diminished by disease. Rehabilitation programmes may incorporate exercise and/or information after an event such as a myocardial infarction.

# 9. In patients with non-communicable diseases do interventions targeted at adherence improve outcomes?

Definition: Patient adherence has been defined as the extent to which a person's behaviour - taking medication, following a diet, and/or executing lifestyle changes - corresponds with agreed recommendations from a health care provider.

No.	Recommendation	Strength of recommendation	Quality of evidence
	1. In patients with non-communicable diseases do self-care strategies targeted at the community and/or support networks rather than the individual improve outcomes?		
1.1	Community interventions can complement primary health care. Structured training for community workers should be undertaken to aid the detection and on-going management for NCDs.	Weak	Very low
R1	Research is needed to identify pragmatic community based interventions Community programmes should be evaluated for their coverage, generalise		
	In patients with non-communicable diseases do lay led self-management patient programmes improve outcomes?		
2.1	The use of highly structured lay led self-management patient programmes for self-care in NCDs is not recommended at the present time for LMIC.	Weak	Very low
R2	Research is needed to evaluate lay led self-management programmes in lactive components of such programmes and their feasibility in low resour		ntification of the
	3. In patients with non-communicable diseases do online resources for self-care improve outcomes?		
3.1	Health care organisations should provide access to user-friendly, valid and reliable online information targeted at NCDs and their management. Online resources could provide some benefit.	Weak	Very low
R3 Research is needed to evaluate interactive health care web resources, particularly in LMI0		rticularly in LMIC set	tings.
	4. In patients with non-communicable diseases do self-monitoring devices improve outcomes?		
4.1	Self-measurement to monitor blood pressure is recommended for the management of hypertension in appropriate patients where the affordability of the technology has been established.	Strong	Low
4.2	Self-monitoring of blood coagulation is recommended for appropriate patients treated with oral anticoagulation agents, where the affordability of the technology has been established.	Weak	Moderate
4.3	The use of self-monitoring of blood glucose in the management of patients with type 2 diabetes not on insulin is not recommended at the present time because there is insufficient evidence to support such a recommendation.	Weak	Moderate
4.4	People with type 1 and type 2 diabetes on insulin should be offered self-monitoring of blood glucose based on individual clinical need.	Weak	Low
R4	Research is needed to evaluate the impact of self-monitoring, including as LMIC.	ssessment of the cos	t-effectiveness in
	5. In patients with non-communicable diseases do mobile telephone and/or telemonitoring interventions targeted at self-care improve outcomes?		
5.1	The use of telemonitoring for self-care in NCDs is not recommended at the present time, because there is insufficient evidence to support such a recommendation.	Weak	Low

No.	Recommendation	Strength of recommendation	Quality of evidence
5.2	The use telehealth for self-care in NCDs is not recommended at the present time, because there is insufficient evidence to support such a recommendation.	Weak	Low
R5	Research is needed to evaluate telemonitoring and telehealth in LMIC, ide components of such programmes and their feasibility in low resource sett		n of the active
	6. In patients with non-communicable diseases do self-treatment interventions improve outcomes?		
6.1	Self-monitoring of blood coagulation and self-adjustment of dosage in patients receiving oral anticoagulation agents is recommended if affordable and according to an agreed action plan with a health professional.	Weak	Moderate
6.2	Self-monitoring in asthma and COPD and self-adjustment of dosage is recommended according to an agreed action plan with a health professional.	Weak	Very low
6.3	Self-adjustment of diuretics based on body weight monitoring in heart failure is not recommended at the present time.	Weak	Very low
6.4	Self-monitoring and self-adjustment of insulin dosage is recommended in type 1 diabetes according to an agreed action plan with a health professional.	Weak	Very low
R6	Research is needed to establish a consistent evidence base upon which v self-monitoring and self-adjustment of treatments, particularly in LMIC. To benefits, outcomes, cost and quality of life and also acceptability and potentials.	he research should e	
	7. In patients with non-communicable diseases do self-care education/information programmes improve outcomes?		
7.1	Group education programmes, rather than individual education may offer a cost effective strategy to deliver education in LMIC.	Weak	Very low
	8. In patients with non-communicable diseases do self-care rehabilitation programmes improve outcomes?		
8.1	Appropriate patients could benefit from being educated on the benefits of cardiac rehabilitation, and can be encouraged to undertake rehabilitation exercise in the home setting.	Weak	Very low
8.2	Appropriate patients could benefit from being educated on the benefits of COPD rehabilitation , and encouraged to undertake rehabilitation exercise.	Weak	Very low
R7	Research is needed to evaluate the effectiveness of rehabilitation program NCDs, particularly in LMIC.	nmes in the home or	community across
	9. In patients with non-communicable diseases do interventions targeted at adherence improve outcomes?		
9.A	Strategies to improve adherence should form part of self-care for NCDs. Promotion of self-care in NCDs should take into account patients' beliefs and concerns about medicines, and their effects on adherence.	Strong	Very low
9.1	No single strategy to improve overall adherence is recommended over another.	Weak	Very low
R8	Research is needed on interventions to improve adherence, particularly in	LMIC.	

### Introduction

Current epidemiological evidence indicates four non-communicable diseases (NCDs) make the largest contribution to mortality in the majority of low and middle income countries (LMIC), namely: cardio-vascular disease, diabetes, cancer and chronic respiratory disease.<sup>1</sup>

There is growing recognition that all countries face the problem of an ageing population and an increase in NCDs accounting for substantial morbidity and increased medical costs.<sup>2</sup> Although self-care should not be used to replace the basic components of essential health care it may offer an approach for countries to optimize management of NCDs and aid well-being. Self-care implementation strategies should reflect the complexity and co-existence of NCDs, aim to avoid vertical programmes and focus on an integrated health care strategy. Self-care should reflect the diversity of health care systems, their context and be sensitive to the resources available. Although self-care interventions have been integrated into various disease management programs, the evidence on the effectiveness of various interventions and the mode of their implementation have not been synthesized. The NCD Global Action Plan endorsed by the World Health Assembly in 20081 highlighted the need for a guideline on self-care that provides evidence based recommendations in relation to major noncommunicable diseases.

Determining which self-care strategies are underpinned by evidence of effectiveness and gaining an understanding of the barriers to implementation will aid effective delivery of health care for NCDs.

"Self-care is the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a health-care provider."<sup>3</sup>

Self-care strategies therefore include both self-care and self-management by the individual. Inherent in the concept is the recognition that whatever factors and processes may determine behavior, and whether or not self-care is effective and interfaces appropriately with

<sup>1</sup> World Health Organization. 2008-2013 Action plan for the global strategy for the prevention and control of noncommunicable diseases. http://www.who.int/nmh/publications/9789241597418/en/

<sup>2</sup> World Health Organization, *Global status report on noncommunicable diseases*," World Health Organization, Geneva, Switzerland, 2010.

<sup>3</sup> World Health Organisation. 2009. "Self-care in the Context of Primary Health Care". Report of the Regional Consultation, Bangkok, Thailand.

professional care, it is the individual person that acts (or does not act) to preserve health or respond to symptoms.<sup>4</sup>

Self-care involves all health decisions that individuals make for themselves and their families to maintain physical and mental well-being. Self-care strategies include a variety of strategies such as staying fit and healthy, both physically and mentally, avoiding hazards such as smoking and improved management of long-term health conditions. To achieve these strategies, self-care also includes elements of self-monitoring, self-management and self-medication.

Self-care practices in many different societies may represent a wide spectrum of options such as using body massage, religious and cultural rituals. Thus self-care also includes managing or minimising the way a chronic condition limits an individual's life in their own social-cultural context.

A broader framework for self-care emphasizes the behavioural and cognitive dimensions. This would then encompass an individual's behaviour towards symptom recognition and evaluation, and decisions to treat by a selection of self-determined actions or to seek appropriate advice regarding subsequent management decisions.

The target audience for this guideline are health care policy makers and health workers, but it will also be useful to researchers and relevant non-governmental organizations.

The update of the guideline is planned in 5-7 years. Given the number of different interventions and critical/important outcomes, it is unlikely that the evidence base of high or moderate quality will increase earlier,

The guideline was funded by WHO funds. No funds from commercial sources were used.

Within WHO activities on improving the management of chronic NCDs at the primary care, regional and country level will be conducted. Workshops will be held to adapt the guideline to local priorities and assist its implementation.

<sup>4</sup> Dean K, Kickbusch I (1995). "Health related behaviour in health promotion: utilizing the concept of self care". *Health Promotion International*, 10(1), 35-40.

### **Methods**

### **Databases searched (only English language)**

CDSR - Cochrane Database of Systematic Reviews (Cochrane reviews) (up to March 2013)

DARE - Database of Abstracts of Reviews of Effects (other reviews) (up to march 2013)

CENTRAL - Cochrane Central Register of Controlled Trials (clinical trials) (up to March 2013)

MEDLINE - Medical Literature Analysis and Retrieval System Online (from 2001 to March 2013)

EMBASE - Biomedical and pharmacological database (from 2001 to March 2013)

### The evidence

The five levels of the review process are summarised in Figure 1.

Titles and abstracts of retrieved citations were screened by one reviewer against the inclusion criteria. Any disagreements were resolved by discussion with the Guideline Systematic Review Group Oxford. Full versions of all included studies were obtained.

Full-text articles were retrieved and excluded for one or more of the following reasons: not relevant for self-care, not a review of NCDs, not a systematic review, no clinical outcomes. Each article was screened by one reviewer and checked by a second reviewer. Any disagreements were resolved by discussion with the Guideline Systematic Review Group.

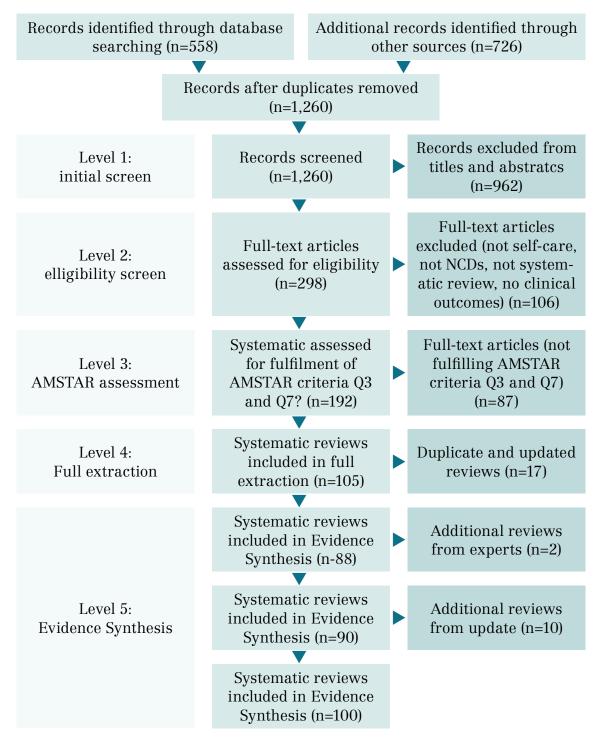
Each eligible review was scored by the AMSTAR tool<sup>5</sup>. Systematic reviews were included if the response was "yes" to two essential AMSTAR quality criteria: Question 3: "Was a comprehensive literature search performed?" and Question 7: "Was the scientific quality of the included studies assessed and documented?".

Each article was scored by one reviewer and checked by a second reviewer. Any disagreements were resolved by discussion with the Guideline Systematic Review Group.".

<sup>5</sup> Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, Porter AC, Tugwell P, Moher D, Bouter LM. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Med Res Methodol.* 2007 Feb 15;7:10.

Any disagreements between two reviewers were resolved by discussion with the Guideline Systematic Review Group.

Figure 1. Flow chart WHO self-care guideline\*



<sup>\*</sup> References of retrieved systematic reviews that referred to them. References to systematic reviews in publications and guidelines related to self-care.

All reviews relevant to each of the nine questions were summarised for each of the four disease categories.

We used Grading of Recommendations Assessment, Development and Evaluation (GRADE) to assess quality of evidence in the most relevant and/or recent reviews.<sup>6</sup> Several systematic reviews used the standardized mean difference(SMD), as the summary statistic for absolute effect in meta-analysis when the studies all assess the same outcome but measure it in a variety of ways. The standardized mean difference expresses the size of the intervention effect in each study relative to the variability observed in that study:

SMD = Difference in mean outcome between groups
Standard deviation of outcome amon participants

Thus studies for which the difference in means is the same proportion of the standard deviation will have the same SMD, regardless of the actual scales used to make the measurements.<sup>7</sup>

<sup>6</sup> Guyatt GH, Oxman AD, Schünemann HJ, Tugwell P, Knotterus A. GRADE guidelines: A new series of articles in the Journal of Clinical Epidemiology. *J Clin Epidemiol*. 2011:64:380-2.

 $<sup>7 \</sup>quad http://handbook.cochrane.org/part\_2\_general\_methods\_for\_cochrane\_reviews.htm$ 

## **Outcomes**

In the full summary GRADE tables (Appendix 4), we presented the effects of interventions on one or more of the following outcomes:

### **Primary outcomes**

- Mortality
- Clinical complications and/or disease progression
- Surrogate outcomes that correlate with clinical complications and/ or disease progression (e.g. blood pressure)
- Adherence to treatment

### **Secondary outcomes**

In addition we presented information for the following secondary outcomes:

- Health Related Quality of Life
- Psychosocial outcomes
- Hospitalisation and/or health care utilization
- Cost effectiveness, cost impact, cost savings
- Harms of self-care interventions
- Self-efficacy, knowledge and patient empowerment

See Appendix 1 for GRADE ranking of importance of outcomes.

### Formulation of recommendations

The Guideline Development Group (Appendix 3) met twice: once to develop the questions for which recommendations were required and once to review the evidence synthesised and formulate the recommendations.

The recommendations were drafted by the co-chairs of the GDG and the WHO Secretariat. They were then presented and discussed at a meeting of the GDG. They are based on the GRADE evidence tables and the evidence-to-recommendation framework presented for each recommendation in Annex 5. The group gave special consideration to the feasibility of the guideline implementation in low resource settings. Consensus was a priori defined as agreement of the simple majority, without strong objections from the minority. Consensus was reached on every recommendation and there was no need for voting.

Each recommendation was graded as strong when there was confidence that the benefits clearly outweigh the harms (for recommendations to use the intervention), or that harms clearly outweigh the benefits (for recommendations against the intervention). A weak recommendation for an intervention was given when the benefits probably outweigh the harms, but there was considerable uncertainty about the trade-offs, typically due to lack of data. A weak recommendation against an intervention was given when there was considerable uncertainty about the magnitude of benefits and harms.

### Peer review

The draft guideline was reviewed by 5 external experts (Appendix 3). The reviewers had a few requests for clarification, but no objections to the recommendations. One reviewer expressed concern that the local decisions on the implementation of the guidelines would not be easy, given that most recommendations were weak for or weak against the intervention. This reviewer questioned the use of GRADE given the general paucity of good quality research, and proposed an alternative method for arriving at the recommendations, but this was not accepted by the GDG.

### **Declarations of Interest**

All the members of the Guideline Development Group, the Systematic Review Group, Observers and Guideline reviewers completed the standard WHO Declaration of Interest Form.

Interest was declared on the WHO forms by the following persons and disclosed orally at the meetings:

Dr William Summerskill is employed by Elsevier, a publisher of several medical journals, as an editor of The Lancet. The GDG approved his participation in the Systematic Review Group.

Dr Richard Chapman had been emplyed by IMS (Intercontinental Medical Statistics) Health. He conducted health economics and outcomes research. His employment ceased 3 months before his engagement in the GDG. The WHO secretariat decided that this did not constitute conflict of interest and that Dr Chapman can participate at all stages of guideline development.

No other participant declared conflict or potential conflict of interest.

All members of the Guideline Development Group participated fully in the discussions and formulation of the recommendations.

### Results

We identified 1,260 potential systematic reviews from the searches.

After initial screening we retrieved 298 full-text articles to be assessed for eligibility. Studies were excluded at this stage if they fulfilled one or more of the following conditions: not self-care, not NCDs, not a systematic review or had no clinical outcomes (n=106).

The remaining 192 articles were assessed for quality. Full data extractions were performed for the 88 studies (excluding updated/duplicate studies) fulfilling questions 3 and 7 of the AMSTAR checklist. Two further reviews were identified by experts and an additional ten reviews were identified when the search was updated in March 2013 giving a total of 100 reviews.1-100 GRADE tables were provided for studies that were the most recent and relevant.

We also identified 87 lower quality reviews. 101-187

The results are presented below for each of the nine questions.

# Question 1: In patients with non-communicable diseases do self-care strategies targeted at the community and/or support networks rather than the individual improve outcomes?

Definition: Self-care strategies for NCDs targeted at the community are designed to be delivered beyond health care institutions either by the health care system or by the local community through its members, trained or untrained, paid or unpaid. Self-care interventions delivered through community action can be complementary to conventional health care or stand-alone programmes.

#### **Summary of evidence**

We identified seven systematic reviews of trials of interventions focused on support groups or family members. <sup>17</sup> <sup>24</sup> <sup>45</sup> <sup>53</sup> <sup>59</sup> <sup>76</sup> <sup>92</sup>

One systematic review examined the role of peer support, including one-to-one sessions, self-help or support groups, online computer mediated groups, or peer support within an educational environment for individuals with heart disease, compared with usual care. The six included trials were heterogeneous in intervention and outcomes measured. The trials demonstrated some positive effects of peer support for individuals with heart disease, including higher levels of self-efficacy, improved activity, reduced pain, and fewer emergency room visits. However, the trials had methodological problems: allocation concealment was only clear in one study and high attrition occurred in three.<sup>76</sup>

In a systematic review of various types of social support amongst patients with diabetes, the interventions in the four trials were highly varied and meta-analysis was not possible. One trial showed limited evidence of reduction in HbA1c with patient group consultations to the physician. There was no evidence of improved diabetes control by support from the spouse or by family and friends.<sup>92</sup>

A further systematic review examined the role of interventions involving the family in the treatment of adult patients with chronic physical diseases, on the assumption that families can be highly influential on an individual's self-care. Interventions were either psychoeducational, about the disease and its treatments, or focused on improving relationships within the family, so as to facilitate problem solving and reduce illness related stress. The comparison was groups undergoing usual care, which in some cases included additional education or counselling at the request of the patient. In 52 RCTs, there was considerable heterogeneity in the interventions, disease types studied, outcomes and time frames. There was some evidence of benefit for family based interventions: mean overall effect sizes were 0.32 (95% CI 0.18 to 0.45) for the patients' physical health, 0.28 (0.12 to 0.43) for the patients' mental health, and 0.35 (0.05 to 0.66) for the family members' health.<sup>45</sup>

A systematic review of interventions to support caregivers amongst families of those with terminal illness showed some evidence of benefit of psychosocial interventions.<sup>53</sup> However, trials had high heterogeneity in terms of their design and outcomes and no meta-analysis was performed. Only one of five trials demonstrated no benefit, and the others reported improved carer perceptions of their situation or improved quality of life.

One systematic review examined non-pharmacological interventions for the caregivers of stroke survivors focussing on what kinds of services could help. Eight RCTs were identified, with substantial variation in their design and statistical heterogeneity prevented pooling of results. Interventions included information provision, training for caring, others were psychosocial, aiming to raise resilience and promote well-being in the carers. Two studies using a support and information intervention provided data on the Caregivers Strain Index: pooling these gave a SMD -0.29 (95% CI -0.86 to 0.27) for the intervention, but with substantial heterogeneity (I2=61%). Data were pooled from two other studies on the outcome stress/burden of caregivers, intervention versus comparator SMD was 0.01 (-0.34 to 0.36) with no significant heterogeneity (I2=0%).<sup>59</sup>

We found seven lower quality reviews in the following disease areas: CVD, diabetes and combined chronic diseases including CVD and cancer. 116 136 148 157 159 163 166 In hypertension, a community health worker did not improve blood pressure (BP) control when compared with usual

care. Interventions aimed at couples had small significant effects on patient depressive symptoms on a number of chronic diseases including cancer and CVD.

In conclusion, community support and family involvement are opportunities to strengthen knowledge, self-efficacy and build capacity to deliver self-care across a range of chronic diseases. In some settings, these may offer the main route to providing structured support for self-care, where other forms of health delivery are lacking. Anecdotal evidence suggests that chronic disease programmes involving the community are widespread. However, there is little randomised trial evidence on the effectiveness of such interventions.

#### Recommendations

No.	Recommendation	Strength of recommendation	Quality of evidence
1.1	Community interventions can complement primary health care. Structured training for community workers should be undertaken to aid the detection and on-going management for NCDs.	Weak	Very low
Res	earch recommendations		
R1	R1 Research is needed to identify pragmatic community based interventions for self-care of NCDs in LMIC.  Community programmes should be evaluated for their coverage, generalisability, impact and cost effectiveness.		

GRADE tables for question 1 are presented in Appendix 4.

The evidence-to-recommendation table is presented in Appendix 5.

# Question 2: In patients with non-communicable diseases do lay led self-management patient programmes improve outcomes?

Definition: Lay led self-management education programmes are highly structured programmes for people with NCDs which are primarily educational, and address self-care of the disease with the majority of course content delivered by lay individuals.

#### **Summary of evidence**

Three systematic reviews were identified which examined trials relating to lay led self-management programmes in self-care.26 39 65 Within these, one trial was performed within LMIC.

One systematic review examined evidence of one-to-one volunteer support among women with breast cancer, compared with usual care, or cancer nurse support, or psychopharmacological treatment. The review presented limited, poor quality evidence to show any benefit of such peer support programmes among those with breast cancer.65

In a systematic review of peer support telephone calls for patients with a variety of health problems meta-analysis was not performed. Peer support telephone calls were found to improve uptake of mammograms in women > 40 years. For myocardial infarction patients, peer support telephone calls were found to improve diet at six months (54% intervention versus 44% usual care (p = 0.03)) but no differences in outcomes were found in patients with poorly controlled diabetes.26

One review examined the evidence on lay led self-management patient programmes across a range of disease conditions. This directly aimed to evaluate the benefits of structured, manualized, lay led self-management programmes among 17 trials randomising 7,442 study participants with long-term health conditions, including arthritis, diabetes, hypertension, chronic pain and other diagnoses. In these trials the comparison was usual care which typically incorporated standard education materials and in some trials, the offer of the lay led course once the trial was completed. The follow-up period for most of these studies was three to six months. Improvement in terms of pain, disability, fatigue and exercise were small and not clinically important.<sup>39</sup>

In conclusion, the use of lay (peer) led self-management disease programmes has grown based on utilising the knowledge and commitment of individuals who have chronic disease to educate and support others with chronic disease. Lay led programmes may help support individuals to take more responsibility for their own health. In regions with highly developed health care systems, lay led programmes may support a shift towards a more partnership model of health care; in areas with little health care coverage they may provide an essential basis for self-care.

We found no lower quality reviews on this topic.

#### **Recommendations**

No.	Recommendation	Strength of recommendation	Quality of evidence
2.1	The use of highly structured lay led self-management patient programmes for self-care in NCDs is not recommended at the present time for LMIC.	Weak	Very low
Res	earch recommendations		
R2	R2 Research is needed to evaluate lay led self-management programmes in LMIC, ideally with identification of the active components of such programmes and their feasibility in low resource settings.		

GRADE tables for question 2 are presented in Appendix 4.

The evidence-to-recommendation table is presented in Appendix 5.

# Question 3: In patients with non-communicable diseases do online resources for self-care improve outcomes?

Definition: Online resources for self-care include: health information, interactive health communication applications (web based information packages that can combine health information with at least one component of support, decision support or behaviour change support).

#### **Summary of evidence**

We obtained data from three systematic reviews evaluating evidence on online resources in self-care. One focused on diabetes<sup>84</sup> and the other two included studies of a range of chronic diseases including CVD, diabetes and respiratory (chronic obstructive pulmonary) disease.<sup>35 73</sup>

One review examined the evidence for web based interventions in the management of type 2 diabetes. The evidence was generally poor quality and the authors reported that goal-setting, personalised coaching, interactive feedback and online peer support groups were some of the successful approaches which were applied in e-interventions to manage type 2 diabetes. There was no pooled analysis and the effects on clinically relevant outcomes were limited.<sup>84</sup>

One review examined the evidence on interactive health communications applications (IHCAs) which are web based information packages for patients that combine health information with at least one of social support, decision support, or behaviour change support. Interventions could be a game or information website. IHCAs had a significant positive effect on knowledge (SMD 0.46, 95% CI 0.22 to 0.69), social support (SMD 0.35, 0.18 to 0.52) and clinical outcomes (SMD 0.18, 0.01 to 0.35). Results suggest that IHCAs might have a positive effect on self-efficacy (SMD 0.24, 0.00 to 0.48). It was not possible to determine the effects on emotional or economic outcomes and there was considerable heterogeneity amongst outcomes.<sup>73</sup>

A systematic review of e-health (monitoring, treatment instructions, self-management training and general information and communication between patient and caregiver), or e-health in addition to usual care found most studies showed small to moderate positive effects on health outcomes. Due to the different study populations that were included and differences in the way that e-health interventions were delivered (instead of usual care or in addition to usual care), results could not be combined and meta-analysis was not performed. However, not all outcomes improved, and in some measures, comparable effect sizes were seen in the intervention and control group.<sup>35</sup>

In conclusion, accessing health information online has become wide-spread in developed regions. Health care providers may provide medical information, but content provided by pharmaceutical companies and businesses promoting herbal or complementary preparations is also commonly accessed. Internet accessibility, although extensive, is not uniform worldwide, with some regions having low access and some regions experiencing government control over access. Literacy and language barriers make internet resources inaccessible to some groups.

We found ten reviews deemed to be lower quality. 103 104 109 117 121 131 149 158 170 176 Within these, cardiovascular disease home based secondary programmes and remote patient monitoring seemed to improve quality of life and reduced hospitalisations. One review of telemonitoring in heart failure reported modest improvements in quality of life and decreased hospitalisations. In hypertension, computer based interventions had no effects. In diabetes, web based educational tools showed small improvements in clinically relevant outcomes and enhanced patient-provider communication. There was some evidence that a simple pocket sized insulin dosage computer reduces hypoglycaemic events and insulin doses.

#### **Recommendations**

No.	Recommendation	Strength of recommendation	Quality of evidence	
3.1	Health care organisations should provide access to user-friendly, valid and reliable online information targeted at NCDs and their management. Online resources could provide some benefit.	Weak	Very low	
Research recommendations				
R3	R3 Research is needed to evaluate interactive health care web resources, particularly in LMIC settings.			

GRADE tables for question 3 are presented in Appendix 4.

The evidence-to-recommendation table is presented in Appendix 5.

# Question 4: In patients with non-communicable diseases do self-monitoring devices improve outcomes?

Definition: On-going management of NCDs often involves monitoring of a biochemical or physical measure (e.g., blood pressure, blood glucose, peak flow etc.). Whilst these measures can be undertaken in the clinic setting they may be self-monitored in the home setting by the patient or within the community and the results communicated to a health professional for subsequent management.

#### **Summary of evidence**

We found 22 systematic reviews on oral anticoagulation, heart failure, hypertension, diabetes (types 1 and 2) and asthma.<sup>18 11 14 16 19-22 37 40 43 47 49</sup>
<sup>51 67 78 81 85 87 94 98</sup> We found no reviews on self-monitoring in cancer.

A review on self-monitoring and self-management of oral anticoagulation reported the combined interventions produced significant clinical benefits. Self-monitoring alone (7 trials, 1027 participants) significantly reduced major haemorrhages (RR 0.56. 0.35 to 0.91) but not thromboembolic events (RR 0.57, 0.32 to 1.00), nor mortality (RR 0.84, 0.50 to 1.41).<sup>40</sup> The self-management studies are reviewed under Question 6.

A systematic review of RCTs that looked at multidisciplinary interventions among participants with heart failure, some of which included home monitoring, was identified. Overall, multidisciplinary interventions reduced all-cause admission (RR 0.87, 95% CI 0.79 to 0.95). All-cause mortality was also reduced (RR 0.79, 0.69 to 0.92) and heart failure admission (RR 0.70, 0.61 to 0.81). In relation to self-monitoring, data could not be isolated from the overall data presented in the review.<sup>49</sup>

A review of 25 trials of self-monitoring in hypertension, compared with usual care found systolic BP and diastolic BP were significantly reduced with self-monitoring: WMD -3.82 mmHg (95% CI, -5.61 to -2.03) for systolic and -1.45 mmHg (-1.95 to -0.94) for diastolic. The likelihood of meeting BP targets was increased (RR 1.09, 95% CI 1.02 to 1.16). This substantial evidence indicates that at a population level, self-monitoring in hypertension may give rise to small but clinically important reductions in blood pressure.<sup>11</sup>

One review looked at the role of continuous blood glucose monitoring via a wire-type glucose sensor implanted in the subcutaneous tissue to monitor the glucose concentration of interstitial fluid in people with diabetes compared with conventional self-monitoring. Comparing the continuous monitor group with the standard self-monitoring of blood glucose, the mean difference in HbA1c was -0.30% (95% CI -0.43 to -0.17). Again, the difference is statistically significant but not clinically meaningful, although in this case the direction of effect supported the use of continuous monitors rather than standard self-monitoring.<sup>78</sup>

A pooled analysis of individual patient data from six randomised trials of self-monitoring of blood glucose in people with non-insulin treated type 2 diabetes found at six months follow-up, mean HbA1c was reduced in the self-monitoring group compared with the usual care group -2.7 (95% CI -3.9 to -1.6). At one year, it was -2.5 (-4.1 to -0.9). This high quality evidence showed that self-monitoring of blood glucose levels among patients with type 2 diabetes produces a statistically significant but not clinically meaningful reduction in HbA1c.<sup>37</sup>

We found fourteen lower quality reviews in the following areas: CVD (10), diabetes (4). $^{102\ 119\ 123\ 129\ 134\ 139\ 150\ 161\ 167\ 168\ 179\ 181\ 182\ 184}$ 

In conclusion, self-monitoring of symptoms, body weight or other health indicators and communication of this information to a health care professional for medical guidance is currently undertaken across a wide variety of NCDs. Several devices to support this have been marketed, including blood pressure monitors, blood or urine glucose monitors and oral anticoagulation monitors. Self-monitoring offers the opportunity for more frequent data collection about an individual's condition, potentially more convenient to the individual than visits to a health centre and at lower cost overall, particularly if there is a large distance to a clinical facility.

#### **Recommendations**

No.	Recommendation	Strength of recommendation	Quality of evidence	
4.1	Self-measurement to monitor blood pressure is recommended for the management of hypertension in appropriate patients where the affordability of the technology has been established.	Strong	Low	
4.2	Self-monitoring of blood coagulation is recommended for appropriate patients treated with oral anticoagulation agents, where the affordability of the technology has been established.	Weak	Moderate	
4.3	The use of self-monitoring of blood glucose in the management of patients with type 2 diabetes not on insulin is not recommended at the present time because there is insufficient evidence to support such a recommendation.	Weak	Moderate	
4.4	People with type 1 and type 2 diabetes on insulin should be offered self-monitoring of blood glucose based on individual clinical need.	Weak	Low	
Research recommendations				
R4	R4 Research is needed to evaluate the impact of self-monitoring, including assessment of the cost-effectivened LMIC.			

GRADE tables for question 4 are presented in Appendix 4.

The evidence-to-recommendation tables are presented in Appendix 5.

# Question 5: In patients with non-communicable diseases do mobile telephone and/or telemonitoring interventions targeted at self-care improve outcomes?

Definition: Telemonitoring involves remotely monitoring patients who are not in the same location as the health care provider. Monitoring devices will transmit information on symptoms and/or vital signs via the telephone to a remote monitoring service provider and/or to their

health care provider. Telemedicine is a broader concept that includes patient consultations using telecommunications.

#### **Summary of evidence**

We extracted data from 14 systematic reviews on CVD (heart failure, hypertension and myocardial infarction), diabetes and respiratory disease (asthma and COPD). Among these, one trial was performed in a low or middle income country.<sup>1 4 9 26 27 36 49 55 61 69 70 80 85 93</sup> We found no reviews on mobile telephone or telemonitoring interventions among participants with cancer. One trial was performed in LMIC.

A review of multidisciplinary interventions among participants with chronic heart failure, some of which included telecare, found all-cause hospital admissions (RR 0.87, 95% CI 0.79 to 0.95), mortality (RR 0.79, 0.69 to 0.92) and heart failure admission (RR 0.70, 0.61 to 0.81) were all reduced. But it was difficult to identify the role of telemonitoring within these and the comparison groups were poorly described.<sup>49</sup>

One review, of 25 RCTs in chronic heart failure patients, reviewed structured telephone support (using simple technology) and telemonitoring (digital/ broadband/satellite/wireless or Bluetooth transmission data). Telemonitoring reduced all-cause mortality (RR 0.66, 95% CI 0.54 to 0.81) and structured telephone support also reported a non-significant reduction in mortality (RR 0.88, 0.76 to 1.01). Both interventions reduced CHF related hospitalisations: telephone support (RR 0.77, 0.68 to 0.87) and telemonitoring (RR 0.79, 0.67 to 0.94). Several studies reported improvements in quality of life as well as reduced health care costs and acceptability to patients.<sup>55</sup>

A systematic review of 22 trials of home BP monitoring compared with clinic monitoring included five trials of telemonitoring. Overall results showed an improvement for systolic BP for home monitoring (-2.63mmHg, 95% CI -4.24 to -1.02) and diastolic BP (-1.68mmHg, -2.58 to -0.79). Reductions in home BP monitoring-based therapy were greater when telemonitoring was used (five trials) (SMD -3.20 mmHg, -4.66 to -1.73) compared to when telemonitoring was not used (17 trials) (SMD -1.26 mmHg, -2.20 to -0.31) for systolic BP but not for diastolic BP.

A review of the role of telemedicine compared with usual care among participants with type 1, type 2 or gestational diabetes on HbA1c control reported two trials used a mobile phone, most transmitted blood glucose data, self-management information and insulin dose, two transmitted blood glucose data and self-management information and one only transmitted blood glucose data. Half the studies used advanced signal processing and six displayed blood glucose data. Among nine RCTs there was no significant benefit of telemedicine for HbA1c (WMD -0.11, 95% CI -0.27 to 0.04).

A review of mobile phone interventions among individuals with type 1 or 2 diabetes reported most of the 22 included trials used a mobile phone short message service SMS to deliver blood glucose test results and self-management information among participants with type 1 or type 2 diabetes. The overall result was a small reduction in HbA1c in the intervention group (SMD -0.51, 95% CI -0.69 to -0.33) over a median of 6 months follow-up. The effect of mobile phone intervention did not significantly differ by other participant characteristics or intervention strategies.<sup>61</sup>

Six trials were included in a review of interventions incorporating tele-consultation, videoconferencing or videoconferencing combined with tele-consultation in the care of individuals with diabetes. There was little evidence of benefit of these interventions: HbA1c was not reduced with tele-consultation compared with usual care (WMD 0.03, 95% CI -0.31 to 0.24). There was no evidence of heterogeneity. The study also looked at patient satisfaction and other non-clinical outcomes. The benefits of videoconferencing were mainly related to its effects on socioeconomic factors such as education and cost reduction, but also on monitoring disease. Additionally, videoconferencing seemed to maintain quality of care while producing cost savings.<sup>93</sup>

A review of 24 studies of mhealth (mobile health technologies) interventions in type 1 and 2 diabetes reported that studies were inconsistent, often of poor quality, which negated the evidence for effectiveness.<sup>4</sup>

A review of 21 studies looked at telecare interventions among participants with asthma compared with usual care or any other form of control. A range of technologies were included: telephone (n = 9); video conferencing (n = 2); internet (n = 2); other networked communications (n = 6); Short Messaging Service (text) (n = 1); or a combination of text and internet (n = 1). Over a 12-month period, telecare resulted in a non-significant increase in the odds of emergency department visits (OR 1.16, 95% CI 0.52 to 2.58) but, over the same period led to a significant reduction in hospitalisations (OR 0.21, 0.07 to 0.61). The effect size was more marked in those with more severe asthma: those managed predominantly in secondary care settings.<sup>69</sup>

Telemonitoring in chronic obstructive pulmonary disease was analysed in a review including six studies, two of which used control groups and two used a before and after design. Four of six studies reported a reduction in hospital admission, but only one of these was a RCT.<sup>9</sup>

In a review of telehealthcare among participants with COPD the interventions were: video or telephone links with health care professionals; internet based telecommunication with health care professionals; wired and wireless telemetry for telemonitoring of spirometry (FEV1/FVC), respiratory rate, BP and O2 saturations. In two trials

telehealthcare was associated with a non-significant increase in quality of life (MD -6.57, 95% CI -13.62 to 0.48). Telehealthcare also showed significant reductions in emergency department attendances over a 12-month period (OR 0.27, 0.11 to 0.66) and admissions to hospital (OR 0.46, 0.33 to 0.65). There was no significant difference in deaths over the same period (OR 1.05, 0.63 to 1.75).

In a review of peer support telephone calls for patients with a variety of health problems meta-analysis was not performed. Peer support telephone calls were found to improve uptake of mammograms in women > 40 years. For myocardial infarction patients peer support telephone calls were found to improve diet at six months (54% intervention versus 44% usual care, p = 0.03), but no differences in outcomes were found in patients with poorly controlled diabetes.<sup>26</sup>

Evidence from 22 lower quality reviews suggested home based interventions, including telephone based interventions, improved quality of life in patients with cardiovascular disease. <sup>106</sup> <sup>114</sup> <sup>123</sup> <sup>127</sup> <sup>128</sup> <sup>137</sup> <sup>140</sup> <sup>141</sup> <sup>144</sup> <sup>145</sup> <sup>149</sup> <sup>152</sup> <sup>156</sup> <sup>158</sup> <sup>162</sup> <sup>169</sup> <sup>171</sup> <sup>173</sup> <sup>174</sup> <sup>183</sup> In stroke, one review reported home based telerehabilitation showed promising results in improving the health of stroke patients. In COPD, telehealth (telemonitoring and telephone support) reduced rates of hospitalisation and emergency department visits. Eight reviews reported on combined cardiovascular conditions including CVD, heart failure, coronary artery disease, diabetes, hypertension and one review also included respiratory disease (COPD and asthma), which commonly reported improved clinical outcomes. We found no reviews in cancer.

In conclusion the expansion of the mobile telephone (cell phone) networks offers a potential route for communication with health care providers.

#### Recommendations

No.	Recommendation	Strength of recommendation	Quality of evidence
5.1	The use of telemonitoring for self-care in NCDs is not recommended at the present time, because there is insufficient evidence to support such a recommendation.	Weak	Low
5/2	The use telehealth for self-care in NCDs is not recommended at the present time, because there is insufficient evidence to support such a recommendation.	Weak	Low
Res	earch recommendations		
R5 Research is needed to evaluate telemonitoring and telehealth in LMIC, ideally with identification of the ac components of such programmes and their feasibility in low resource settings.			n of the active

GRADE tables for question 4 are presented in Appendix 4.

The evidence-to-recommendation tables are presented in Appendix 5.

# Question 6: In patients with non-communicable diseases do self-treatment interventions improve outcomes?

Definition: Self-treatment intervention includes self-monitoring and adjustment of dosage of medicines by the individual, based on a prespecified action plan agreed jointly by a health care practitioner / worker and the patient. A situation can occur in NCD management in which the patient could or will alter the doses and/or frequency of the treatment depending upon the change in the nature severity of symptoms and/or biochemical markers of a disease under the guidance of a professional health care provider (e.g. physician) with treatment recommendation.

#### **Summary of evidence**

We extracted data from 12 systematic reviews evaluating self-treatment intervention programmes in cardiovascular disease (oral anticoagulation, chronic heart failure), diabetes, respiratory disease (COPD and asthma), and combined chronic diseases. 8 20 22 30 34 40 41 58 71 79 82 96 We found no reviews of self-care treatment interventions in cancer.

Self-management of oral anticoagulation, comprised of self-monitoring and self- treatment, when compared with usual care showed significant reductions in thromboembolic events (RR 0.47, 95% CI 0.31 to 0.70) and all-cause mortality (RR 0.55, 0.36 to 0.84); there was no evidence of effect on major haemorrhage (RR 1.12, 0.78 to 1.61).<sup>40</sup>

In one review, of patients with heart failure, the self-treatment intervention groups involved patients who were educated about early recognition of signs and symptoms of heart failure, the importance of pharmacological treatment adherence, daily weighing and changing lifestyle. Comparison was with usual care, or an education package. There was some evidence that self-management reduced all-cause hospital admissions and hospital admissions due to chronic heart failure. However, the trials were heterogeneous and mostly at high risk of bias.<sup>30</sup>

One review looked at studies testing interventions to increase type 2 diabetes patients' adherence to self-management in terms of requirements in diet, exercise, smoking and alcohol. Some studies also looked at blood glucose monitoring. The interventions were classified as either educational or behavioural psychosocial interventions. The analysis showed a 0.36% (95% CI 0.21 to 0.51) improvement in glycaemic control. Most studies were assessed as having a high or unclear risk of bias.<sup>71</sup>

A further review in patients with type 1 or type 2 diabetes looked at disease management programmes which consisted of patient follow-up

that included two or more of the following: patient education, coaching, monitoring, care coordination, and treatment adjustment by a disease manager. Comparison groups were somewhat heterogeneous with varying levels of education and health care worker contact. Among 41 RCTs (over 7,000 participants), disease management programmes resulted in a significant reduction in HbA1c (SMD -0.38, 95% CI -0.47 to -0.29). Programmes in which treatment adjustment was by a disease manager resulted in a greater reduction in HbA1c (SMD -0.60 versus -0.28).<sup>79</sup>

One systematic review examined interventions aiming to improve the delivery of asthma medications by self-management education. Self-management involved self-monitoring by peak expiratory flow or symptoms, together with regular medical review and a written action plan. These self-treatment educational interventions were compared with usual care, which varied between no intervention, education, self-monitoring or regular medical review but not written action plans. Self-management education reduced nocturnal asthma (RR 0.67, 95% CI 0.56 to 0.79); hospitalisations (RR 0.64, 0.50 to 0.82); emergency room visits (RR 0.82, 0.73 to 0.94); unscheduled visits to the doctor (RR 0.68, 0.56 to 0.81). Measures of lung function were little changed: SMD for peak flow was 0.18, 95% CI 0.07 to 0.29 and SMD for FEV1 0.10, -0.02 to 0.22. The trials included in this review were mostly at a high risk of bias.<sup>41</sup>

A further review of studies comparing asthma self-management using a written action plan based on peak flow expiratory flow with a plan based on symptoms showed no significant effects on emergency room visits, hospitalisation and days off work. This review also analysed three studies comparing the asthma self-management with self-adjustment of medications according to an individualised written action plan to medication adjustment by a doctor. For intervention versus control peak flow was improved (SMD 0.16, 95% CI 0.01 to 0.31) as well as FEV1 (SMD 0.10, -0.05 to 0.25). The evidence, based on studies at high or unclear risk of bias, suggests optimisation of asthma control can be achieved equally as well by self-adjustment with the aid of a written action plan or by regular medical review.<sup>82</sup>

A review of COPD self-management education interventions found hospital admissions were reduced (OR 0.64, 95% CI 0.47 to 0.89), which translates, in patients with a moderate risk of exacerbation into a number needed to treat (NNT) of 10 (6 to 35) and a NNT of 24 (16 to 80) for patients at low risk.<sup>34</sup>

In a systematic review of actions plans with minimal or no education for COPD, the action plans gave guidance on self-initiated interventions including medication modification. The use of action plans did not reduce hospitalisation, emergency room visits and increased the use of oral corticosteroids over 12 months (MD 0.74, 95% CI 0.14 to 1.35). Antibiotic use over 12 months was also increased (MD 0.78, -0.24 to 1.79). There was also no significant difference in knowledge about self-management for exacerbations.<sup>96</sup>

There were five lower quality reviews. 137 138 146 147 167 In oral anticoagulation self-management results were consistent with other reviews. In heart failure, one review reported self-management interventions led to increased adherence to prescribed medical advice but with no improvement in functional capacity. In type 2 diabetes, there was low quality evidence that tracking systems for medication use may improve HbA1c.

#### **Recommendations**

No.	Recommendation	Strength of recommendation	Quality of evidence
6.1	Self-monitoring of blood coagulation and self-adjustment of dosage in patients receiving oral anticoagulation agents is recommended if affordable and according to an agreed action plan with a health professional.	Weak	Moderate
6.2	Self-monitoring in asthma and COPD and self-adjustment of dosage is recommended according to an agreed action plan with a health professional.	Weak	Very low
6.3	Self-adjustment of diuretics based on body weight monitoring in heart failure is not recommended at the present time.	Weak	Very low
6.4	Self-monitoring of blood glucose and self-adjustment of insulin dosage is recommended in type 1 diabetes according to an agreed action plan with a health professional.	Weak	Low

#### Research recommendations

R6 Research is needed to establish a consistent evidence base upon which valid recommendations can be made for self-monitoring and self-adjustment of treatments, particularly in LMIC. The research should evaluate risks and benefits, outcomes, cost and quality of life and also acceptability and potential barriers.

GRADE tables for question 6 are presented in Appendix 4.

The evidence-to-recommendation tables are presented in Appendix 5.

# Question 7: In patients with non-communicable diseases do self-care education/information programmes improve outcomes?

Definition: Education is the process of receiving or giving systematic instruction about a specific aspect of disease whilst information is the knowledge communicated about a particular aspect of a disease.

We extracted data from 35 systematic reviews in cardiovascular disease (coronary heart disease, hypertension and stroke), diabetes,

respiratory disease (asthma and COPD), cancer and combined chronic diseases. <sup>2 5-7 10 15 24 29 31-34 38 42-44 50 52 54 57 60 62-64 68 74 75 77 88-90 94 97 99 100</sup>

One review of the impact of psychoeducation programmes among people with coronary heart disease comprised of interventions delivered by trained health care professional, group or individual based, conducted in the home or community or as part of a cardiac rehabilitation programme. The comparison was with exercise only, standard cardiac rehabilitation or medical care. Psychoeducational interventions produced a significant positive effect on physical activity levels over the medium term (six to 12 months) when compared with exercise and risk factor education (SMD 0.62, 95% CI 0.30 to 0.94). There was little change in smoking and dietary behaviour. The studies were mostly at high or unclear risk of bias.<sup>2</sup>

A review of psychosocial interventions for smoking cessation in patients with coronary heart disease found that there was a positive effect on abstinence (OR 1.66, 95% CI 1.25 to 2.22). The interventions were either stand-alone smoking cessation interventions or ones which were included in more comprehensive rehabilitation programmes. They consisted of behavioural therapeutic interventions, phone support and self-help material. Comparison was with usual care, which varied between studies. Long-term data on whether quitting smoking was maintained were not available.<sup>5</sup>

A systematic review investigated a range of psychological interventions for coronary heart disease. There was little evidence that psychological interventions reduced mortality (RR 0.89, 95% CI 0.75 to 1.05). Psychological interventions in a smaller number of studies reporting cardiac mortality showed a small positive effect (RR 0.80, 0.64 to 1.00). Psychological interventions resulted in small to moderate improvements in depression (SMD -0.21, 95% CI -0.35 to -0.08) and anxiety (SMD -0.25, -0.48 to -0.03).<sup>99</sup>

One systematic review focussed on the effects of information provision among stroke patients (and their caregivers), including 21 RCTs of which nine included active information delivery interventions (lectures, home visits, or multi-component interventions) and 12 included only passive information provision (leaflets, in some cases tailored to the participant). Overall the risk of bias was moderately high and the high heterogeneity prevented pooling thus limiting the ability to draw conclusions. From subgroups of studies, there was mixed evidence as to whether anxiety or depression was reduced by information provision, and no evidence of reduction in mortality.

In a review of 17 studies of the evidence on interventions to increase self-efficacy among participants after stroke, which included four RCTs, the interventions were highly varied, and meta-analysis was not performed. Four self-efficacy interventions were identified; the evidence for the effects of these interventions was inconclusive.<sup>57</sup>

A review of interventions to improve the control of BP among participants with hypertension included a range of interventions, some of which were educational interventions directed towards the patient. Trials were heterogeneous but appeared unlikely to be associated with large net reductions in BP by themselves (WMD systolic BP -0.57 mmHg, 95% CI -1.22 to 0.08), and diastolic BP (0.46 mmHg, 0.07 to 0.86).<sup>134</sup>

A review of dietary interventions in hypertensive patients showed that body weight and BP were reduced in patients assigned to weight loss diets as compared to controls. The interventions were dietary education and direction, such as advising caloric restrictions or reduction in fat intake, and were compared with no interventions aiming to reduce body weight. Comparing intervention with control, body weight was reduced (WMD -3.98kg, 95% CI -4.79 to -3.17) over 6 months to three years. In addition, there was evidence that BP was reduced (WMD -4.5 mmHg, -7.2 to -1.8 mm Hg) and diastolic BP (WMD -3.2 mmHg, -4.8 to -1.5 mmHg).<sup>89</sup>

Systematic reviews of type 2 diabetes education or information programmes demonstrated variable results and reported only modest reductions in clinically relevant outcomes. Most of the evidence available for these reviews were derived from studies at high risk of bias. Group based educational interventions compared with usual care or remaining on the waiting list for the intervention, delivered modest reductions in HbA1c and reduced the need for diabetes medications. At four to six months follow-up, HbA1c was reduced by -1.35 (95% CI -1.93 to -0.78). At 12 to 14 months follow-up, this reduction was -0.82 (-0.99 to -0.65). There was also evidence of reduced need for diabetes medication, based on five RCTs with 654 participants.<sup>29</sup>

There was limited, inconsistent evidence that education on foot care could reduce foot ulceration or amputation. This systematic review examined 12 studies, of which three studies described the effect of foot care education compared with usual care, two studies examined the effect of tailored foot care educational needs compared with no intervention and seven studies described the effect of intensive versus brief educational interventions. The studies were too heterogeneous to allow meta-analysis, and the results were inconsistent and overall too limited to draw conclusions from.<sup>31</sup>

A second review evaluating face-to-face education showed no improvement; however, in a subgroup analysis of patients with higher baseline HbA1c levels there was some evidence of modest benefit. In studies comparing individual face-to-face education to usual care,

individual education did not significantly improve HBA1c (WMD -0.08, 95% CI -0.25 to 0.08) over 12 to 18 months. In this same review, a comparison of individual education with group based education detected no difference in the effects of these interventions.<sup>33</sup>

Evidence for educational interventions among people with diabetic kidney disease was limited and inconclusive. The systematic review identified only two trials, with low to moderate methodological quality, and more data are needed.<sup>60</sup>

There was limited and inconclusive evidence on the effect of educational interventions focussed on weight loss among type 2 diabetes patients: only modest weight loss was achieved, and comparison groups also often achieved weight loss. This systematic review identified 22 RCTs of weight loss or weight control interventions, via dietary, physical activity or behavioural strategies, compared with either usual care, similar interventions at lower intensity, or any other weight loss or weight control intervention; thus, the comparisons were not consistent. Among 585 participants, any weight loss intervention led to a reduction WMD -1.72kg (95% CI -3.15 to -0.29) in weight, equivalent to 3.1% of average baseline body weight. Changes in HbA1c usually corresponded to changes in body weight and were not significant when between-group differences were examined.<sup>75</sup>

One review examined the impact of interventions aimed at improving adherence to treatment recommendations. In nine studies HbA1c was improved (WMD -0.49, 95% CI -0.73 to -0.25). Most of the studies examined by the systematic reviews on this topic were at high or unclear risk of bias and sample sizes were frequently small.<sup>94</sup>

A review of limited asthma education found it did not significantly reduce hospitalisations (WMD -0.03, 95% CI -0.09 to 0.03) but did reduce emergency department visits (WMD -2.76, -4.34 to -1.18).42 A further review examined the evidence for mite control measures among people with house dust mite sensitive asthma. Thirty-seven trials assessed physical methods including mattress encasings (26 trials). Ten trials examined chemical methods and eight trials involved a combination of both. Compared with usual care, there was little evidence of benefit of the interventions. There were no statistically significant differences in the number of patients who improved (RR 1.01, 95% CI 0.80 to 1.27).44

In a review of trials of breathing exercises for participants with asthma five trials compared breathing retraining with no active control and two with asthma education control groups. Comparing intervention with control, rescue bronchodilator use was lower WMD -5.82 (95% CI -8.70 to -2.94), FEV1 was no different WMD -0.19 (-0.70 to 0.31) and daily peak flow improved WMD 72 Litres (30.15 to 113.85).

Overall, benefits of breathing exercises were found in isolated outcome measures across single studies.<sup>50</sup>

In a review of studies of relaxation therapies among participants with asthma, the interventions included progressive relaxation, hypnotherapy or autogenic training. Comparison group interventions varied widely from assertiveness training, sitting quietly, placebo relaxation method and listening to relaxing music. Two of five RCTs reported benefits of progressive muscle relaxation or mental and muscular relaxation. One RCT investigating hypnotherapy, one of autogenic training, and two of biofeedback techniques revealed no therapeutic effects. Overall, the methodological quality of the studies was poor. There was no evidence of benefit of psychological interventions among asthma patients from a review of 12 RCTs with 384 participants, which compared psychological interventions with some form of control intervention. No meta-analysis could be performed due to the diversity of interventions and the outcomes assessed and overall there was no evidence to show benefit of psychological interventions.<sup>54</sup>

A systematic review of the role of COPD-specific patient education compared with usual care, the intervention amongst 10 RCTs included various education delivery methods and settings. No meta-analysis was possible due to study heterogeneity. Self-management education tended to reduce hospital admissions, and tended to decrease costs associated with GP visits, but overall, there was insufficient evidence that increased knowledge leads to better self-care in COPD.7 A further review of self-management education interventions for COPD patients found that the probability of hospital admissions was reduced with these interventions (OR 0.64, 95% CI 0.47 to 0.89), which translated into a NNT of 10 (6 to 35) for patients with a moderate risk of exacerbation, and a NNT of 24 (16 to 80) for patients with a low risk of exacerbation.<sup>34</sup>

A systematic review of the provision of pain management of cancer patients was identified. Six studies gave estimates suggesting reduced pain in the intervention group: pain interference: (SMD 0.02, 95% CI -0.11 to 0.16); usual/average pain: (SMD 0.43, 0.13 to 0.74); and five studies for worst pain: (SMD 0.22, -0.20 to 0.64). It was not possible to isolate the results for studies targeting family/community from patients alone.<sup>24</sup>

Another review of educational interventions on cancer pain identified four RCTs using information, behavioural instructions via verbal, written or recorded audio-visual messages. Outcomes assessed included pain and pain intensity, quality of life scores such as functional status, perceived pain control, well-being and anxiety. The comparator was either usual care or a less intensive educational intervention such as a leaflet being given. These studies were heterogeneous in participant group, the type and delivery method of the intervention, outcome

assessment and all were at moderate risk of bias. There was very little consistent evidence of benefit of the educational interventions on pain or quality of life scores.<sup>62</sup>

A review of psychosocial interventions to reduce cancer pain, which pooled data from 37 RCTs, reported reductions in pain and interference by pain among those receiving the interventions. Interventions comprised skills training, cognitive-behavioural therapy, relaxation, hypnosis, and conditioning cues; the comparator was usually usual care. Study quality was typically low. For pain severity, the weighted average effect was 0.34 (95% CI, 0.23 to 0.46) and relative risk for pain interference was 0.40 (0.21 to 0.60) among the intervention compared with usual care.<sup>88</sup>

Limited, inconsistent evidence on self-management education among breast cancer patients suggested no benefit on quality of life or anxiety.<sup>74</sup>

A review of pelvic floor muscle training among men who have had radical prostatectomy, reported that one trial of 300 men found that training improved continence rates; men receiving biofeedbackenhanced training were more likely to achieve continence or have no continual leakage than those with no training within one to two months, but that the relative benefit increase was no longer significant after three to four months. Biofeedback enhanced pelvic floor muscle training was comparable to written or verbal pelvic floor muscle training instruction. Extracorporeal magnetic innervation and electrical stimulation were found to be initially (within one to two months) more effective than pelvic floor muscle training in one trial, but there were no significant differences between groups at three or more months.<sup>64</sup>

In chronic diseases, general advice and education interventions had limited effects. One review looked at studies of single risk factor interventions to promote physical activity among patients with chronic diseases, compared with usual care. Three trials were identified: one looked at general practitioners' prescription; counselling by practice nurses; and distribution of an education leaflet. A second examined advice about becoming more active and an eight week follow-up including visits with the health care provider and two booster telephone calls from a counsellor in physical activity. The third looked at material and medical advice encouraging more physical activity and to manage their hypertension better, supplemented with a self-help booklet. Two studies reported that the interventions evaluated had no effect on level of physical activity. One study reported a short-term increase in physical activity levels with use of an intensive intervention that was based on the theory of planned behaviour and integrated nurses into the general practitioner counselling process.<sup>52</sup>

A further review investigated self-management education programmes across a range of chronic diseases. Interventions involving face-to-face contact were associated with better outcomes. No other trial characteristics were associated with improved outcomes. Among diabetic patients, comparing education with usual care reduced HbA1c by 0.45% (95% CI 0.17 to 0.74), reduced systolic BP by 0.20mmHg (0.01 to 0.39), but did not significantly reduce diastolic BP (0.10 mmHG, -0.06 to 0.26 mmHg). Among participants with asthma, comparing education with usual care reduced asthma attacks: log rate ratio was 0.59 (95% CI 0.35-0.83). In a meta-regression, interventions involving face-to-face contact were associated with better outcomes; no other intervention characteristics were associated with improved outcomes.<sup>97</sup>

Thirty-six lower quality reviews were found in the following disease areas: cardiovascular disease, diabetes, respiratory disease and cancer.  $^{101\ 105\ 107-113\ 115\ 118\ 120\ 122\ 124-126\ 129\ 130\ 132\ 133\ 135\ 142\ 143\ 153\ 155\ 157\ 160\ 164\ 165\ 175\ 176\ 178\ 180\ 185-187}$ 

#### **Recommendations**

No.	Recommendation	Strength of recommendation	Quality of evidence
7.1	Group education programmes, rather than individual education, may offer a cost effective strategy to deliver education in LMIC.	Weak	Very low
Res	earch recommendations		
	None		

GRADE tables for question 7 are presented in Appendix 4.

The evidence-to-recommendation table is presented in Appendix 5.

# Question 8: In patients with non-communicable diseases do self-care rehabilitation programmes improve outcomes?

Definition: Rehabilitation therapy aims to improve function that has been lost or diminished by disease. Rehabilitation programmes may incorporate exercise and/or information after an event such as a myocardial infarction.

Rehabilitation is used among patients after interventions such as coronary angioplasty, heart surgery, or after stroke, in patients with chronic heart failure or respiratory problems. It consists of exercise training, usually combined with counselling and advice. The aim is to reduce the risk of future problems, help patients understand their condition, and help patients make lifestyle changes to support better health. Where the patient undertakes exercise by themself, this is self-care. As in all areas of self-care, the model is that health care

professionals deliver the education and training to the individual, and the individual may then take on more responsibility and autonomously perform the intervention. In practice, the ability of individuals to self-care during rehabilitation will vary and it will not be appropriate for all individuals. It is also essential that the programme be performed in the context of advice and support from health care professionals. The presented reviews examine various facets of these interventions.

#### **Summary of evidence**

We identified 13 reviews. 3 12 13 18 23 25 28 48 56 72 83 91 95

A review of home based rehabilitation versus centre based rehabilitation reported across the 12 included trials. The components of the interventions varied. Home based was not better than centre based for systolic BP (WMD 0.58mmHg, 95% CI -3.29 to 4.44) and for total cholesterol (WMD -0.13mmol/L, -0.31 to 0.05). There was no difference in mortality for home based versus centre based (RR 1.31, 0.65 to 2.66).<sup>25</sup>

In terms of exercise based interventions either alone or as a component of comprehensive cardiac rehabilitation, there was no significant difference in pooled mortality between groups in the 13 trials with less than one year follow-up.<sup>28</sup> There was a non-significant a reduction in pooled mortality in the four trials with more than one year follow-up (RR 0.88, 95% CI 0.73 to 1.07).

Home based exercise programmes comprising aerobic exercise with or without resistance exercise compared to usual care or usual activity among individuals with chronic heart failure,18 led to an increased six minute walking distance WMD 41 metres (95% CI 19 to 63) and peak VO2 WMD 2.71 ml/kg/min (0.7 to 4.7). Home based exercise did not significantly increase hospitalisation rates (OR 0.75, 95% CI 0.19 to 2.92) more than usual activity.

A review of the efficacy of physical fitness training for patients after stroke compared with no intervention, a non-exercise intervention or usual care reported trials were heterogeneous in outcomes, and in quality, and data pooling was difficult. There were no data on mortality or hospitalizations. Training involving walking had a positive effect with the mean maximum walking speed improving by 8.66 metres per minute, (95% CI 2.98 to 14.34). The effects were retained at the end of follow-up. Resistance training did not report sufficient data to assess its effects whilst the effects of physical training on mortality and disability were not clear.<sup>12</sup>

One review looked at the effectiveness of therapy based rehabilitation interventions delivered more than one year after stroke. There was insufficient evidence to form conclusions as to whether interventions

delivered more than one year after stroke could bring benefits to patients after stroke.<sup>3</sup>

One review investigated interventions specifically targeted at upper limb function among participants who had a stroke. Included studies each comprised a therapy programme with several treatment interventions, involving various exercise and task performance. Primary outcomes were activities of daily living and functional movement of the upper limb as primary outcomes. Four RCTs including 166 participants were identified, comparing interventions with usual care or another intervention, and overall there was no evidence of improvement in the primary outcomes. Currently there are not enough data to support the use of home based therapy focussing on upper limb function, and more research is needed.<sup>23</sup>

In a review of 12 RCTs of pulmonary care rehabilitation in COPD, two RCTs and eight studies compared home based rehabilitation to standard care (no pulmonary rehabilitation); three studies compared home based rehabilitation to hospital care and one study made both comparisons. The methodological quality of the included studies was low to moderate and meta-analysis was not performed. Most studies showed increased quality of care and exercise capacity with home based pulmonary care rehabilitation compared with no pulmonary rehabilitation. There was no evidence of differences in outcomes for home based compared with hospital based rehabilitation.<sup>95</sup>

Another recent review of pulmonary care rehabilitation among those with COPD focussed on those recently experiencing a hospital admission for a COPD exacerbation. Nine RCTs compared an intervention delivered in the community with usual care and assessed hospital admissions, as well as mortality, health related quality of life and exercise capacity. There was good evidence from trials at moderate risk of bias that pulmonary care rehabilitation substantially reduced hospital admissions over six months (OR 0.22, 95% CI 0.08 to 0.58), and mortality over a two year period (OR 0.28, 0.10 to 0.84).<sup>83</sup>

One review investigating the role of rehabilitation among participants who had previously completed treatment for cancer (not including the terminally ill or those under hospice care) was identified.72 The review focussed on whether exercise interventions could improve quality of life. 40 RCTs randomizing 3,694 participants were included, with an exercise intervention such as strength training, resistance training, walking, cycling or yoga. These were compared to usual care or another, non-exercise, intervention, and health related quality of life was assessed using a variety of measures. The trials were heterogeneous in design, exercise intervention and outcome measures and most were at high risk of bias. There was some weak evidence of benefit but the lack of consistency and wide confidence intervals means that

more high quality data are needed before such interventions can be recommended.

There were three lower quality reviews. 143 154 177

#### **Recommendations**

No.	Recommendation	Strength of recommendation	Quality of evidence
8.1	Appropriate patients could benefit from being educated on the benefits of cardiac rehabilitation, and can be encouraged to undertake physical activity for rehabilitation in the home setting.	Weak	Very low
8.1	Appropriate patients could benefit from being educated on the benefits of COPD rehabilitation , and encouraged to undertake rehabilitation exercise.	Weak	Very low
Res	earch recommendations		
R8	Research is needed to evaluate the effectiveness of rehabilitation program NCDs, particularly in LMIC.	nmes in the home or	community across

GRADE tables for guestion 8 are presented in Appendix 4.

The evidence-to-recommendation tables are presented in Appendix 5.

# Question 9: In patients with non-communicable diseases do interventions targeted at adherence improve outcomes?

Definition: Patient adherence has been defined as the extent to which a person's behaviour - taking medication, following a diet, and/or executing lifestyle changes - corresponds with agreed recommendations from a health care provider.

#### **Summary of evidence**

Evidence was provided from five systematic reviews, three among participants with diabetes and three in combined chronic diseases. $^{46}$ 

A review of studies testing interventions to increase the adherence of patients with type 2 diabetes to self-management requirements in diet, exercise, smoking and alcohol reported an improvement in HbA1c of PMD 0.36% (95% CI 0.21 to 0.51). Most studies were assessed as having a high or unclear risk of bias.<sup>71</sup>

Another review examined the impact of interventions aimed at improving adherence to treatment recommendations.<sup>94</sup> In nine studies HbA1c was reduced MD -0.49 (95% CI -0.73 to -0.25).

In a review of the role of reminder packaging in adherence to taking medications, interventions included a reminder system for the day of the week or the time that the medication was to be taken, and formed part of the packaging.<sup>66</sup> Trials of reminders that were separate to the intervention (such as a mailed or SMS reminder) were excluded. Packaging aids were included irrespective of whether the medication required a prescription or not. Trials of over-the-counter medications or vitamin supplements were included. Injected, topical or inhaled medicines, and co-packaged or fixed-dose combinations were included, as long as the packaging included a reminder system. Reminder packaging increased the percentage of pills taken: MD 0.11 (95% CI 0.06 to 0.17), significantly decreased diastolic BP, MD -5.89 mmHg (-6.70 to -5.09). No effect was seen on systolic BP (-1.01 mmHg, -2.22 to 0.20). Reminders significantly reduced HbA1c (MD -0.72, -0.83 to -0.60). In one study, the presence of a reminder packaging aid was preferred by patients with low literacy levels.

A further review reported a broad range of interventions targeted at improving adherence to medications.46 The majority of effective interventions for chronic diseases were complex in nature. They included combinations of more convenient care, information, reminders, self-monitoring, reinforcement, counselling, family therapy, psychological therapy, crisis intervention, manual telephone follow-up, and supportive care. However, they did not lead to large improvement in adherence. This finding was confirmed by a second review.<sup>86</sup>

In one lower quality review a wide variety of strategies in chronic disease seemingly improve medication adherence, with no single strategy appearing to be the best.<sup>172</sup>

#### **Recommendations**

No.	Recommendation	Strength of recommendation	Quality of evidence
9.1	Strategies to improve adherence should form part of self-care for NCDs. Promotion of self-care in NCDs should take into account patients' beliefs and concerns about medicines, and their effects on adherence	Strong	Very low
9.2	No single strategy to improve overall adherence is recommended over another	Weak	Very low
Rese	earch recommendations		
R9	Research is needed on interventions to improve adherence, particularly in	LMIC.	

GRADE tables for question 9 are presented in Appendix 4.

The evidence-to-recommendation tables are presented in Appendix 5.