

Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS (Review)

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[Intervention Review]

Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS

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ABSTRACT

Background

Home-based care (HBC), to promote quality-of-life and limit hospital care, is used in many countries, especially where public health services are overburdened.

Objectives

This review assessed the effects of HBC on morbidity and mortality in those with HIV/AIDS.

Search strategy

Randomised and controlled clinical trials of HBC including all forms of treatment, care and support offered in the home were included. A highly sensitive search strategy was used to search CENTRAL, MEDLINE, EMBASE, AIDSearch, CINAHL, PsycINFO/LIT. Risk of bias of all trials was assessed.

Selection criteria

All randomised and controlled clinical trials were included of HIV/AIDS positive individuals, adults and children, of any gender, and from any setting. Home-based care, provided by family, lay and/or professional people, including all forms of treatment, care and support offered in the HIV/AIDS positive person's home as compared to hospital or institutional based care

Data collection and analysis

Titles, abstracts and descriptor terms of the electronic search results were screened independently by two authors for relevance based on the types of participants, interventions, and study design. Full text articles were obtained of all selected abstracts and an eligibility form was used to determine final study selection. Data extraction and assessment of risk of bias were done independently. Narrative synthesis of results were done. Relevant effect measures and the 95% confidence intervals were reported.

Main results

Ten studies randomised individuals and trial sizes varied from n=31 to n=549. One study randomised 392 households and enrolled a total of 509 persons with HIV and 1,521 HIV-negative household members. Two ongoing studies were identified. Intensive home-based nursing significantly improved self-reported knowledge of HIV and medications, self-reported adherence and difference in

pharmacy drug refill (1 study). Another study, comparing proportion of participants with greater than 90% adherence, found statistically significant differences over time but no significant change in CD4 counts and viral loads. A third study found significant differences in HIV stigma, worry and physical functioning but no differences in depressive symptoms, mood, general health, and overall functioning. Comprehensive case management by trans-professional teams compared to usual care by primary care nurses had no significant difference in quality-of-life after 6-months of follow-up (n=57) and average length of time on service (n=549). Home total parenteral nutrition had no significant impact on overall survival and rate of re-hospitalisation. Two trials comparing computers with brochures/nothing/standard medical care found no significant effect on health status, and decision-making confidence and skill, but a reduction in social isolation after controlling for depression. Two trials evaluating home exercise programmes found opposing results. Home-based safe water systems reduced diarrhea frequency and severity among persons with HIV in Africa.

Authors' conclusions

Studies were generally small and very few studies were done in developing countries. There was a lack of studies truly looking at the effect of home based care itself or looking at significant end points (death and progression to AIDS). However, the range of interventions and HBC models evaluated can assist in making evidence-based decisions about HIV care and support.

PLAIN LANGUAGE SUMMARY

Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS

Home-based care (HBC), to promote quality-of-life and limit hospital care, is used in many countries, especially where public health services are overburdened. The objectives of this review was to assess the effects of HBC on morbidity and mortality in those with HIV/AIDS. A comprehensive search for clinical trials of HBC including all forms of treatment, care and support offered in the home was done. Eleven completed and two ongoing studies were identified. Studies were generally small and very few studies were done in developing countries. There was a lack of studies truly looking at the effect of home based care itself or looking at significant end points (death and progression to AIDS). Intensive home-based nursing significantly improved self-reported knowledge of HIV and medications, and self-reported adherence to medication. Another study, comparing proportion of participants with greater than 90% adherence, found statistically significant differences over time but no significant change in CD4 counts and viral loads. A third study found significant differences in HIV stigma, worry and physical functioning but no differences in depressive symptoms, mood, general health, and overall functioning. Comprehensive case management by trans-professional teams compared to usual care by primary care nurses had no significant difference in quality-of-life after 6-months of follow-up and average length of time on service. Home total parenteral nutrition had no significant impact on overall survival and rate of re-hospitalisation. Two trials comparing computers with brochures/nothing/standard medical care found no significant effect on health status, and decision-making confidence and skill, but a reduction in social isolation after controlling for depression. Two trials evaluating home exercise programmes found opposing results. Home-based safe water systems reduced diarrhea frequency and severity among persons with HIV in Africa.

BACKGROUND

Along with tuberculosis and malaria, HIV/AIDS is the major cause of illness and death in low and middle-income countries where health services already struggle with limited resources (staff, drugs, equipment, etc) and poor infrastructure (UNAIDS 2004). Thirty three million people are living with HIV and in 2007, an estimated 2.5 million people became newly infected with HIV/AIDS and 2.1 million people died (UNAIDS 2007).

Comprehensive management and control strategies for HIV/AIDS include prevention, treatment, care and support. The treatment required varies as the clinical stage of the disease progresses (Morrison 1993). Despite the availability of an-

tiretroviral treatment, hospital admissions related to HIV/AIDS care still accounts for a big proportion of the expenditures for people with AIDS (, Floyd 2001). As a result, home-based care (HBC) is increasingly being used as a key management strategy in many countries, especially where the public health services are already overburdened with limited human and financial resources.

Home-based care (HBC) has been defined by the Committee on a National Strategy for AIDS (CNSA) for the United States of America as care at the patients' residence to supplement or replace hospital care including medical management, palliative care and social support (Uys 2003). A similar definition is used by the World Health Organisation where community HBC is defined

as any form of care given to ill people in their homes (WHO 2002) WHO . This include physical, psychosocial, palliative and spiritual activities with the goal to provide hope through high-quality and appropriate care that helps ill people and

families to maintain their independence and achieve the best possible quality of life.

There are various models of home-based care: integrated HBC where all service providers are involved, single service HBC involving one organisation, and the informal HBC model with no formal support structure (Uys 2003). The care offered can include counselling and teaching, palliative care, increasing the health of the patient with symptom control and lightening the care load. It has also been proposed to offer home based care for all diseases and thus move away from a disease-specific approach aiming to reduce the stigma associated with HIV/AIDS (Havens 1999). With the roll out of antiretroviral treatment programmes there is also a need for some diversification in how the activity is viewed in terms of community-based workers doubling as treatment supporters.

Cited benefits of HBC include lower costs (direct and opportunity costs) at both individual and country level, personalised care, being in familiar surroundings, culturally appropriate care and increasing the time family members have for other responsibilities. It is also said to reduce the pressure on hospital beds and to increase effective time use in hospitals (Afroaidsinfo).

So far resources have been committed to implementing this strategy with the focus placed on cost assessment. However, its effectiveness has not been assessed (Hansen 1998). Cost-effectiveness has been demonstrated for home care substituting for acute care but less frequently where home care substitutes for long-term institutionalization. Research questions raised include the impact of HBC on the community, stigma, cost, hospital bed occupancy and the effectiveness of HBC (Uys 2003).

Assessing the quality of health care is difficult in any setting and particularly complex where care is delivered at home (NNRA 1994). The need has been identified to assess the quality of home care in a systematic manner (NNRA 1994) documenting the process of care delivery as well as the outcomes of this care. A number of reviews have examined the effectiveness of home care. Hedrick 1989 reviewed 13 studies on the effects of home care on mortality and nursing-home placements. The analysis demonstrated a small beneficial, but statistically insignificant, effect of home care on mortality and nursing-home placements. Similarly, Elkan 2001 found that home visits to older people can reduce mortality and admission to long term institutional care. Hughes 1997 examined the impact of home care on hospital days. The effect on the reduction of hospital days tended to be larger in studies with terminally-ill patients, with quasi-experimental designs, and when the impact was measured at six months or less versus measuring impact at greater than six months. In contrast, Smeenk 1998 concluded

that the effectiveness of home care programmes for patients with terminal cancer remains unclear.

No systematic review has assessed the impact of HIV/AIDS home care. In considering this approach the evidence of its effectiveness needs to be evaluated as an essential first step.

OBJECTIVES

To assess the effectiveness of home-based care to reduce morbidity and mortality in people infected with HIV/AIDS.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised and controlled clinical trials were included. Analytic observational studies were not considered because clinical trials were available.

Types of participants

HIV/AIDS positive individuals, adults and children, of any gender, and from any setting.

Types of interventions

Home-based care, provided by family, lay and/or professional people, including all forms of treatment, care and support offered in the HIV/AIDS positive person's home as compared to hospital or institutional based care

Types of outcome measures

Primary outcomes

Progression to AIDS

Death

Secondary outcomes

Psychosocial outcomes (mood scores, stigma, patient and carer preferences)

Quality of care

Quality of life

In patient days

Number and type of opportunistic infections

Search methods for identification of studies

To identify studies both electronic and manual searches were done.

Electronic searches

The following electronic databases were searched from 1980 to June 2005: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, AIDSearch, CINAHL, PsycINFO/LIT. An updated search was performed in March 2007 for the period July 2005 to March 2007, and again in September 2008 for the period April 2007 to September 2008, in CENTRAL, MEDLINE, EMBASE and AIDSearch.

Detailed search strategies were compiled for each database searched (Table 1 details the MEDLINE search strategy). This was based on the Cochrane HIV/AIDS Review Group comprehensive search strategy which included phases 1, 2 and 3 of the Cochrane Highly Sensitive Search Strategy for Randomised Controlled Trials as published in Appendix 5b2 of the Cochrane Reviewers' Handbook (Alderson 2004).

Table 1. MEDLINE search strategy

Search	Most recent queries	Result
#1	Search HIV Infections[MeSH] OR HIV[MeSH] OR hiv[tw] OR hiv-1*[tw] OR hiv-2*[tw] OR hiv1[tw] OR hiv2[tw] OR hiv infect*[tw] OR human immunodeficiency virus[tw] OR human immunodeficiency virus[tw] OR human immunodeficiency virus[tw] OR human immunodeficiency virus[tw] OR ((human immun*) AND (deficiency virus[tw])) OR acquired immunodeficiency syndrome[tw] OR acquired immunodeficiency syndrome[tw] OR acquired immunodeficiency syndrome[tw] OR acquired immunodeficiency syndrome[tw] OR ((acquired immun*) AND (deficiency syndrome[tw])) OR "Sexually Transmitted Diseases, Viral"[MeSH:NoExp]	193690
#2	Search randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized controlled trials [mh] OR random allocation [mh] OR double-blind method [mh] OR single-blind method [mh] OR clinical trial [pt] OR clinical trials [mh] OR ("clinical trial" [tw]) OR ((singl* [tw] OR doubl* [tw] OR trebl* [tw] OR tripl* [tw]) AND (mask* [tw] OR blind* [tw])) OR (placebos [mh] OR placebo* [tw] OR random* [tw] OR research design [mh:noexp] OR comparative study [mh] OR evaluation studies [mh] OR follow-up studies [mh] OR prospective studies [mh] OR control* [tw] OR prospectiv* [tw] OR volunteer* [tw]) NOT (animals [mh] NOT human [mh])	3040377
#3	Search HOME-BASED CARE OR HOMEBASED CARE OR HOME BASED CARE	7502
#4	Search HOME CARE OR HOMECARE OR HOME-CARE	111975

Table 1. MEDLINE search strategy (Continued)

#5	Search HOME	99148
#6	Search #3 OR #4 OR #5	174266
#7	Search #1 AND #2 AND#6	857
#8	Search #7 Field: All Fields, Limits: Publication Date from 1980 to 2005	856

Clinicaltrials.gov and the WHO International Clinical Trials Registry Platform were searched to identify ongoing trials.

Manual searches

The strategy was iterative, in that references of included studies were searched for additional references. Due to lack of access, handsearching was not performed of abstracts of the International Conference on HIV/AIDS in Africa (ICASA).

All languages were included.

Data collection and analysis

1. Selection of studies

Titles, abstracts and descriptor terms of the electronic search results were screened independently by two authors (TY and KB) for relevance based on the types of participants, interventions, and study design specified in the criteria for selecting studies for the review. Full text articles were obtained of all selected abstracts and an eligibility form was used to determine final study selection. Differences were resolved by discussions with the review mentor.

2. Risk of bias

The risk of bias of included studies was evaluated independently by the two authors (TY and KB).

- The likelihood of selection bias was assessed by evaluating the method of allocation sequence generation and the adequacy of allocation concealment.
- Performance bias was assessed by establishing if any additional interventions happened as well as looking at the presence or absence of blinding.
- Detection bias was assessed by evaluating the method of outcome assessment and whether the same method of ascertainment was used in both groups as well as assessing blinding.
- Attrition bias was assessed by looking at the follow up to see if at least 80% of participants in all groups were included in the final analysis and also if the description of those not included is suggestive of bias.

3. Data extraction

Data was extracted independently by 2 authors (TY and KB) using a standardised data extraction form. Any disagreements were

adjudicated by the review mentor. The following information was gathered from each included study:

Administrative details - Identification; author(s); published or unpublished; year of publication; year in which study was conducted; details of other relevant papers cited

Details of study - study design; method(s) of recruitment; inclusion and exclusion criteria; number of participants assessed for eligibility, number excluded, number enrolled, number analysed; type, duration, frequency and completeness of follow-up; country and location of the study; setting in which the study was performed (e.g. urban or rural); number of participants, characteristics of participants - age; education; socio-economic status.

Details of intervention - type of home-based care offered; by whom; frequency; etc

Details of outcomes - primary and secondary outcomes; effectiveness of intervention studied

Details of study ethics - informed consent obtained for participation; approving institution(s)

Missing or inadequate data were addressed by contacting authors.

4. Data analysis

Narrative synthesis of results were done. Relevant effect measures and the 95% confidence intervals (CI) were reported. In [Lule 2005](#), generalized estimating equation methods with an exchangeable correlation structure and an offset for the number of days at risk were used to control for intra-household and intra-individual disease clustering.

No meta-analysis was performed. In future updates, if possible, a meta-analysis will be undertaken to measure the appropriate measure of effect and 95% CI. Heterogeneity will be explored and if significant, subgroup analysis will be done for different type of carers, different models of home-based care and baseline disease stage i.e. WHO stages 1 or 2, which correlates with CD4 greater than 200, versus WHO stages 3 or 4 correlating with CD4 less than 200 ([French 1999](#)).

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Trial selection

The literature searches yielded 2472 titles of potentially relevant articles ([Table 2](#)). After screening these titles and abstracts, 25 full text articles were obtained for detailed evaluation of which 13 were eligible for inclusion ([Figure 1](#)). These 13 articles referred to 11 clinical trials. In addition, two ongoing trials being conducted in Uganda, Africa, were identified.

Figure 1. Flow diagram of study selection

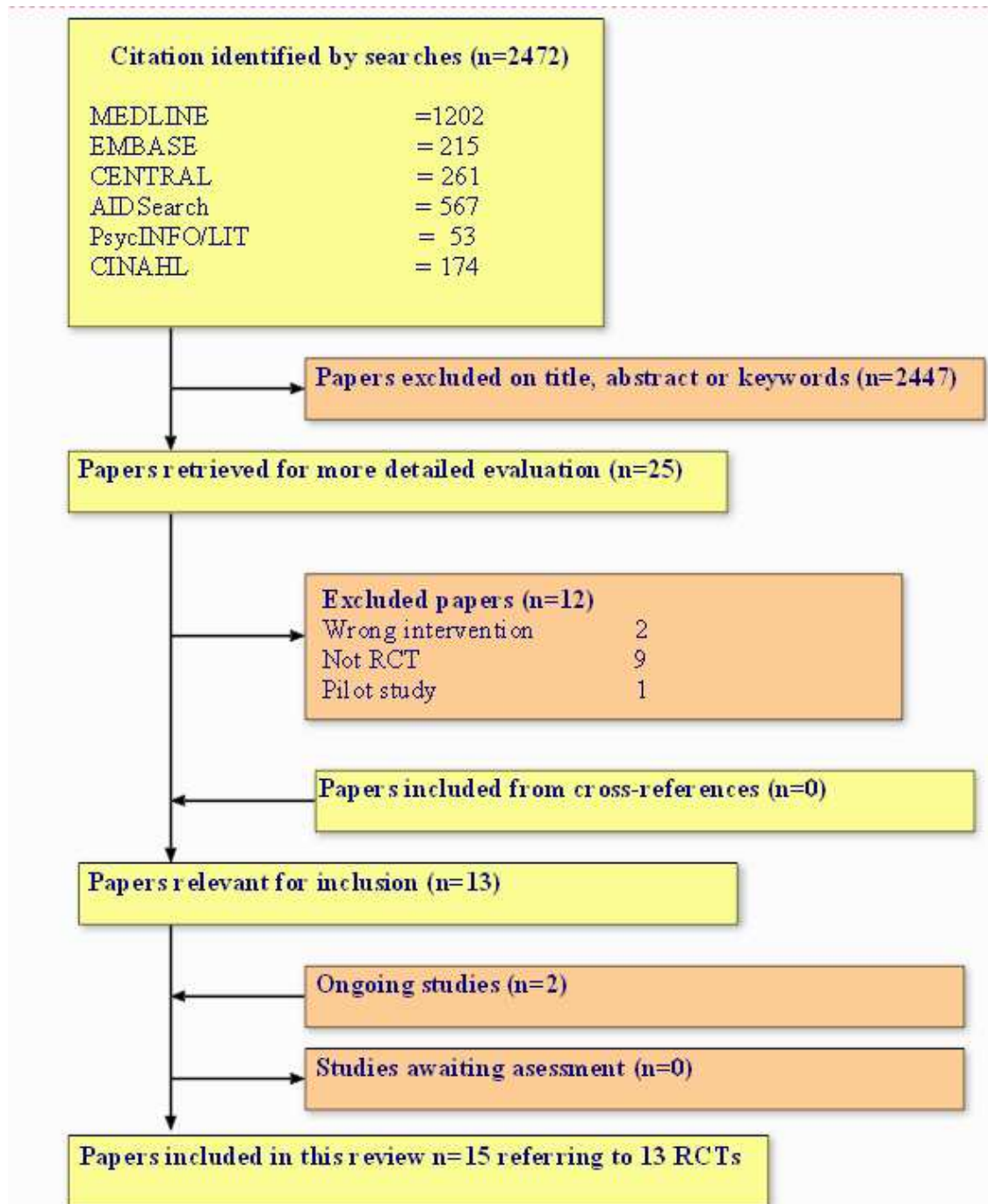


Table 2. Search results

Database	1980 - June'05	July'05 - March'07	April 07 - September 2008
MEDLINE	856	122	224
AIDSearch	314	27	226
EMBASE	157	34	24
CENTRAL	154	100	7
PsycINFO/LIT	53	Not done	Not done
CINAHL	174	Not done	Not done

Excluded studies

Twelve studies were excluded. Reasons for exclusion are detailed in the [Characteristics of excluded studies](#) table.

Included studies

Ten studies randomised individuals and trial sizes varied from n=31 to n=549. Another study, [Lule 2005](#), randomised 392 households and enrolled a total of 509 persons with HIV and 1,521 HIV-negative household members. Trials included both males and females, and only one trial ([Berrien 2004](#)) was conducted amongst children. Nine trials were conducted in USA, one in France ([Melchoir 1996](#)) and one in Uganda ([Lule 2005](#)).

The interventions studied and outcomes measured varied between studies ([Table 3](#)). Three trials compared home based nursing vs. standard care ([Berrien 2004](#); [Miles 2003](#); [Williams 2006](#)), two trials compared a trans-professional team vs. an independent primary nurse ([Cherin 1998](#); [Nickel 1996](#)), two trials evaluated computer vs. brochures/nothing/standard medical care ([Flatley-Brennan 1998](#); [Gustafson 1999](#)), one looked at home total parenteral nutrition compared to dietary counselling ([Melchoir 1996](#)), one examined the effect of home-based water chlorination and safe storage ([Lule 2005](#)) and two evaluated a home based exercise program ([Baigis 2002](#); [Dolan 2006](#)).

Table 3. Description of studies: Interventions and outcomes

Type of intervention	Number of studies	Study ID	Outcomes
Home based nursing v.s. standard care	1	Miles 2003	Emotional distress (depression, stigma, worry) and health related quality of life

Table 3. Description of studies: Interventions and outcomes (Continued)

	2	Berrien 2004 and Williams 2006	Changes in patients knowledge of HIV and meds; adherence; viral load and CD4
Transprofessional team v.s. independent primary nurse	1	Cherin 1998	Time in program, costs
	1	Nickel 1996	Quality of life and functioning
Computer v.s. brochures/nothing/standard medical care	2	Flatley-Brennan 1998 and Gustafson 1999	Perceived social isolation, decision making confidence, health status, quality of life, risk behaviors, health service utilization, CHES usage
Home total parenteral nutrition v.s. dietary counseling	1	Melchior 1996	Change in % of initial lean body mass and BCM, nutritional subjective global assessment, Karnofsky index, rate re-hospitalisation, adverse events
Exercise v.s. control	1	Baigis 2002	Physiological status; self reported physical functioning and wellbeing
	1	Dolan 2006	Cardiorespiratory fitness; strength; changes in body composition, biochemical measures (total cholesterol, low and high-density lipoprotein cholesterol, triglycerides, glucose, CD4, and HIV viral load) and dietary intake
Home-based water chlorination and safe storage	1	Lule 2005	Incidence and severity of diarrhoea

Detailed information on the participants, interventions, controls and outcomes are in the [Characteristics of included studies](#) table.

Ongoing studies

One ongoing study is comparing facility and home-based antiretroviral delivery systems ([NCT00144365](#)), while the other randomized study is evaluating strategies for monitoring antiretroviral therapy ([NCT00119093](#)).

Risk of bias in included studies

The risk of bias assessment is summarised in [Figure 2](#) and [Figure 3](#).

Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

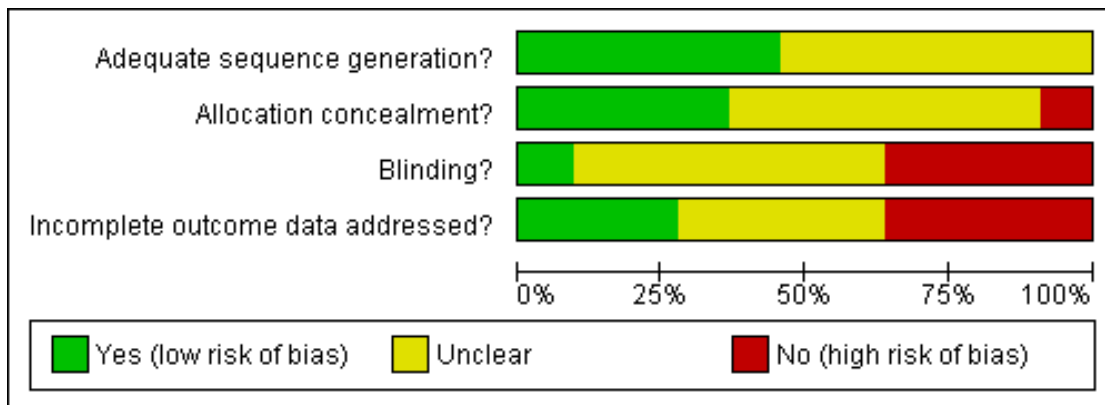


Figure 3. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Adequate sequence generation?	Allocation concealment?	Blinding?	Incomplete outcome data addressed?
Baigis 2002	?	+	-	-
Berrien 2004	+	+	-	+
Cherin 1998	+	-	?	?
Dolan 2006	?	?	?	+
Flatley-Brennan 1998	?	?	-	-
Gustafson 1999	+	+	?	?
Lule 2005	?	?	?	+
Melchoir 1996	?	+	-	?
Miles 2003	+	?	?	-
Nickel 1996	?	?	?	?
Williams 2006	+	?	+	-

Allocation generation

All trials stated that participants were randomised. Five trials used adequate methods for generating the allocation sequence (Berrien 2004; Cherin 1998; Gustafson 1999; Miles 2003; Williams 2006). Of these five trials, four used tables of random numbers and one used SAS programming (Williams 2006). Six trials did not describe how the allocation sequence was generated.

Allocation concealment

Allocation concealment was adequate in four trials (Baigis 2002; Berrien 2004; Gustafson 1999; Melchoir 1996), inadequate in one (Cherin 1998) and not reported in the remaining six trials.

Blinding

In Williams 2006 all personnel (except the home visit intervention team) and the interviewers were blind throughout course of study whereas in Miles 2003 the data collectors were blinded. Four trials used no blinding (Baigis 2002; Berrien 2004; Flatley-Brennan 1998; Melchoir 1996) and the other five did not report blinding.

Loss to follow-up

Four trials reported loss to follow-up of less than 20% (Berrien 2004; Dolan 2006; Flatley-Brennan 1998; Gustafson 1999).

Effects of interventions

1. Home based intensive nursing vs. standard care

1.1 Two studies, one in adults (Williams 2006) and one in children (Berrien 2004), examined the effects of an intensive nursing programme compared to standard care on patients knowledge of HIV and related medication, adherence, viral load and CD4 counts.

Berrien 2004 offered eight structured home visits over a 3-month period by the same home care experienced registered nurse. The intervention was designed to improve knowledge and understanding of HIV infection and HIV medications and to resolve or modify barriers to adherence. Standard care, in the clinic setting, included the physician, nurse, and social worker providing standard medication adherence education. The intensive home based nursing intervention significantly improved self reported patient knowledge of HIV and medications when comparing both post test scores (n=37, WMD 2.5, 95%CI 2.14 to 2.86, Analysis 1.1), and change scores (n=37, WMD 2.8, 95%CI 2.23 to 3.37, Analysis 1.2). Self reported adherence to medication was significantly different (n=37, WMD 2.9, 95%CI 2.39 to 3.41, Analysis 1.3) as well as the difference in pharmacy drug refill (reported p=0.002). There were no significant differences in CD4 counts or viral loads. Williams 2006 (n=171) examined the effects of an adherence intervention which included social and educational components. Adherence was measured as the ratio of the number of recorded Medication Event Monitoring Systems cap (MEMS cap) openings to the number of openings to be expected if the medication were taken as prescribed. The median CD4 counts were 345 and 341 for the intervention and control arms respectively. Comparing the proportion of participants with greater than 90% adherence,

there was a statistically significant difference between the two arms over time (reported extended Mantel-Haensel test 5.80, p=0.02). There was no significant change in CD4 counts and viral loads.

1.2 One study (Miles 2003) assessed the impact on emotional distress (depression, stigma, worry) and health related quality of life.

The intervention was conducted by three nurses in the homes of African American women with HIV who were primary caregivers for at least one child under the age of nine years. The content and process for each visit involved four phases. The intervention was embedded in a therapeutic relationship between the mother and the nurse. Relationship strategies included (a) accepting the woman and her family, (b) valuing her perspectives about the management of her illness, (c) listening to and reflecting feelings, and (d) reinforcing the steps the woman took to improve her life and the lives of her family. A semi-structured clinical interview based on the goals of the intervention was used, but was driven by the mother's specific concerns and needs. The control group received usual care that involved health visits for primary care and specialty visits for HIV related care, although most of the women got all their care at the tertiary care HIV clinics. At these clinics, the focus of care was on health problems rather than self-care symptom management. Both clinics did offer assistance with social problems and transportation.

Considering the scores at 6 months (n=109) there was a statistically significant difference in HIV stigma (WMD -0.25, 95%CI -0.49 to -0.01), HIV worry (WMD -0.46, 95%CI -0.89 to -0.03) and physical functioning (WMD 1.45, 95%CI 0.01 to 2.89). No statistically significant difference was found for depressive symptoms, mood, general health, and overall functioning.

2. Trans-professional team vs. independent primary nurse

2.1 Nickel 1996 assessed quality of life and survival.

Comprehensive case management by a trans-professional team, as detailed in the table of included studies, was compared with usual care by the primary care nurse. After 6 months of follow-up (n=57) there were no significant differences in quality of life scores or the survival curves.

2.2 Cherin 1998 assessed the time in program and cost

An interdisciplinary team care management approach including curative as well as palliative care were compared to independent services primarily nurse driven with the focus on curative rather than palliative care. There was no significant difference in average length of time on service (n=549).

3. Computer vs. brochures/nothing/standard medical care

Three studies evaluated perceived social isolation, decision making confidence, health status, quality of life, risk behaviors, health service utilization, and Comprehensive Health Enhancement Support System (CHESS) usage.

Flatley-Brennan 1998 (n=57) provided information, communication and decision support via a computer in the homes of people

living with AIDS and compared it with printed brochures and monthly telephone calls. There were no significant effect on health status, and decision making confidence and skill. There was a reduction in social isolation if controlling for depression.

Gustafson 1999 (n=204) installed the CHES for 3-6 months in the home and compared it to no intervention. With regard to quality of life there were increased cognitive functioning, sense of social support, more active life, and reduced negative emotions. There was no significant difference in depression, physical functioning and level of energy. Also no significant change in sex risk behavior. At 6 months there were increased attitudes toward risk behavior and toward disclosure of HIV status. Related to health service utilization there were no significant change in number of out patient visits but a reduced time spent with providers as well as a significantly reduced probability of admission.

4. Exercise

Baigis 2002 (n=123) compared 20 minute work out on a fitness master ski machine brought by a nurse or trainer three times per week to a 30 minute visit per week over 15 weeks. They found no significant difference in physical endurance, immune status, and self reported physical functioning and well being between the two groups.

Dolan 2006 (n=40) compared a supervised home-based progressive resistance training and aerobic exercise program to no intervention over 16 weeks. In both groups more than 80% of participants were receiving antiretroviral therapy. The change in VO_2 max at 16 weeks was significant (1.5 ± 0.8 vs -2.5 ± 1.6 mL/kg/min; $p < 0.001$). Strength measured by change in 1-repetition maximum increased significantly at the knee extensors, pectoralis, knee flexors, shoulder abductors, ankle plantar flexors, elbow flexors (right), and elbow flexors (left). Body mass index, abdominal and total fat did not change between groups. Waist circumference decreased more in the exercise-treated group than in the control group (-1.0 ± 0.6 vs 1.5 ± 1.0 cm; $p = 0.03$). No significant difference was seen in lipid levels, glucose, CD4 count, viral load, or blood pressure. Eighty nine percent of the exercise group compared to 16% of the control group self-reported a change in their cardiovascular health in the past 4 months. Dietary intake of total calories, fat, carbohydrate, and protein did not differ over time between the treatment groups.

5. Two months home total parenteral nutrition vs. dietary counselling

One study (**Melchoir 1996**) n=31 examined the effect of home total parenteral nutrition (TPN) via central venous line by cyclic nocturnal administration 6 days weekly with that of oral dietetic supplements and vitamins. There was a significant change in lean body mass and body cell mass. The nutritional subjective global assessment, and subjective health feeling and functioning (as mea-

sured by the Karnofsky index) were also improved by TPN. Overall survival and rate of re-hospitalisation were not significantly different. No TPN related severe complications were observed.

6. Home-based water chlorination and safe storage

Lule 2005 compared the effect of home-based water chlorination and safe storage and education to education only in a cluster RCT. Among those with HIV, the intervention was associated with a 25% reduction in diarrhea episodes (adjusted rate ratio 0.75; 95% CI 0.59 to 0.94) and 33% fewer days with diarrhea (adjusted rate ratio 0.67; 95% CI 0.48 to 0.94).

DISCUSSION

Summary of main results

Intensive home-based nursing significantly improved self-reported knowledge of HIV and medications, self-reported adherence and difference in pharmacy drug refill (1 study). Another study, comparing proportion of participants with greater than 90% adherence, found statistically significant differences over time but no significant change in CD4 counts and viral loads. A third study found significant differences in HIV stigma, worry and physical functioning but no differences in depressive symptoms, mood, general health, and overall functioning. Comprehensive case management by trans-professional teams compared to usual care by primary care nurses had no significant difference in quality-of-life after 6-months of follow-up (n=57) and average length of time on service (n=549). Home total parenteral nutrition had no significant impact on overall survival and rate of re-hospitalisation. Two trials comparing computers with brochures/nothing/standard medical care found no significant effect on health status, and decision-making confidence and skill, but a reduction in social isolation after controlling for depression. Two studies evaluating home exercise programmes found opposing results. Home-based safe water systems reduced diarrhea frequency and severity among persons with HIV in Africa.

Overall completeness and applicability of evidence

Any RCT investigating the effect of home-based care, provided by family, lay and/or professional people, including all forms of treatment, care and support offered in the HIV/AIDS positive person's home as compared to hospital or institutional based care were eligible for inclusion in this review. Care offered in outreach settings other than the home was not included. Eleven completed and two ongoing studies investigating a range of interventions were included. Studies were generally small and very few studies were done in developing countries. None of the studies addressed the primary outcomes (death and progression to AIDS) stated in

protocol. Furthermore, comparisons included studies comparing either two different approaches to delivering care or single interventions compared to no intervention or a control, whereas the protocol originally stated that the studies should be of an intervention versus hospital or institutional care. The review did not include outcomes related to the carers or family.

As a result, the conclusions which can be drawn from this review are limited. Furthermore, the evidence base of how home-based care fits into the current treatment context, especially in low resource countries, need further development.

Quality of the evidence

Assessment of risk of bias was hampered by incomplete data in more than half of the included studies. Allocation generation was adequate in five studies while allocation concealment was only adequate in four studies. Blinding was not feasible for the types of interventions studied and only two studies reported blinding of personnel and data collectors respectively. Four studies reported loss to follow-up of less than 20%.

Potential biases in the review process

A comprehensive search was done to identify published and unpublished literature to avoid publication bias. All languages were included. To avoid selection bias two authors worked independently to select studies and perform data extraction.

Agreements and disagreements with other studies or reviews

This review provides additional information to existing reviews (Hedrick 1989, Elkan 2001, Hughes 1997, Smeenk 1998) which focused on the effects of home care in general. Hedrick 1989 reviewed 13 studies on the effects of home care on mortality and nursing-home placements. The analysis demonstrated a small beneficial, but statistically insignificant, effect of home care on mortality and nursing-home placements. Similarly, Elkan 2001 found that home visits to older people can reduce mortality and admission to long term institutional care. Hughes 1997 examined the impact of home care on hospital days. The effect on the reduction of hospital days tended to be larger in studies with terminally-ill patients, with quasi-experimental designs, and when the impact

was measured at six months or less versus measuring impact at greater than six months. In contrast, Smeenk 1998 concluded that the effectiveness of home care programmes for patients with terminal cancer remains unclear.

AUTHORS' CONCLUSIONS

Implications for practice

The results indicate that intensive home-based nursing significantly improved self-reported knowledge of HIV and medications, self-reported adherence and difference in pharmacy drug refill. It also significantly impacted on HIV stigma, worry and physical functioning but not depressive symptoms, mood, general health, and overall functioning. Comprehensive case management by trans-professional teams and that provided by primary care nurses had the same impact in the short term. Home-based safe water systems reduced diarrhea frequency and severity among persons with HIV in Africa. Considerations for practice should recognise that none of the included studies evaluated death or progression to AIDS.

Implications for research

Studies were generally small and very few studies were done in developing countries. There was a lack of studies truly looking at the effect of home based care itself or looking at significant end points (death and progression to AIDS). Further large studies should therefore focus on evaluating these significant end points, on feasible interventions for developing countries and on how home-based care fits into the current treatment context.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Baigis 2002

Methods	Allocation generation: Reported that stratified block randomization using gender as the stratifying variable was used however not how this was generated. Allocation concealment: Yes Blinding: None Loss to follow-up: 30% - control 17% - intervention
Participants	Included: 18 years or older; HIV+; CD4 count 200-500/mm ³ ; No AIDS-defining conditions; no report of regular aerobic conditioning program in prior 3 months; residence in greater Washington DC area Excluded: Presence of absolute or relative contraindications to exercise testing as outlined by American College of Sports Medicine
Interventions	Intervention: 20-minute workout on FM 340 Fitness Master Ski machine brought by nurse/trainer to individual's home three times per week. Control: 30-minute visit per week from study personnel to pick up completed diary sheets and provide social contact. In addition two phone calls per week to check on participant's health by asking standard questions. Duration of treatment 15 weeks
Outcomes	Primary: Physiologic status (physical endurance, immune status) and self-reported physical functioning and well-being Secondary: None
Notes	Location of trial: USA Ethics: Georgetown University and Whitman-Walker clinic in Washington DC and John Hopkins University of Baltimore, Maryland Informed consent: written

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Reported that stratified block randomization using gender as the stratifying variable was used however not how this was generated.
Allocation concealment?	Yes	A - Adequate
Blinding? All outcomes	No	None

Baigis 2002 (Continued)

Incomplete outcome data addressed? All outcomes	No	Loss to follow-up: 30% - control 17% - intervention
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Berrien 2004

Methods	Allocation generation: Randomized 1:1 to either intervention or control group using the Small Table of Random digits. Allocation concealment: yes Blinding: None Loss to follow-up: 5% - Intervention 11% - Control
Participants	Included: HIV+ children Excluded: Not reported
Interventions	Intervention: The intervention consisted of eight structured home visits over a 3-month period by the same home care experienced registered nurse. The intervention was designed to improve knowledge and understanding of HIV infection and HIV medications and to resolve or modify barriers to adherence. Control: In the clinic setting, the physician, nurse, and social worker provided standard medication adherence education. Patient clinic appointments were generally scheduled at 3-month intervals. One single home visit was planned when and if clinic staff believed medication adherence was poor.
Outcomes	Primary: Changes in patient knowledge of HIV and their medications Changes in adherence measured by self-report and pharmacy drug refill history Secondary: Changes in viral load (Roche Amplicor HIV-1 Monitor Test) and CD4 T-cell percentages and counts.
Notes	Location of trial: Connecticut, USA Ethics: Connecticut Children's Medical Center's Human Subjects Review Board Informed consent: Consent from legal guardian obtained. Assent was obtained from all minors older than 7 years of age.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomized 1:1 to either intervention or control group using the Small Table of Random digits.
Allocation concealment?	Yes	A - Adequate
Blinding? All outcomes	No	none

Berrien 2004 (Continued)

Incomplete outcome data addressed? All outcomes	Yes	5% - Intervention 11% - Control
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Cherin 1998

Methods	Allocation generation: Random number charts were used Allocation concealment: numbers on the charts were designated as either experimental or control group Blinding: not reported Loss to follow-up: not reported
Participants	Included: AIDS patients who were referred to Visiting Nurses Association of Los Angeles Excluded: criteria not reported
Interventions	Intervention: trans-professional care management approach offering an interdisciplinary care management approach covering both curative and palliative services Control: Independent services primarily nurse driven with a focus on curative rather than palliative Duration: 20 months
Outcomes	Primary: Patterns of retention in services Secondary: Time in the programme, units of services, costs of services, number of days patient retained in the programme
Notes	Location of trial: Los Angeles, USA Ethics: not reported Informed consent: written

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random number charts were used
Allocation concealment?	No	C - Inadequate
Blinding? All outcomes	Unclear	not reported
Incomplete outcome data addressed? All outcomes	Unclear	not reported

Dolan 2006

Methods	<p>Allocation generation: Randomization to the exercise program was performed by the General Clinical Research Center Biostatistics Center, using a permuted block algorithm.</p> <p>Allocation concealment: not reported</p> <p>Blinding: no blinding</p> <p>Loss to follow-up: 5% - Intervention 5% - Control</p>	
Participants	<p>Included: Consecutive HIV-infected subjects between 18 and 60 years of age with a waist-hip ratio of 0.85 or more and self-report and physical evidence of fat redistribution were eligible for participation.</p> <p>Excluded: Subjects who used megestrol acetate, androgens, growth hormone, or glucocorticoid therapy; who had significant liver or kidney disease or severe anemia; who were receiving current therapy with insulin, had a history of diabetes mellitus, or had a fasting glucose level of 126 mg/dL (7.0 mmol/L) or more; who actively engaged in substance abuse; who were pregnant, actively seeking pregnancy, or breastfeeding; or who had had an acute infection or initiated a new antiretroviral therapy regimen within 1 month of the study.</p>	
Interventions	<p>Intervention: Subjects randomized to exercise training were seen in their homes by a member of the study staff 3 times a week, on alternating days, for 16 weeks (48 sessions, 2 hours per session, with makeup sessions scheduled for missed sessions). Required exercise equipment for home use was provided to each subject randomized to the exercise regimen. Equipment included an upright stationary bicycle, a flexion-extension bench, a free-standing squat stand, weight sets, and a heart monitor. Each training session began with a 5-minute warm-up on a stationary bicycle at 50% of estimated maximal heart rate (maximal heart rate = 220 – age), followed by a standard flexibility routine to minimize the risk of injury. Subsequently, the supervised aerobic and strength training protocol was performed, followed by a cool-down period.</p> <p>Control: Subjects not randomized to the exercise program were encouraged to maintain their normal activities, without further proscription as to activity.</p>	
Outcomes	<p>Cardiorespiratory fitness as measured by VO₂max</p> <p>Strength measured by 1-repetition maximum</p> <p>Changes in body composition, biochemical measures (total cholesterol, low and high-density lipoprotein cholesterol, triglycerides, glucose, CD4, and HIV viral load) and dietary intake</p>	
Notes	<p>Location of trial: Boston, USA</p> <p>Ethics: The study was approved by the Human Research Committee at Massachusetts General Hospital.</p> <p>Informed consent: Written</p>	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomization to the exercise program was performed by the General Clinical Re-

Dolan 2006 (Continued)

		search Center Biostatistics Center, using a permuted block algorithm.
Allocation concealment?	Unclear	not reported
Blinding? All outcomes	Unclear	none
Incomplete outcome data addressed? All outcomes	Yes	Loss to follow-up: 5% - Intervention 5% - Control

Flatley-Brennan 1998

Methods	Allocation generation: Unclear. Mention that a 2-group randomized design was used. Allocation concealment: Not reported Blinding: No Loss to follow-up: 19% - Intervention 12% - Control
Participants	Included: Persons living with AIDS; Ability to read and type English language and have a private telephone line in their residence Excluded: None
Interventions	Special computer network: Using computerLink, information, communication and design support were provided via computer terminals placed in the homes of PLWA; Duration 6 months Placebo: Printed brochures and a monthly telephone call to maintain contact with the research staff; Duration 6 months
Outcomes	Primary: Improved decision confidence; improved decision making skill; reduced social isolation; differential decline in health status Secondary: None
Notes	Location of trial: Cleveland, Ohio, USA Ethics: Unclear Informed consent: Yes but not reported how

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Mention that a 2-group randomized design was used.
Allocation concealment?	Unclear	B - Unclear

Flatley-Brennan 1998 (Continued)

Blinding? All outcomes	No	No
Incomplete outcome data addressed? All outcomes	No	Loss to follow-up: 19% - Intervention 12% - Control

Gustafson 1999

Methods	Allocation generation: Tables of random digits; third party Allocation concealment: Yes Blinding: not reported Loss to follow-up: 12% - Intervention 12% - Control
Participants	Included: HIV positive Excluded: None
Interventions	CHES: Receive Comprehensive Health Enhancement Support System (CHES) which is a PC based system offering the following services - - Questions & Answers - Instant Library includes full-text articles covering a broad range of topics drawn from scientific journals, newsletters, and the popular press. - Getting Help/Support contains descriptions of approximately 300 relevant health services, ways to find a provider, and how to be an effective consumer. - Referral Directory has descriptions and ways to contact a set of national services that offer information, support, and referrals of value on the health problem. - Assessment asks questions about a person's life style, assesses the risk, and offers specific advice on how he/she can reduce his/her risks. - Decision Aid helps patients think through difficult decisions. Users learn about the options, clarify their values, the consequences of their actions, and the misconceptions they have. - Action Plan helps users plan how to successfully implement decisions. They identify goals and resources, and learn how to overcome obstacles. - Discussion Groups are facilitated online support groups allowing patients and families with similar problems to share information and support. - Ask an Expert allows patients to write a question and receive confidential responses from experts. - Personal Stories are real-life accounts of people with similar problems, living and coping with their illness. Control: Standard medical treatment
Outcomes	Primary: Effects on quality of life; Health services utilization; health behaviours Secondary: None
Notes	Location of trial: Southern Wisconsin, USA Ethics: Yes; Not stated Informed consent: Written; Signed an informed consent

Gustafson 1999 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Tables of random digits; third party
Allocation concealment?	Yes	A - Adequate
Blinding? All outcomes	Unclear	Not reported
Incomplete outcome data addressed? All outcomes	Unclear	Loss to follow-up: 12% - Intervention 12% - Control

Lule 2005

Methods	Allocation generation: not reported Allocation concealment: not reported Blinding: no Loss to follow-up: unclear
Participants	Persons with HIV-1 infection who were clients of The AIDS Support Organization (TASO) in the rural Tororo district in Uganda and without access to chlorinated municipality water were consecutively enrolled in the study. A household was defined as persons who shared a hearth and slept in the same house or cluster of houses for at least five days of the week for the preceding three months. Seventy-four percent of the persons with HIV were female and median age was 34 years (interquartile range [IQR] 28-40 years); 27 (5%) were less than five years old. At baseline, 27% of the persons with HIV had CD4 cell counts < 200 cells/mm ³ , 37% had CD4 cell counts of 200-500 cells/mm ³ , and 36% had CD4 cell counts > 500 cells/mm ³ . No one was on anti-retrovirals.
Interventions	Intervention: 20-liter polyethylene vessel with a narrow mouth and a spigot (Nampak Co., Johannesburg, South Africa), one 500-mL bottle of 0.5% sodium hypochlorite solution, a cloth, and basic hygiene education. Field workers educated participants in the intervention group how to use the SWS, and replenished the solution as needed during weekly visits. Control: Education alone. Field workers instructed both intervention and comparison households on hygiene and sanitation. After five months, all participants with HIV were provided cotrimoxazole prophylaxis, and data on the incidence of diarrhea continued to be collected until the end of November 2002.
Outcomes	Incidence and severity of diarrhoea

Lule 2005 (Continued)

Notes	Location of trial: Uganda Ethics: The study was reviewed and approved by the Science and Ethics Committee of the Uganda Virus Research Institute, the Uganda National Council of Science and Technology, and the Institutional Review Board of CDC. Informed consent: Written
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Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	not reported
Allocation concealment?	Unclear	not reported
Blinding? All outcomes	Unclear	no
Incomplete outcome data addressed? All outcomes	Yes	intention to treat analysis was performed

Melchoir 1996

Methods	Allocation generation: stratified by Centre however unclear how allocation sequence was generated Allocation concealment: centralised telephone assignment procedure used Blinding: none Loss to follow-up: not reported
Participants	Included: HIV positive, CD4 < 200 X 106/l, either sex, between 18 and 60 years of age, body weight loss > 10% (compared to pre-illness weight), diarrhoea (more than three stools per day during three consecutive days) or impossibility of enteral nutrition or both. Excluded: injecting drug users, heavy alcohol drinkers (>100g/d), lymphoma or kaposi's sarcoma under chemotherapy, active secondary infection, major neurological/endocrine/psychiatric disturbance, cardiac/renal or hepatic failure, total parenteral nutrition at home not feasible for psychological or social reasons, if body weight increased by at least 2kg during the month prior to the study
Interventions	Intervention: Home total parenteral nutrition via central venous line by cyclic nocturnal administration 6 days weekly Control: oral dietetic supplements and vitamins
Outcomes	Primary: change as % of initial lean body mass and BCM, nutritional subjective global assessment and change in subjective health feeling and functional status (karnofsky index) Secondary: overall survival, rate re-hospitalisation during 2 month study, incidence of TPN complications

Melchoir 1996 (Continued)

Notes	Location of trial: France Ethics: Bicaht-Claude Bernard hospital Informed consent: written	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Stratified by Centre however unclear how allocation sequence was generated
Allocation concealment?	Yes	A - Adequate
Blinding? All outcomes	No	None
Incomplete outcome data addressed? All outcomes	Unclear	not reported

Miles 2003

Methods	Allocation generation: Table of random numbers Allocation concealment: not reported Blinding: Data collectors Loss to follow-up: 6 months 51% - Intervention 58% - Control
Participants	Included: African American women with HIV who were primary caregivers for at least one child under the age of 9 years Excluded: not reported
Interventions	Intervention: conducted in the homes of the women by three nurses. The content and process for each visit involved four phases. Intervention was embedded in a therapeutic relationship between the mother and the nurse. Relationship strategies included (a) accepting the woman and her family, (b) valuing her perspectives about the management of her illness, (c) listening to and reflecting feelings, and (d) reinforcing the steps the woman took to improve her life and the lives of her family. A semi-structured clinical interview based on the goals of the intervention was used, but was driven by the mother's specific concerns and needs. Control: received usual care that involved health visits for primary care and specialty visits for HIV related care, although most of the women got all their care at the tertiary care HIV clinics. At these clinics, the focus of care was on health problems rather than self-care symptom management. Both clinics did offer assistance with social problems and transportation.
Outcomes	Emotional distress (depressive symptoms, affective state, stigma, and worry about HIV) Self reported health (number of infections and aspects of health related quality of life)

Miles 2003 (Continued)

	i.e., perception of health, physical function, energy, health distress, and role function). Did not specify which were primary and which secondary. Center for Epidemiologic Studies Depression scale was used to assess depressive symptoms. Profile of Mood States was used to assess mood or general affective state. Stigma was measured using the Demi HIV Stigma Scale. The HIV Worry Scale was designed to assess distress related to worry regarding HIV. Besides the latter scale, all the others had good validity. The number of infections was derived from self-report using a Health Questionnaire (number of infections experienced over past 3 months; specific types of infections were listed). The Medical Outcomes Survey-HIV measured aspects of health quality of life including perception of health, physical function, energy, health distress, and role function.	
Notes	Location of trial: USA Ethics: Approval received from institutional review boards of the respective clinics and agencies. Informed consent: written	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Table of random numbers
Allocation concealment?	Unclear	D - Not used
Blinding? All outcomes	Unclear	Data collectors blinded
Incomplete outcome data addressed? All outcomes	No	Loss to follow-up: 6 months 51% - Intervention 58% - Control

Nickel 1996

Methods	Allocation generation: unclear. Mention that participants were randomly assigned and stratified by agency in preceeded blocks of two. Allocation concealment: Not reported Blinding: Not reported Loss to follow-up: Not reported
Participants	Included: HIV/AIDS patients; had to be part of the 7 participating agencies; Hospice patients Excluded: < 21 years of age; nearing death at the time of the case manager's first visit; refusal of homecare services; lack of confirmed HIV+ diagnosis
Interventions	Case-managed: comprehensive patient assessment by the nurse case managers; care planning with monthly care review by an interdisciplinary team consisting of nurse case managers, agency home care nurse, infectious disease and public health physicians, a social worker, psychiatrist, nutritionist, member of clergy, pharmacist and dentist; twice

Nickel 1996 (Continued)

	- monthly review of subject needs and services by a team core group consisting of the case manager, social worker and public health physician; ongoing case manager community networking for and authorisation of services; ongoing case management observation and monitoring of subject reports on service quality Usual care: care provided by agency nurses who provided care to AIDS patients through procedures comparable to those for patients with other diagnoses.
Outcomes	Primary: Difference in mean group; Quality of well-being scores as measured by Quality of well-being scale Secondary: Functioning
Notes	Location of trial: USA Ethics: Unclear; Not reported Informed consent: Not reported

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Mention that participants were randomly assigned and stratified by agency in pre-eded blocks of two.
Allocation concealment?	Unclear	B - Unclear
Blinding? All outcomes	Unclear	Not reported
Incomplete outcome data addressed? All outcomes	Unclear	Not reported

Williams 2006

Methods	Allocation generation: stratified block randomization with a block size of 10. The three strata were < 400 copies/mL, 400-10,000 copies/mL and >10,000 copies/mL. SAS programming was used Allocation concealment: not reported Blinding: All personnel except home visit intervention team were blind throughout course of study. Interviewers were also blind. Loss to follow-up: at 12 months 28% - Intervention 25% - Control
Participants	Included: HIV positive on combination therapy with at least three drugs, intended to take the medication and English or Spanish speaking Excluded: Severe cognitive impairment, no home, not personally responsible for medication self administration, enrolled into another study for medication adherence and did not intend to take the medication

Williams 2006 (Continued)

Interventions	Intervention: Home based nursing intervention (included social and educational components offered by a nurse and community support worker) and standard care Control: standard care (HIV dedicated clinical services which offered clinic based adherence support)
Outcomes	Primary: Adherence measured as the ratio of the number of recorded MEMS cap openings to the number of openings to be expected if the medication were taken as prescribed Secondary: HIV RNA, CD4
Notes	Location of trial: USA Ethics: approval obtained from the Human subjects investigation committee of Yale school of nursing and all recruitment sites Informed consent: written

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Stratified block randomization with a block size of 10. The three strata were < 400 copies/mL, 400-10,000 copies/mL and >10,000 copies/mL. SAS programming was used
Allocation concealment?	Unclear	D - Not used
Blinding? All outcomes	Yes	All personnel except home visit intervention team were blind throughout course of study. Interviewers were also blind.
Incomplete outcome data addressed? All outcomes	No	Loss to follow-up: at 12 months 28% - Intervention 25% - Control

Characteristics of excluded studies *[ordered by study ID]*

Antoni 2000	The intervention studied was not home-based care.
Brennan 1994	Not a randomised controlled trial
Choy 1990	Not a randomised controlled trial
Colford 2005	Pilot randomised controlled trial with primary outcomes to confirm that enrolment and participation rates will be high, and to replicate earlier results that blinding can be achieved in drinking water trials.
Holzemer 2000	Not a randomised controlled trial
Kraak 1995	Not a randomised controlled trial
Leibowitz 1992	Not a randomised controlled trial
Morales 1994	Not a randomised controlled trial
Ndekha 2005	Not a randomised controlled trial
Sandige 2004	Not a randomised controlled trial
Singer 1997	The intervention studied was not home-based care.
Sjolander 1988	Not a randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

NCT00119093

Trial name or title	Home-Based AIDS Care Project
Methods	The Home-based AIDS care program (HBAC) pilot project was designed to deliver and monitor ARV and tuberculosis (TB) medications at the homes of 1,000 people with HIV living in a rural area of Uganda. Nested within the Home-Based AIDS Care (HBAC) project, is a randomized study of strategies for monitoring ARV therapy that involves 3 arms: 1) Quarterly CD4 cell counts, viral loads and home visits by trained lay persons; 2) Quarterly CD4 cell counts and home visits; and 3) Home visits alone.
Participants	Inclusion Criteria: <ul style="list-style-type: none"> • HIV infection • CD4 cell count <250 or symptomatic AIDS • Age >13 years • Karnofsky score >40% • AST or ALT < 5 times normal values • Creatinine clearance >25 ml/min
Interventions	Strategies for monitoring ARV therapy that involves 3 arms: <ol style="list-style-type: none"> 1) Quarterly CD4 cell counts, viral loads and home visits by trained lay persons; 2) Quarterly CD4 cell counts and home visits; and 3) Home visits alone.
Outcomes	Primary Outcome Measures: <ul style="list-style-type: none"> • Equivalence of 3 different monitoring regimens for ART Secondary Outcome Measures: <ul style="list-style-type: none"> • Sexual risk behavior • medication adherence • quality of life • depression • cost-effectiveness • viral load • CD4 cell count
Starting date	May 2003
Contact information	Jordan Tappero jwt0@cdc.gov Jonathan Mermin jhm7@cdc.gov
Notes	

NCT00144365

Trial name or title	Comparison of Facility and Home-Based ART Delivery Systems in Uganda
Methods	The trial is conducted with The AIDS Support Organization (TASO) clinic in Jinja, Uganda. Randomization is conducted through geographic clusters, defined using sub-counties in the district, and stratified by distance from fixed health facilities, and urban/rural. Just over 800 participants, living in 40 clusters, will be recruited over a period of 3-6 months and followed-up over a period of 3 years.

Participants	<p>Inclusion Criteria: HIV infection Plan to remain resident in the area for at least 12 months CD4 cell count <200 cells/mm³ or severe symptomatic HIV (WHO stage 3 or 4) Identify a medicine companion who will assist in adherence to ART treatment Age 18 years or above.</p> <p>Exclusion Criteria: Abnormal liver and renal function test results (AST or ALT 5x upper limit of normal Calculated creatinine clearance < 25 ml/min). The tests are conducted only in individuals in whom they are clinically indicated</p>
Interventions	<p>The study compares ART delivery through two different models: a) ART delivered through health facilities by clinically qualified staff and b) home-based care in which lay workers, i.e. non-medically qualified people, play a major role in the ART delivery and clients are followed up at health facilities less frequently.</p>
Outcomes	<p>Primary Outcome Measures:</p> <ul style="list-style-type: none"> ● HIV viral load <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none"> ● Medication adherence ● Treatment failure ● Morbidity ● Survival ● Sexual behavior ● Family member HIV testing ● Cost-effectiveness
Starting date	February 2005
Contact information	Rebecca Bunnell rrb7@cdc.gov Shabbar Jaffar Shabbar.Jaffar@lshtm.ac.uk
Notes	

DATA AND ANALYSES

Comparison 1. Home based intensive nursing v.s. standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Changes in patient knowledge of HIV and their medications: Post test scores	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2 Changes in patient knowledge of HIV and their medications: change scores	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3 Changes in adherence: self report	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Analysis 1.1. Comparison 1 Home based intensive nursing v.s. standard care, Outcome 1 Changes in patient knowledge of HIV and their medications: Post test scores.

Review: Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS

Comparison: 1 Home based intensive nursing v.s. standard care

Outcome: 1 Changes in patient knowledge of HIV and their medications: Post test scores

Study or subgroup	Treatment		Control		Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
	N	Mean(SD)	N	Mean(SD)		
Berrien 2004	20	26.4 (0.22)	17	23.9 (0.72)	+	2.50 [2.14, 2.86]

Analysis 1.2. Comparison 1 Home based intensive nursing v.s. standard care, Outcome 2 Changes in patient knowledge of HIV and their medications: change scores.

Review: Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS

Comparison: 1 Home based intensive nursing v.s. standard care

Outcome: 2 Changes in patient knowledge of HIV and their medications: change scores

Study or subgroup	Treatment		Control		Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
	N	Mean(SD)	N	Mean(SD)		
Berrien 2004	20	4.5 (0.71)	17	1.7 (1)	++	2.80 [2.23, 3.37]

Analysis 1.3. Comparison 1 Home based intensive nursing v.s. standard care, Outcome 3 Changes in adherence: self report.

Review: Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS

Comparison: 1 Home based intensive nursing v.s. standard care

Outcome: 3 Changes in adherence: self report

Study or subgroup	Treatment		Control		Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
	N	Mean(SD)	N	Mean(SD)		
Berrien 2004	20	34.8 (0.41)	17	31.9 (1)	++	2.90 [2.39, 3.41]

HISTORY

Protocol first published: Issue 3, 2005

Review first published: Issue 1, 2010

11 April 2008	Amended	Converted to new review format.
20 May 2005	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Taryn Young (TY) wrote the protocol. TY and Karishma Busgeeth (KB) reviewed the search results and selected potential studies for inclusion. TY and KB then worked independently to do a formal eligibility assessment and then extracted data from included studies. TY wrote the review and KB provided input.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Cochrane HIV/AIDS mentoring programme, South Africa.
- South African Cochrane Centre, South Africa.

External sources

- No sources of support supplied