Abstract of dissertation entitled
“An evidence-based guideline to improve disease management and
develop healthy lifestyle for patients with Type I Diabetes Mellitus
by community nurses”

Submitted by

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In Hong Kong, about 700,000 people suffer from Diabetes Mellitus
(“DM” or “diabetes” in short) which is a life-long disease and it is
necessary to manage it well because of its complications leading to
lifetime disability or death. Diabetes can be divided into 3 types and 3%
diabetes patients belongs to type 1 diabetes often occurring in young
people aged below 30. However, every year about 400 type 1 diabetes
patients admit to hospitals because of different complications resulting
from poor lifestyle and poor drug compliance. In order to reduce this
admission rate, nurses in Hong Kong had used different methods such as
increase frequency of medical consultation in outpatient clinics, insert a
small machine continuously monitoring blood glucose for 72 hours, etc.
However, these methods’ costs are high and they cannot solve
fundamental problems which are poor drug compliance and unhealthy
lifestyle. Therefore, literatures show that home visits by community
nurses may be a good method to improve disease management and
develop a healthy lifestyle for type 1 diabetes patients but there is no
available nurse guideline or systematic review about it. Therefore, it is
necessary to develop an evidence-based guideline based on the best
existing findings.

3 electric databases are used in searching for journals systemically.
They are PubMed, Cumulative Index to Nursing and Allied Health
database (CINAHL) and JBI COmNECT. After filtering with inclusive
and exclusive criteria, 7 randomized controlled trials (RCTs) were found.
Then data are extracted and evaluated their quality and validity by
Scottish Intercollegiate Guidelines Network (SIGN). It shows that all 7
journals are in high quality. Then the implementation potential of
proposed program in term of target group and setting, transferability,
feasibility and cost-benefit ratio is assessed. After that, an
evidence-based guideline of regular home visits by community nurses
for type 1 diabetes patients is developed and an implementation plan is
formed in which a communication plan with stakeholders and a pilot test
are conduced to test its feasibility. Finally, an evaluation plan is made to
evaluate the proposed guideline and program’s effectiveness.

It is expected that after having home visits by community nurses, type
1 diabetes patients can develop a healthy lifestyle associated with better
disease management so that chance of occurring diabetes complications
can be minimized and the admission rate can be reduced. Also, nurses’
workloads can be reduced and the health cost in Hong Kong can also be
reduced, too.
An evidence-based guideline to improve disease management and develop healthy lifestyle for patients with Type I Diabetes Mellitus by community nurses

by Lau Sin Ying

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Declaration

I declare that this dissertation represent my own works, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed __________________________________________

Lau Sin Ying
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1. Introduction

1.1 Background

Every day when we eat food, our bodies would break down sugars and carbohydrate into glucose which is a fuel for our bodies’ cells by a hormone called insulin produced in pancreas but someone may not be able to produce adequate insulin and thus their blood glucose levels abnormally maintain in a high level over extended periods of time and this disease is called diabetes mellitus (“DM” or “diabetes” in short) (Hospital Authority, 2016). Up to now, there is no cure for this disease and if patients do not control it well for a long time, various complications such as stroke, renal failure, foot ulcers etc may be occurred and this may be resulted in lifelong disability or death. According to American Diabetes Association (2016), there are three types of diabetes, namely type 1, type 2 and gestational diabetes. Type 1 diabetes is often diagnosed in children and young adults aged below 30. As their pancreatic beta cells are completely non-functional, they cannot produce insulin endogenously so the only treatment is to administrate insulin by self-injection compared to type 2 diabetes patients who may use diet control or oral medication to control this lifelong disease.

According to the data from Centre for Health Protection in 2016, in Hong Kong, around 70,000 people constituting 10% of the whole population suffer from diabetes mellitus and among these diabetes patients, 3%, about 2,100 people belong to type 1. Statistics report from Hospital Authority (2014-15) shows that diabetes is the tenth leading cause to deaths in Hong Kong and about 400 patients die every year
because of diabetes complications. In addition, 393 type 1 diabetes patients admitted to hospitals in 2014 due to diabetes or related complications such as severe hypoglycemia, Diabetes Ketoacidosis (DKA), foot ulcer resulted from uncontrolled diabetes (Hospital Authority, 2015). Moreover, it is found that over 50% of type 1 diabetes patients admitted to hospitals more than two times per year due to diabetes complications which are mainly due to poor medical adherence and unhealthy lifestyle with excess sweet and few exercise (Sayed et al., 2016; American Diabetes Association, 2016; Centre for Health Protection, 2016). Therefore, it shows that those diabetes complications and unplanned admission can be avoided when patients maintain good drug compliance with a healthy lifestyle. In this aspect, nurses are an important role in providing related knowledge and monitoring their compliance but now there is no local standard guideline for it and it is also necessary in conducting researches for providing evidence based guideline for nurses to improve current practices.

1.2 Affirming the needs

In Hong Kong, Hospital Authority (“HA”) has issued Guidelines for Specialty Nursing Services Diabetes Care (SAG (Endocrinology), 2014) which provides guidelines for nurses to give appropriate nursing cares for diabetes patients. However, this guideline does not have standard plans and guidelines for type 1 diabetes patients after discharge. Additionally, from my observation, it is noted that diabetes education is only provided for inpatients during hospitalization and there is no continual diabetes education for them after discharge. Now when
doctors notice that diabetes patients have poor drug compliance in
out-patient clinics, they often increase frequency of medical
consultations or implement a single-use 72-hour continuous blood
glucose monitor. However, these methods’ costs are high and they
cannot run in a long term.

Additionally, it shows that in Hong Kong, over 60% type 1 diabetes
patients’ blood glucose is not well-controlled and their average HbA1c
level is over 8% in which is a common and significant indicator to show
if diabetes is well controlled because HbA1c level reflects the average
blood glucose level in the past three months and the normal one should
be equal or lower than 7% (Sayed et al., 2016; Hospital Authority, 2015).
When HbA1c level maintains in a high level for a period of time,
number of complications such as renal failure, foot ulcer etc may be
occurred (Hospital Authority, 2015).

Moreover, literature shows that 68.5% type 1 diabetes patients feel
loss and cannot adapt with this disease in their daily life and 59.7%
would return to have unhealthy lifestyle with poor medical adherence
after discharge (Alvarado-Martel et al., 2015). For example, they may
miss insulin injection for than one time per week and they may have too
little exercise with too much sugar and fast food in their life leading to
hyperglycemia. As a result, they will be admitted to hospitals within one
year due to acute diabetes complications such as DKA (Alvarado-Martel
et al., 2015; Sayed et al., 2016).

In view of the disadvantages of current practices and the problems of
type 1 diabetes patients facing now, researches show that home visits by
community nurses may be a better intervention for them in which patients can minimize their negative feelings and adapt to daily life with this disease under their familiar environment (Rothshild et al., 2014; Chow et al., 2008; Wong et al., 2004). Now I work in Community Nurses Service (“CNS”) department and I observe that about 1% of patients belong to type 1 diabetes patients. However, it is rare for us to educate type 1 diabetes patients about healthy lifestyle and now there is no evidence-based guideline for us or published systematic review for supporting to translate existing evidences into practice in the reality.

Therefore, as this idea is a new good evidence emerged from other studies which has not been included in any systematic review so it is necessary for us to have a systematic review and develop an well-planned evidence based program on the intervention by providing regular home visits for type 1 diabetes patients by community nurses to improve their disease management and develop a healthy lifestyle.
1.3 Objectives and significance

The research question of this proposed study in PICO format is: How effective the home visits by community nurses, in comparison to the ones without home visits, in improving disease management and developing healthy lifestyle for type 1 diabetes patients?

1.3.1 Objectives

The aim of proposed study is to develop an evidence based guideline to improve disease management and develop a healthy lifestyle for type 1 diabetes patients by community nurses. The supposed objectives can be achieved as below:

1) To review evidences systematically on the effectiveness of improving disease management and developing healthy lifestyle for type 1 diabetes patients by community nurses.
2) To summarize, synthesize the data and evaluate quality of studies.
3) To develop an evidence-based guideline to improve disease management and develop healthy lifestyle for type 1 diabetes patients by community nurses’ home visits.
4) To assess the transferability and feasibility of implementing regular home visit program for type 1 diabetes patients in community setting.
5) To propose and develop regular home visits program guidelines for type 1 diabetes patients by nurses in community setting.

1.3.2 Significance

As an evidence-based guideline is developed, community nurses can use it to aid them on providing diabetes and healthy lifestyle knowledge
during home visits. Besides, it is supposed that healthy lifestyle of type 1 diabetes patients can be developed and they can know how to manage hypoglycemia and hyperglycemia in their daily life after home visit program and their admission due to diabetes complications can be reduced and they can improve their quality of life with this lifelong disease. Then the medical cost and resources using on hospitalized type 1 diabetes patients can be changed on other aspects so patients’ satisfaction and confidence toward health care system can be improved.
2 Critical Appraisal

2.1 Search and Appraisal Strategies

In this transitional nursing research, the first step is to find potential high level evidence. To begin with, a clear searching strategy with inclusive and exclusive criteria in reliable databases is needed.

2.1.1 Search strategies

3 databases are used in searching for journals systemically. They are PubMed, Cumulative Index to Nursing and Allied Health database (CINAHL) and JBI COnNECT.

The keywords to search studies in these 3 databases searching engines are according to PICO format in which “disease management”, “develop healthy lifestyle”, “type 1 diabetes patients”, “chronic diseases patients”, “community nurse” and “home visits”. These keywords are used in different combination separately or together by using “OR” or “AND” in between.

2.1.2 Inclusive and exclusive criteria

Five criteria have to be met when we find journals in the review:
1) The journals are in community setting and all interventions are prone to patients.
2) The target populations are patients aged 18 years old or above with chronic diseases such as diabetes, hypertension, cardiac diseases, chronic pulmonary disease (COPD), etc.
3) The publication years have to be from 2000 to current so that up-to-date data can be got.
4) Journals have to be Randomized Controlled Trials (RCTs) to have high level evidence.

5) Full text is available and written in English or Chinese to avoid language barrier.

   On the other hand, there are three exclusive criteria:

1) Journals are in hospital based and those interventions are done to caregivers.

2) Patients are unable to communicate because they are illiterate or they have other diseases such as severe mental retardation.

3) Journals are published before 2000.

   Then all data such as study type, patient characteristics, nursing intervention, and outcome with effect size will be extracted from journals and are shown in table of evidence from Appendix 2 to Appendix 8. After that, each journal is critically appraised by using methodology checklist by SIGN (Scottish Intercollegiate Guidelines Network, 2014) illustrated from Appendix 10 to Appendix 16: SIGN checklist (5) assessing them into high quality (1++), acceptable (1+) or unacceptable (1-).
2.2 Results

2.2.1 Findings

Appendix 1: PRIMA Flow Diagram describes how journals are found during the procedure of searching. Initially, over 5,000 articles are found from CINAHL, JBI COnNECT and PubMed in which 1,169 journals are recorded from CINAHL, 1,100 are searched from JBI COnNect and 2,303 studies are found in PubMed.

Then the published journals year is set from 2000 to the current and limit findings to primary studies, then 954 journals are left. After that, irrelevant content is filtered by title and abstract and 150 journals remain. Finally, the journals have to be Randomized Controlled Trial (RCT) and 7 journals are left finally. They are:

“Rasjo et al. (2015): Nurse-led empowerment strategies for patients with hypertension: a randomized controlled trial”: It indicates that nursing intervention is important to support and change chronic disease patients in the community.

“Rothschild et al. (2014): Mexican American Trial of Community Health Workers: A Randomized Controlled Trial of a Community Health Worker Intervention for Mexican Americans With Type 2 Diabetes Mellitus”: An American study that home visits by nurses are better than only giving newsletters to change chronic disease patients’ lifestyle.

“Brown et al. (2012): Six Features of Medicare Coordinated Care Demonstration Programs That Cut Hospital Admissions Of High-Risk Patients”: It shows that community nurses’ phone services can reduce admission rate and improve quality of life with those chronic illness
patients.

“Chow et al. (2008): Community nursing services for postdischarge chronically ill patients”: It is a Hong Kong study indicating that chronic disease patients have better outcome in different aspects after receiving community nurses’ visits.

“Sayed et al. (2016): Risk factors and predictors of uncontrolled hyperglycemia and diabetic ketoacidosis in type 1 diabetic children and adolescents, in Jeddah, Western Saudi Arabia”: It concludes type 1 diabetes patients can improve blood result with better drug compliance and lifestyle under nurses’ monitoring.

“Nathan et al. (2005): Intensice Diabetes Treatment and Cardiovascular Disease in Patients with Type 1 Diabetes”: Compare intensive treatment regimen and standard care for type 1 diabetes patients and it shows that intensive one can have better outcomes but it stresses that care plans should be made according to individual needs.

“Wong et al. (2004): Nurse follow-up of patients with diabetes: randomized controlled trial”: A Hong Kong study that nurses have phone follow-ups for type 2 diabetes patients for 3 months and they have better medical adherence, daily life habits and self satisfaction after nursing intervention.

2.2.2 Table of evidence

Appendix 2 to Appendix 8 shows the tables of evidence for each journal. Each table is divided into six parts which are research articles’ citation, sample characteristics, intervention, control, outcomes with assessment time and the effect size. It is seen that each journal has more
than one author and their published year is from 2004 to 2016. Also, all sample characteristics in these seven journals are local people with different types of chronic diseases and they are divided into two groups in which one receives nursing intervention and one receives standard care or no intervention received.

As a result, seven studies show that community nurses’ intervention has positive effects in objective and subjective aspects. Objectively, patients’ vital signs, body weight, blood result are improved. Subjectively, intervention groups in seven journals express that their quality of life and medical adherence have been improved and a healthy lifestyle is developed after nursing intervention. Moreover, seven studies’ results are significant and reliable because their p-values are equal or lower than 0.05. According to American Statistical Association (2016), p-value indicates the reliability of result and it shows that the result is significant when it is equal or lower than 0.05.
2.3 Summary and Synthesis

2.3.1 Summary of data

These seven journals (Sayed et al., 2016; Brown et al., 2012; Rasjo et al., 2015; Rothschild et al., 2014; Chow et al., 2008; Nathan et al., 2005; Wong et al., 2004) are RCTs published from 2004 to 2016. Participants are recruited and selected randomly in hospitals or in DM center and all intervention groups receive nursing cares by different methods such as home visits, phone follow-ups, DM education in DM center, etc. On the other hand, all control groups do not receive any interventions or get standard care. It is noted that seven studies are lasted from 6 months to 6.5 years in community based. Then, all interventions are evaluated by both subjective and objective measurements and all measurements show that nursing interventions after discharge have positive effects on patients’ medical adherence and quality of life.

2.3.2 Synthesis of data

Although all seven literatures show nursing intervention is good for chronic disease patients, they have still difference in-between in respect of study design, subject characteristics, intervention and control results, outcome and methodological quality.

2.3.2.1 Study design

All seven literatures are experimental researches with longitudinal randomized study in which one group has nursing intervention while another group does not have any intervention or receive standard care and compare their results after a period of time. However, those content
of nursing interventions are difference in which two have phone follow-ups (Rasjo et al., 2015; Wong et al., 2004); three have nurses’ home visits (Rothschild et al., 2014; Brown et al., 2012; Chow et al., 2008); one goes to DM center to receive DM education twice weekly (Sayed et al., 2016) and one has diabetes intensive treatment regimen (Nathan et al., 2005).

2.3.2.2 Study characteristics:

For these seven journals, two studies are from Australia (Brown et al., 2012; Rasjo et al., 2015) and two are from USA (Rothschild et al., 2014; Nathan et al., 2005), one is from Western Saudi Arabia (Sayed et al., 2016) and the remaining two are from Hong Kong (Chow et al., 2008; Wong et al., 2004). Cultural difference may affect the study results. For example, Chow et al. (2008) state that in Hong Kong, participants may feel embarrassing when exposing daily activities or teaching insulin injection technique under nurses’ supervision and this may affect study results. Therefore, cultural sensitivity is important when systematic review of literatures.

There is no significant difference for participants in seven studies in the beginning in term of age, types of chronic diseases, nationality. Each research recruits more than 100 patients and they are selected and assigned randomly into intervention or control groups. But for binding issue, 3 studies do not use double blind method because of study nature (Rasjo et al., 2015; Brown et al., 2012; Nathan et al., 2005) while 4 studies have kept participants and investigators blind about treatment allocation (Sayed et al., 2016; Rothschild et al., 2014; Chow et al.,
2008; Wong et al., 2004). High level of blinding needs to be considered during systematic review of evidence because this can minimize bias.

Moreover, both groups in seven studies will be evaluated after interventions but the measuring methods are different. Three of them have both subjective and objective methods (Brown et al., 2012; Chow et al., 2008; Wong et al., 2004) such as vital signs checkup and self-reported health conditions while four studies have objective methods solely (Sayed et al., 2016; Rasjo et al., 2015; Rothschild et al., 2014; Nathan et al., 2005) by filling in questionnaires to express self-reported health conditions.

2.3.2.3 Intervention results

From these seven journals, participants in intervention groups have positive results in different aspects after receiving nursing interventions. For example, participants’ HbA1c level improves 0.5% (Wong et al., 2004) to 0.62% (Rothschild et al., 2014), weight averagely loses 0.2 pounds (Rothschild et al., 2014) and admission rate decreases 1.3% (Chow et al., 2008). Moreover, it shows that self-reported health condition improves from 21.6% to 30% (Rasjo et al., 2015; Chow et al., 2008; Wong et al., 2004).

2.3.2.4 Control results

In these seven journals, participants in control groups do not receive any nursing interventions or get standard cares and after a period of time, they will receive the same evaluation methods and the results will be compared to intervention groups.
It is shown that although some aspects such as HbA1c level, self-reported health conditions are better than before, their improvements are not as large as the intervention group ones. In the control group, their HbA1c level improves about 0.2% (Rothschild et al., 2014; Wong et al., 2004) and their self-reported health condition improves from 15.3% to 21.7% (Rasjo et al., 2015; Chow et al., 2008; Wong et al., 2004). Additionally, admission rate and their weight do not change compared with participants’ previous data (Rothschild et al., 2014; Chow et al., 2008).

2.3.2.5 Outcomes

From the above, it is noted that patients with chronic illnesses have better disease management and develop healthy lifestyle after getting nursing interventions compared with ones do not have any interventions or get standard cares (Sayed et al., 2016; Rasjo et al., 2015; Rothschild et al., 2014; Brown et al., 2012; Chow et al., 2008; Nathan et al., 2005 and Wong et al., 2004).

Moreover, one study (Wong et al., 2004) states that community nurses’ home visits can largely decrease the medical costs especially the cost spending on inpatient expenses in Hong Kong. This is because admission rate and hospitalization rate are decreased after nursing intervention and the length of hospital stays can shorten because patients can learn how to manage disease after discharge and they are not necessary to learn during hospitalization so about HKD$18 million can thus be saved every year.
2.3.2.6 Methodological quality assessment

These seven studies are RCTs and in order to assess their quality, Scottish Intercollegiate Guidelines Network (SIGN) will be used. In this SIGN checklist (Appendix 8 to Appendix 12), 10 items will be assessed and all studies are in higher level in hierarchy of evidence (1++ to 1-) because they are RCTs (Appendix 9) (SIGN, 2004). Besides, three studies are ranked as high quality study (++) (Rothschild et al., 2014; Chow et al., 2008; Wong et al., 2004) while two of them are ranked as acceptable (+) (Sayed et al., 2016; Brown et al., 2012) and the remaining two are ranked as low quality (-) (Rasjo et al., 2015; Nathan et al., 2005):

1) Clear and suitable question:
   All seven studies have clear and appropriate questions and a clear conclusion is stated in each study.

2) Randomized allocating to intervention or control group:
   Participants in these seven studies are randomly assigned into intervention groups or control groups.

3) Enough concealment methods:
   Five studies use computerized allocation systems while two studies (Rasjo et al., 2015; Nathan et al., 2005) do not do so and investigators allocate participants into different groups because of study nature.

4) Treatment assignment is double blinded:
   Rasjo et al. (2015), Brown et al. (2012) and Nathan et al. (2005) do not use double blind method because of study nature while the
other four studies (Sayed et al., 2016; Rosthschild et al., 2014; Chow et al., 2008; Wong et al., 2004) have kept participants and investigators blind about treatment allocation.

5) The background of intervention and control group is similar:
All seven studies’ participants’ background is similar in term of age, types of disease, nationality and then they are assigned into intervention groups and control groups.

6) The treatment is the only difference between intervention and control group:
The backgrounds are similar in seven studies so the only difference in between is the nursing interventions.

7) Outcome is measurable and reliable:
Standard measurement tools are used and objective data and subjective data in number form is measured. This can increase degree of objectivity.

8) Drop-out rate is low:
All seven studies’ drop-out rate is below 20% ranging from 0% (Rasjo et al., 2015; Chow et al., 2008) to 15.8 (Wong et al., 2004) which is still acceptable.

9) All participants are analysed:
All participants will be evaluated after interventions and they will be evaluated through both subjective and objective methods such as vital signs checkup and self-reported health conditions (Brown et al., 2012; Chow et al., 2008; Wong et al., 2004) or just objective methods (Sayed et al., 2016; Rasjo et al., 2015; Rothschild et al.,
2014; Nathan et al., 2005).

10) Result can be carried out in other sites:

In these seven journals, it is shown that better medical outcomes are resulted and patients can receive better quality of life when we extend and continue nursing cares from hospitals to community for patients with different chronic diseases so it is possible to carry out same intervention in other sites for other patients like type 1 diabetes patients.

However, conclude from seven studies, one factor needs to be considered in which a tailor-made nursing care plan is needed for patients and it is necessary to adjust it when any factor changes such as changing working environment. Besides, other factors such as peer group effect should be considered as this may affect the study results.

In conclusion, after reviewing effectiveness of improving disease management for type 1 diabetes patients by community nurses by using systemically methods, seven RCTs in different quality of journals in which three studies are ranked as high quality study (++), two are ranked as acceptable (+) and two are ranked as low quality (-). By making use of them, it is necessary to do nursing care plans according to individual needs and change it time-to-time so the maximum effect can be achieved.
3 Implementation Potential and Clinical Guideline

After reviewing literatures, it is shown that home visits by community nurses can improve disease management and develop healthy lifestyle for type 1 diabetes patients so that admission rate due to diabetes complications can be reduced. This effective intervention is proposed to be launched into practices in Hong Kong.

In this chapter, its implementation potential will be analyzed in respect of target group and target setting, transferability and feasibility of findings and the cost-benefit ratio of this program. Besides, an evidence-based guideline will also be elaborated.

3.1 Transferability

3.1.1 Target Group and Target setting

3.1.1.1 Target Group

The target group is Hong Kong patients with type 1 diabetes mellitus aged 18 years old or above recruited during hospitalization because of poor disease management and unhealthy lifestyle leading to diabetes complications. They are aged 18 years or above because they are adults legally to make decisions. Besides, participants have to be able to speak and read Chinese because this can reduce language barrier.

3.1.1.2 Target setting

After participants discharge from hospitals, they will be invited to have regular visits at their homes by community nurses for three months so that participants can receive diabetes and health education in their
familiar environment. After 3-month nursing intervention, participants will have an evaluation in CNS center in Tsuen Wan.

3.2 Transferability of the findings

3.2.1 Similarity of the target group and target setting

It is noted that background of target group, target setting and nursing interventions are similar in those seven literatures.

The populations of seven studies are patients with different types of chronic diseases and recruited during hospitalization and this is similar with our target group which has type 1 diabetes and it is a life-long illness. It is planned that participants are recruited during hospitalization which matches those seven studies. Besides, two studies’ target population (Chow et al., 2008; Wong et al., 2004) is Hong Kong people who are the same as our target group.

On the other hand, our target setting is similar with three studies’ nursing intervention (Rasjo et al., 2015; Brown et al., 2012; Chow et al., 2008) in which participants will be educated about health and disease knowledge by community nurses in their homes for a period of time.

3.2.2 Innovation’s philosophy of care and current one

The philosophy of CNS care under HA is an important factor to affect the finding’s transferability to actual one. Now the goal of CNS is to “provide a continuous and holistic care for patients who are discharged from hospitals and allow patients to recover under their familiar home environment” (Hospital Authority, 2015). From our program,
community nurses will provide education to type 1 diabetes patients in their homes for three months so that they can have a better disease management and develop a healthy lifestyle in their well-known environment. This totally matches with CNS goal and thus transferability can be increased.

3.2.3 Number of patients benefit from innovation

According to statistics from Hospital Authority (2014-15) in 2014, over 15,000 people admitted to hospitals due to diabetes complications and about 400 patients are type 1 diabetes. Therefore, it is supposed when this program is carried out, about 400 patients every year can get the benefit and thus admission rate due to diabetes complications can be reduced about 2.67%.

3.2.4 Length of implementation and evaluation

It is supposed that total length of this program will be twelve months. Appendix 17 shows the working plan of the program. It shows that preparation, pilot test, implementation and evaluation will contribute three months respectively. These are similar with two studies which have implemented for 3 months and the programs are lasted for about 1 year (Rasjo et al., 2015; Wong et al., 2004). Additionally, a committee with six members will be set up to plan and prepare, implement and evaluate the whole program. This committee will include 2 CNS Advanced Practice Nurses (“APN”) and 4 CNS Registered Nurses (“RNs”) and this is similar with three studies (Rothschild et al., 2014; Brown et al., 2012; Chow et al., 2008) and these can increase the program’s transferability.
3.3 Feasibility

There are six factors affecting the feasibility of the program. They are the support from administration and staffs autonomy, influence on staffs and services, consensus among staffs, competence of staffs, equipment and facilities and the evaluation of program.

3.3.1 Nurses’ autonomy and administration support

When this program is carried out actually, nurses can have certain autonomy. In this program, CNS RNs have autonomy in home visit schedules and they would discuss when to have home visits with participants. Besides, CNS RNs can have autonomy in deciding what to teach during home visits so that they can prioritize the sequences of education content.

On the other hand, it is supposed that CNS Department Operation Manager (“DOM”) and CNS Ward Manager (“WM”) would fully support this program. This is because now CNS DOM and WMs value staff’s feedbacks and they are welcome to all innovations especially to the ideas which are benefit to patients. Therefore, staff meetings are held regularly in which staffs can freely express their opinions or suggest improvements towards their works. For example, last year some staff suggested having warm packs during winters and having rain-covers for nursing bags during rainy days. Then these suggestions are really implied in this year.

Therefore, it is seen that nurses can have certain autonomy and administrators support this program thus its feasibility can be increased.
3.3.2 Influence on the current staffs and service functions

As mentioned before, a committee which includes two CNS APNs and four CNS RNs will be set up and they would carry out this program around one year. At first, it is supposed that each CNS APN would spend about five hours per week lasted for three months on preparing education materials and recruiting participants. Then each CNS RN would use about four hours per month on home visits for each participant during implementing pilot test and real study which are totally lasted for six months. At the same time, CNS APNs would supervise the progress and amend the content when needed. After that, all of them would use three months about nine hours per month to evaluate program outcome.

That means totally each CNS APN spends 111 hours and each CNS RN spends 24 hours on this program. However, originally they have cases on other patients and they need to spend extra time in this program and this may increase their workloads. Moreover, other staffs’ workloads may thus be increased too because they may need to share workloads. As a result, the current staff may feel tired and this may affect the moral and service quality.

3.3.3 The degree of consensus among staffs and the support from authority

Implementation of this program may increase current staffs’ workloads so consensus among staffs is important to carry the program out smoothly. Therefore, it is supposed a meeting will be held for administrators and
CNS staffs before implementation to let staffs in CNS can understand the reason of implementing this program and its benefits for patients, caregivers, healthcare providers and the whole system.

Besides consensuses among the staffs, climate of HA in Hong Kong also affect the feasibility of program implementation. Luckily, HA always encourages staffs to have practices on evidence based and we can see that there is convention every year for staffs to share their evidence based findings and carry out those findings in actual practices. Therefore, it is supposed that HA will fully support this program because this program is evidence based and it is supported from staff and administrators.

3.3.4 Staff skills necessary for carrying out the program

The skills necessary for this program are the communication skills towards patients and related community nurse service experience. It is believed that all CNS RNs have such kinds of skills because they have sufficient experience in community nurse service and they have competence to carry this program out. Additionally, meetings will be held before and during implementation so that CNS RNs can know its objectives, working plan, content of education materials and they can also express their opinions towards the program anytime they want.

3.3.5 Equipment and facilities needed for the program

There is few equipment and facilities needed for this program. This program needs one conference room for committee meeting, one printer,
one computer and stationery for editing and printing education materials. We see that there are two conference rooms, two printers, ten computers and large amount of stationery in CNS center and these can fulfill this program’s requirements and all of them can be used in this program.

3.3.6 Evaluation tools for the program

Two evaluation tools corresponding to program’s objectives which are HbA1c level and questionnaires will be used in evaluation phrase.

The first one is the HbA1c level. Each participant will take blood to test their HbA1c level after 3-month implementation to show patients’ average blood glucose level in the past three months and the optimal level is equal or below 7% (American Diabetes Association, 2016; Sayed et al., 2016). Therefore, by taking blood to test their HbA1c level, it can show if participants have good drug compliance and healthy lifestyle to maintain normal blood glucose level in their daily life.

The second one is the questionnaires. Before implementation, participants will be invited to finish a questionnaire (Appendix 22a/22b) and then after implementation, they will be invited to finish the same questionnaire so that we can see if there is any change for participants in respect of disease management and healthy life habits before and after community nurses’ home visits for three months.

3.4 Cost-benefit ratio of the Innovation

3.4.1 Cost to target group

The only cost for the participants for this program is the time. During the implementation, participants need to stay at home to wait for
community nurses’ home visits and they also need to spend time on blood taking and finish questionnaires before and after 3-month home visits as evaluation.

3.4.2 Potential risks and benefits for the target group

There are two potential benefits and two potential risks for target group when we implement this program.

The first benefit is the reduction in admission rate. In this program, disease management will be educated and reinforced thus their chance of developing diabetes complications can be reduced so their admission rate can thus be decreased.

The second benefit is the development of a healthy lifestyle. Apart from disease management, participants will be educated about healthy lifestyle during home visits. Therefore, it is supposed a healthy lifestyle can be developed after this program.

However, on the other hand, when those objectives cannot be achieved, participants may waste time and cannot get benefits from this program. This is because those objectives are not guaranteed to be achieved and when those objectives are not achieved, participants may waste time for this program and continue their unhealthy lifestyle.

Besides, those objectives may not be maintained in the long run. This is because this program just lasts for three months and there is no one to monitor participants afterwards so they may collapse and cannot maintain good disease management or healthy lifestyle in the long run.
3.4.3 Total cost needed for implementing the program

The cost would be HKD$74,862. The details of the budget plan are shown in Appendix 18.

We can see that all costs in this program are spent on nurses’ salaries which are calculated by using the mid-point of the rank i.e. APN would have $265 per hour and RN would have $167 per hour. Before implementation, each CNS APN needs to spend 60 hours for preparation. Then each CNS APN and CNS RN spends 24 hours for implementation and 27 hours for evaluation. That means the total set-up cost would be HKD$31,800 and the running cost would be HKD$43,062 per year.

All other expenses such as the computers, rental fee of conference rooms, printing fee of education materials and stationery are free of charge because they are now available in CNS centre so the total cost of this program would be around HKD$75,000.

3.4.4 The cost of not implementing the program

There are 393 type 1 diabetes patients admit to hospitals due to diabetes complications in 2014 (Hospital Authority, 2015). Hong Kong government needs to spend HKD$11,888 for each of them (Wong et al., 2004). This means that when this program is not implemented, about HKD$500,000 is needed to spend as extra cost each year and we can use this large amount of money on other aspects such as increasing number of inpatient beds in hospitals, recruiting more staff, increasing number and types of medical equipments, etc so that the length of waiting time for investigation can be shortened and staff’s workload can be decreased.
3.5 Evidence-Based Practice Guideline

After affirming it is feasible and transferable to implement regular home visits for type 1 diabetes patients by community nurses, an evidence-based guideline will then be developed.

This guideline will be based on those seven RCTs found before and seven recommendations are made after combining and evaluating the content of these journals. The details of evidence-based guideline will be shown in Appendix 20. Scottish Intercollegiate Guidelines Network (2014) referring to Appendix 19 will be used to grade recommendation level. In this guideline, one recommendation is in Grade A and the other six recommendations are in Grade B. These recommendations show the content of the proposed program in respect of the frequency of home visits and the content of education for type 1 diabetes patients during home visits in community setting.
4 Implementation Plan

When this program is going to implement, it is needed to get support from stakeholders who affect or involve in this program and a detailed communication plan and process is also needed so that the program can be operated smoothly.

In this program, at the first three months, one CNS APN will search high evidence based literatures to support this program and another CNS APN would edit educational materials which are used for providing diabetes and healthy lifestyle knowledge during home visits. Then, two CNS APNs will present this idea and get approval from CNS DOM and CNS WM so that formal authority and sufficient money can be got to carry this program out. At the same time, another APN will invite four RNs to form a committee which carries this program out and recruit certain number of type 1 diabetes patients to participate in this program. A pilot test will be done in 4th to 6th months then this program will be implemented for three months in 7th to 9th months. After that, the program will be evaluated in the 10th to 12th months by committee to take participants’ blood and finish questionnaires. Finally the result will be presented by two APNs to CNS DOM and CNS WM.

4.1 Communication Plan

4.1.1 Identification of Stakeholder

From the above, we can see that stakeholders in this program would be CNS DOM, CNS WM, CNS APNs, CNS RNs and type 1 DM patients.

CNS DOM and CNS WM are important roles in this program. This is
because it is necessary to get their approval and support to carry this program out before implementation. Besides, it is also needed to get sufficient fund and manpower from them so that this program can have enough money to operate and pay for all necessary expenses such as nurses’ salaries. Also, CNS DOM and CNS WM are the experts in CNS because they have ample experience and knowledge in it and they can provide professional comments on this program so that this program can be improved before implementation.

Besides, CNS APNs are also important too. CNS APNs have many roles in this program: They are the ones who find high evidenced literatures to support this program and present this idea to CNS DOM and CNS WM. Also, they are the ones who edit the educational materials, invite CNS RNs to run this program and recruit type 1 diabetes patients to participate before implementation. When the program is run, they are the ones who lead and supervise the process and in the final stage, they are responsible to evaluate the program and present the results to CNS DOM and CNS WM.

On the other hand, those CNS RNs are the operators in this program. During implementing this program, they run at front line to carry this program out and they can provide and reflect useful feedbacks to CNS APNs when problems or difficulties are identified so the program can be improved as soon as possible. After implementation, they also participate in evaluation phrase with CNS APNs and they are the ones who take participants’ blood and collect their questionnaires in order to see the effect of this program.
Last but not least, Type 1 DM patients are the stakeholders too because they are the ones participating in this program. Without their participation, it is impossible to run this program and it is impossible to see if home visits by community nurses can improve their disease management and develop a healthy lifestyle for them.

4.1.2 The communication process

Two CNS APNs would be important roles in communication process and they will be the “bridge” between CNS DOM, CNS WM and CNS RN. Appendix 21 is the flow chart of communication process.

4.1.2.1 Initial Stage

First, it is observed and found that it is necessary to provide nursing cares for type 1 diabetes patients by community nurses in Hong Kong through nurses’ observation and experience. Then, CNS APNs would find high evidence based literatures and edit educational materials and present this idea to CNS WM in an informal meeting in CNS centre to get his support first. After getting support from CNS WM, two CNS APNs will have a formal meeting accompanied with WM to present this idea to CNS DOM so that approval can be got to run this program with sufficient fund and human resources.

After that, a committee with four CNS RNs selected by CNS APNs will be formed to run this program. Before implementation, CNS APNs will hold a meeting with CNS RNs first to explain this program aim and objectives, procedures and their responsibility so that they can know the program and support it. Besides, CNS APNs will also distribute relevant
educational materials during meeting and teach them what and how they should teach participants during home visits.

4.1.2.2 Implementing and sustaining stage

During the implementation, when participants have any comments, they can reflect them to CNS RNs during home visits or by phone. Then CNS RNs can talk and express opinions to CNS APNs whenever they want so that CNS APNs can solve their problems or transfer their comments to CNS WM. Additionally, CNS WM and CNS APNs would have regular meetings with CNS RNs in CNS centre so that they can evaluate this program or express their opinions towards it. As a result, the program can be improved as soon as possible.

It is noted that in the whole program, CNS APNs are the coordinators no matter in initial stage or in implementing and sustaining stage so that all comments from CNS RNs and participants can be reflected and expressed to CNS DOM and CNSWM.
4.2 Pilot Study Plan

4.2.1 Objectives of the pilot study

Before implementing regular home visits for type 1 DM patients, it is necessary to have a pilot study plan first because it can test the feasibility and transferability of this program and potential barriers and problems can be identified as early as possible so that the innovation can be revised before conducting in the reality. This is because in pilot study, same intervention will be applied for same types of patients with the same time restraint and the only difference between pilot test and the real test is the number of participants.

4.2.2 Preparation of the pilot study

In pilot study, we would recruit 5 type 1 DM patients in hospital because the literature shows that it is appropriate to use 10% samples in full study as the sample size of pilot one (Lynne, 2008).

Then, the inclusive criteria are:
1) Type 1 DM patients who are 18 years old or above admitted to hospitals due to complications like severe hypoglycemia and DKA.
2) Able to read and write Chinese.

The exclusive criteria are:
1) Not able to speak, write or read Chinese.
2) Refuse to have home visit by community nurses after discharge.

4.2.3 Data collection and evaluation

CNS RNs would have home visits at least once per week for 3 months after they are discharged. Before implementation, they would finish a
questionnaire (Appendix 22a/22b) and after 3-month intervention, they would finish the same questionnaire again to compare the difference and also their blood will be taken to test their HbA1c level. Additionally, CNS RNs will also finish the questionnaire in Appendix 23 after pilot test so that their satisfaction and acceptability towards this program can be assessed.

By making use of the pilot test, the amount of necessary resources can be tested and the feasibility of this program can also be assessed so that the budget plan or resources allocation can be changed before implementing in the reality.

Besides, participants and nurses are welcome to report problems or their comments to CNS APNs whenever they want during the pilot test so that the potential problems can be faced in an early stage and the clinical guideline and the content of program can be refined before applying in the reality.
4.3 Evaluation Plan

4.3.1 Objectives of evaluation

Besides carrying out the pilot study plan, it is also necessary to have a detailed evaluation plan so that the outcomes in respect of patients, caregivers, healthcare providers and system can be evaluated to see if this program can achieve its aims and objectives.

At first, number of participants needed would be calculated so that a reliable and convincible program can be achieved. Then two evaluation tools are used in this program which are taking blood to test HbA1c level and collecting questionnaire for patients and nurses to evaluate the program’s effectiveness.

4.3.2 Sample Size Calculating

In this program, HbA1c blood level would be considered as the determinant of the sample size calculation. From a literature from Sayed et al (2016), the standard deviation (SD) is 0.58. By using Lenth’s sample size generator (Lenth, 2006), it is a pair t-test and a sample size (n=58) will be generated with the power of 0.8 and 0.05 significance level. Additionally with estimated attrition rate 13% (Sayed et al., 2016), the total sample size would be 50.

4.3.3 Preparation and implementation of the evaluation

After the 3-month-intervention, two evaluation tools would be used in evaluation phrase:

The first evaluation tools would be the HbA1c level which indicates
the average blood glucose level in the past 3 months (American Diabetes Association, 2016). After nurses’ three months home visits, CNS RNs will date participants a day for blood taking to check their HbA1c level and according to American Diabetes Association (2016)’s indication, the program will be seen as successful when the HbA1c level is equal or below 7%.

The second evaluation tool is the questionnaire. Before implementation of this program, participants would finish the questionnaire shown in Appendix 22a (English version) and 22b (Chinese version) and after implementation, they would finish the same questionnaire and we would compare the difference to see if participants can have improvement in disease management and develop the healthy lifestyle. Moreover, this questionnaire content is based on Sayed et al. (2016) and it indicates that participants have better diabetes management and develop a healthy lifestyle when the difference pre and post test scores 12 or above.

At the same time, CNS RNs are invited to finish a questionnaire which reflects their satisfaction towards this program showing in Appendix 24. This questionnaire is made based on Chow et al. (2008), Wong et al. (2004) and it can reflect if nurses are satisfied and acceptable towards this program and it indicates that the program is successful when this questionnaire scores 30 or above.
4.4 Outcome

4.4.1 Participant outcomes

It is expected that after regular home visits by community nurses, participants can have primary and secondary outcome. Primary outcome for type 1 diabetes patients is to have a better disease management and can develop a healthy lifestyle. Secondary outcome would be their admission rate would be decreased and their quality of life would be improved with their satisfaction towards life accompanied with this lifelong disease.

4.4.2 Caregiver outcome

As our innovation target is patients themselves instead of the caregiver, it is hoped that participants can teach caregivers about the diabetes knowledge and related management after they are taught by community nurses during home visits. It is hoped that the caregivers can be confident to take care of patients afterwards and they can also have sufficient knowledge to manage complications such as hypoglycemia attack.

4.4.3 Healthcare provider and system outcome

It is expected that type 1 diabetes patients can have a better diabetes management with a healthy lifestyle after home visits by community nurses thus the rate of complication occurrences can be reduced and their admission rate can be lower. Therefore, when their admission rate is lower, our government can save about HKD$18 million each year and healthcare providers’ workloads can thus be reduced and more resources can be spent on other patients. As a result, patients’ confidence and
satisfaction towards medical system in Hong Kong can be increased.

### 4.5 Basis for Implementation

In this program, it is necessary to have bases to evaluate if the program is successful when it is fully implemented.

For HbA1c level, the basis level is according to the Centre for Health Protection (2016) guideline in which should be equal or below than 7.5% after 3-month nursing intervention.

For the questionnaire for patients, as we would contribute and compare it before and after regular home visits by community nurses, the content of questionnaire is based on Sayed et al. (2016) and the basis level of the difference should be 9 score which means that participants have improvement in each item after home visits.

For the questionnaire for nurses, the content is based on Chow et al. (2008) and Wong et al. (2004) and it is expected that the basis level of each survey should be 28 scores which means nurses agree and have at least “4” score in each sentence.
5 Conclusion

In conclusion, it is noted that over 50% type 1 diabetes patients admitted to hospitals after discharge due to poor disease management and unhealthy lifestyle leading to different kinds of diabetes complications (Sayed et al., 2016; Center for Health Protection, 2012) and home visits by community nurses seems a cost-effective approach to change fundamental problems for type 1 diabetes patients which have poor disease management and unhealthy lifestyle. After systematic review of evidence, seven high quality RCTs are found and then an evidence-based guideline is developed. Then the implementation potential is assessed and it is proven that it is transferable, feasible and cost-saving for community nurses to improve disease management and develop healthy lifestyle for type 1 diabetes patients by home visits. After that, an implementation plan including a pilot test is formed and this program would be evaluated by subjective method: participants’ blood test and objective method: participants and nurses’ questionnaires.

It is expected that through this program, type 1 diabetes patients can develop a better disease management and a healthier lifestyle and they can have a better quality of life accompanied with this life-long disease. Except type 1 diabetes patients can get the benefits through this program, nurses’ workloads can also be reduced because of decreased chance of diabetes complications and decreased admission rate. Also, the whole medical system in Hong Kong can be improved and the health cost can be reduced, too.
6 Reference


Appendix 1: PRIMA Flow Diagram

Identification
- Records identified through PubMed (n=2,303)
- Records from CINAHL (n=1,169)
- Records searched from JBI COnNECT (n=1,100)

Records after duplicates removed (n=3,534)

Screening
- Records screened (n=954)

Records excluded
Reasons:
- More than 10 years (n=1,760)
- Non-primary studies (n=840)

Eligibility
- Full-text articles assessed for eligibility (n=150)

Full-text articles excluded,
Reasons:
- Exclude by title (n=624)
- Exclude by abstract (n=180)

Included
- Studies included in qualitative synthesis (n=7)

Full-text articles excluded,
Reasons:
- Methodological flaws (n=147)
## 8 Appendix 2: Table of evidence (1)

<table>
<thead>
<tr>
<th>Citation/Design</th>
<th>Sample characteristics (summary statistics of characteristics)</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcome (give assessment time)</th>
<th>Effect size (Intervention-control)</th>
</tr>
</thead>
</table>
| Rasjo et al. (2015) RCT (1-) | 1. Aged equal or older than 18 years old  
2. With hypertension >140/90mmHg  
3. Just have one chronic disease i.e. hypertension | Receive district nurses’ counseling and support (n=59) | Do not receive any support from nurses (n=52) | 1. BP -3 months  
2. Cigarette taken per day -3 months  
3. Exercise done per week -3 months  
4. Low fat low salt diet habit -3 months | 1. -16 (p<0.001)  
2. -5 (p=0.03)  
3. +2 (p=0.03)  
4. +1 (p=0.02) |

## Appendix 3: Table of evidence (2)

<table>
<thead>
<tr>
<th>Citation/Design</th>
<th>Sample characteristics (summary statistics of characteristics)</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcome (give assessment time)</th>
<th>Effect size (Intervention-control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rothschild et al. (2014) RCT (1+)</td>
<td>1. Mexican Americans who have Type 2 diabetes and live in Chicago 2. Aged 18 years old or older 3. Receiving at least 1 oral hypoglycemic agent</td>
<td>Receive Community Health Workers (CHWs) visits (n=144)</td>
<td>No CHWs visits but got newsletter which has CHWs contact and diabetes self-management (n=144)</td>
<td>1. Blood: HbA1c level - &lt;7, 7-9, &gt;9 - 2 years 2. Blood pressure aims at &lt;130/80 - systolic: 110-150 - diastolic: 60-80 - 2 years 3. Weight loss - pounds - 2 years</td>
<td>1. Mean= -0.62 (p&lt;0.005) 2. No significant difference 3. Mean= -0.2 (p=0.01)</td>
</tr>
</tbody>
</table>

10 Appendix 4: Table of evidence (3)

<table>
<thead>
<tr>
<th>Citation/Design</th>
<th>Sample characteristics (summary statistics of characteristics)</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcome (give assessment time)</th>
<th>Effect size (Intervention-control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown et al. (2012) RCT (1+)</td>
<td>1. Patients lives in Sydney who are aged equal or older than 70 years old 2. Had more than three unplanned admissions due to chronic diseases 3. Did not receive any community nurse service before</td>
<td>Receive Community Nurse phone service (n=247)</td>
<td>Received standard care (n=245)</td>
<td>1. Number of admission -24 months 2. Improve in quality of life -24 months</td>
<td>1. -0.78 (p=0.01) 2. 0.19 (p=0.03)</td>
</tr>
</tbody>
</table>

## 11 Appendix 5: Table of evidence (4)

<table>
<thead>
<tr>
<th>Citation/Design</th>
<th>Sample characteristics (summary statistics of characteristics)</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcome (give assessment time)</th>
<th>Effect size (Intervention-control)</th>
</tr>
</thead>
</table>
| Chow et al. (2008) RCT(1++) | 1. Mean age= 72.9  
2. Aged over 18 years old  
3. 332 participants with 166 males and 166 females who are frequently admitted to hospitals  
4. 108 (32.6%) participants have chronic obstructive pulmonary disease (COPD), 116 (34.8%) have cardiac diseases and the remaining (108, 32.6% participants) have other chronic diseases like type 2 diabetes mellitus, renal failure, etc. | Receive 4 Community Nurse Service (CNS) visits after discharge (n=166) | No CNS service after discharge (n=166) | CNS Records under Omaha System Classification  
1. Self reported health conditions  
- 5 point scale  
(Very good, quite good, neutral, quite poor and very poor)  
- 1 year  
2. Objective health condition  
- vital signs of 1st and 4th visit  
- 1 year | 1. Mean= 0.54 (p<0.05)  
2. Mean= 0.42 (p<0.05) |

### Appendix 6: Table of evidence (5)

<table>
<thead>
<tr>
<th>Citation/Design</th>
<th>Sample characteristics (summary statistics of characteristics)</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcome (give assessment time)</th>
<th>Effect size (Intervention-control)</th>
</tr>
</thead>
</table>
| Sayed et al. (2016) RCT (1+) | 1. Saudi who have Type 1 diabetes  
2. Aged 18 years old or below  
3. Follow up endocrinology clinic more than 6 months  
4. Had HbA1c larger than 6.5% | Regular go to DM center to receive DM education (n=272) | Not go to DM center to receive DM education (n=272) | 1. HbA1c blood level - 3 months  
2. Unhealthy activities leading to hyperglycemia - 3 months  
3. Inject insulin in right dosage right time - 3 months  
4. Daily self blood glucose monitoring - 3 months  
5. Regular medical follow up - 3 months | 1. Mean= -1.53 (p<0.001)  
2. Mean= -0.5 (p<0.001)  
3. Mean= +0.49 (p=0.41)  
4. Mean= +1.35 (p=0.006)  
5. Mean= +1.2 (p<0.001) |

### 13 Appendix 7: Table of evidence (6)

<table>
<thead>
<tr>
<th>Citation/Design</th>
<th>Sample characteristics (summary statistics of characteristics)</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcome (give assessment time)</th>
<th>Effect size (Intervention-control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nathan et al. (2005) RCT (1-)</td>
<td>1. Type 1 diabetes patients aged 13 to 40 years old 2. No hypertension or cardiovascular disease</td>
<td>Got diabetes intensive treatment regimen (n=1394)</td>
<td>Got standard diabetes regimen (n=1394)</td>
<td>1. Occurrence of cardiovascular disease -6.5 years 2. Drug compliance -6.5 years 3. Daily self blood glucose monitoring -6.5 years</td>
<td>1. Mean= -1.3 (p=0.001) 2. Mean= +1.5 (p&lt;0.001) 3. Mean= +0.96 (p=0.001)</td>
</tr>
</tbody>
</table>

### 14 Appendix 8: Table of evidence (7)

<table>
<thead>
<tr>
<th>Citation/Design</th>
<th>Sample characteristics (summary statistics of characteristics)</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcome (give assessment time)</th>
<th>Effect size (Intervention-control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wong et al. (2004) RCT (1++)</td>
<td>1. Type 2 Diabetes mellitus patients over 18 years old 2. Stable general condition except glycaemic control 3. Willing to have monitor blood glucose by themselves 4. Able to read and write Chinese</td>
<td>Have nurse phone follow-up after discharge (n=101)</td>
<td>No nurse follow-up after discharge (n=101)</td>
<td>1. Medical adherence (HbA1c level)  - 0-6  - 12 weeks  2. Blood monitoring adherence  - 0-6  - 12 weeks  3. Exercise adherence  - 0-6  - 12 weeks  4. Satisfaction  - 5 point scale (strongly agree, agree, neutral, disagree, strongly disagree)  - 12 weeks.</td>
<td>1. Mean= -0.5 (p=0.05)  2. Mean= 0.49 (p&lt;0.01)  3. Mean= 0.2 (p=0.001)  4. Mean= 0.8 (p=0.05)</td>
</tr>
</tbody>
</table>

## Appendix 9: Level of evidence (SIGN, 2004)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case control or cohort or studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

Retrieved from:
16 Appendix 10: SIGN checklist (1)

Methodology Checklist 2: Controlled Trials

Study identification  (*Include author, title, year of publication, journal title, pages*)

| Guideline topic: state how nursing phone counselling can improve hypertension patients’ vital signs and lifestyle. | Key Question No: No | Reviewer: Lau Sin Ying |

*Before* completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question □  2. Other reason □  (please specify):

**SECTION 1: INTERNAL VALIDITY**

*In a well conducted RCT study…* | *Does this study do it?*
--- | ---
1.1 The study addresses an appropriate and clearly focused question. | Yes ■  No □  Can’t say □ |
1.2 The assignment of subjects to treatment groups is randomised. | Yes ■ Can’t say □  No □ |
1.3 An adequate concealment method is used. | Yes □  No ■  Can’t say □ |
1.4 The design keeps subjects and investigators ‘blind’ about treatment allocation. | Yes □  No ■  Can’t say □ |
1.5 The treatment and control groups are similar at the start of the trial. | Yes ■  No □  Can’t say □ |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes ■ No □ Can’t say □ |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes ■ No □ Can’t say □ |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | Dropout rate: 0% |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes ■ No □ Can’t say □ Does not apply □ |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Yes □ No □ Can’t say □ Does not apply ■ |

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1 | How well was the study done to minimise bias?  
*Code as follows:* | High quality (++ □) Acceptable (+)□  
Low quality (-) ■ Unacceptable – reject 0 □ |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Not wholly due to study intervention because some factors such as individual habits, self realization are not counted in. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. |
| 2.4 | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | It shows that nurses’ phone consultation have positive effects on patients to change their lifestyles and reduce blood pressure after 6 months intervention. But it is noted that only concealment is done on subjects and reduce its overall quality so it may be better when concealment is also done on investigators. |
# Appendix 11: SIGN checklist (2)

## Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Study identification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Include author, title, year of publication, journal title, pages</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guideline topic: A RCT study stating how community health workers’ home visits can improve diabetes patients in blood pressure, blood sugar level and weight loss.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Question No: No</td>
</tr>
<tr>
<td>Reviewer: Lau Sin Ying</td>
</tr>
</tbody>
</table>

### Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

| Reason for rejection: 1. Paper not relevant to key question | 2. Other reason (please specify): |
|---|

## SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study...</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Does this study do it?</strong></td>
</tr>
</tbody>
</table>

| 1.1 | The study addresses an appropriate and clearly focused question. |
|---|
| Yes | No |
| Can’t say |

| 1.2 | The assignment of subjects to treatment groups is randomised. |
|---|
| Yes | Can’t say |
| No |

| 1.3 | An adequate concealment method is used. |
|---|
| Yes | No |
| Can’t say |

| 1.4 | The design keeps subjects and investigators ‘blind’ about treatment allocation. |
|---|
| Yes | No |
| Can’t say |
| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes ■ No □  
| | Can’t say □ |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes ■ No □  
| | Can’t say □ |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes ■ No □  
| | Can’t say □ |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | Dropout rate: 18.7%  
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes ■ No □  
| | Can’t say □ Does not apply □ |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Yes ■ No □  
| | Can’t say □ Does not apply □ |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias?  
| | Code as follows:  
| | High quality (+++) ■ Acceptable (+) □  
| | Low quality (-) □ Unacceptable – reject 0 □ |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Not wholly due to study intervention because some factors such as self realization are not counted in. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. |
| 2.4 | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | It shows that when the background of health workers is similar with the patients, it is easier for patient to accept the disease and adapt to the change. However, it is better to have a tailor-made holistic program accompanying with other parties such as occupational therapists, physiotherapists, etc for each patient. |
## Appendix 12: SIGN checklist (3)

### Methodology Checklist 2: Controlled Trials

**Study identification**  
*Include author, title, year of publication, journal title, pages*


**Guideline topic:** state how community nurse phone service can improve chronic disease patients in reducing admission rate and improve its quality of life.

**Key Question No:** No

**Reviewer:** Lau Sin Ying

---

**Before** completing this checklist, consider:

1. **Is the paper a randomised controlled trial** or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. **Is the paper relevant to key question?** Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:** 1. Paper not relevant to key question  □  2. Other reason □  (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

<table>
<thead>
<tr>
<th></th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomized.</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
</tr>
<tr>
<td>1.4</td>
<td>The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1 | How well was the study done to minimise bias?  
*Code as follows:*  
High quality (++■) Acceptable (+) ■  
Low quality (-)■ Unacceptable – reject 0 □ |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Not wholly due to study intervention because some factors such as self realization are not counted in. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | This journal shows that tailor made nursing care is much better than standard care but it may be difficult to apply in Hong Kong as there are too many patients but too few medical practitioners. Therefore, it may be necessary to increase manpower and coordinate with different parties such as occupational therapists, physiotherapists, etc so that personal nursing care plan can really imply in Hong Kong. |
### 19 Appendix 13: SIGN checklist (4)

#### Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>SIGN</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study identification</strong> <em>(Include author, title, year of publication, journal title, pages)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Guideline topic:</strong> A Hong Kong study that state how community nurse service can improve health condition subjectively and objectively.</td>
<td><strong>Key Question No:</strong> No</td>
</tr>
</tbody>
</table>

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:** 1. Paper not relevant to key question  □   2. Other reason □   (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Does this study do it?</strong></td>
<td></td>
</tr>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td><strong>Yes □</strong>  <strong>No □</strong>  <strong>Can’t say □</strong></td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td><strong>Yes □</strong>  <strong>No □</strong>  <strong>Can’t say □</strong></td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td><strong>Yes □</strong>  <strong>No □</strong>  <strong>Can’t say □</strong></td>
</tr>
<tr>
<td>1.4 The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
<td><strong>Yes □</strong>  <strong>No □</strong>  <strong>Can’t say □</strong></td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td><strong>Yes □</strong>  <strong>No □</strong>  <strong>Can’t say □</strong></td>
</tr>
<tr>
<td></td>
<td>Statement</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias?</td>
<td>High quality (++)■ Acceptable (+)□ Low quality (-)□ Unacceptable – reject 0 □</td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Not wholly because of the intervention as some factors such as self realization are not counted in.</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

Community nurses carry out a holistic health program emphasizing continuous nursing care from hospital to community for chronic disease patients and it have good impacts on disease management and their health conditions. But we cannot say that the improvement is wholly depend on community nurses’ home visits because some factors are not counted in such as self realization, family support, etc.
## Methodology Checklist 2: Controlled Trials

**Study identification**  
*Include author, title, year of publication, journal title, pages*


**Guideline topic:** State how DM education in DM centre can improve diabetes patients in self glucose monitoring, drug compliance, healthy lifestyle and medical follow up.

<table>
<thead>
<tr>
<th>Key Question No: No</th>
<th>Reviewer: Lau Sin Ying</th>
</tr>
</thead>
</table>

**Before** completing this checklist, consider:

1. Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:** 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

<table>
<thead>
<tr>
<th></th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomised.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1.6 | The only difference between groups is the treatment under investigation. | Yes | No | Can’t say |
1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes | No | Can’t say |
1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | Dropout rate: 13% |
1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes | No | Can’t say | Does not apply |
1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Yes | No | Can’t say | Does not apply |

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 | How well was the study done to minimise bias?  

*Code as follows:*  
High quality (++) | Acceptable (+) |  
Low quality (-) | Unacceptable – reject 0 |
2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Not wholly due to study intervention because some factors such as individual habits, self realization are not counted in. |
2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
2.4 | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. |  

*It may be difficult to say the good drug compliance and healthy lifestyle is wholly because of DM education because the participants need to go to DM center regularly to receive DM education and they may be affected by other factors such as peer effects, self realization which are not counted in.*
## 24. Appendix 15: SIGN checklist (6)

**Methodology Checklist 2: Controlled Trials**

**S I G N**

<table>
<thead>
<tr>
<th>Study identification</th>
<th>Key Question No: No</th>
<th>Reviewer: Lau Sin Ying</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Include author, title, year of publication, journal title, pages</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Guideline topic: Test if intensive treatment regimen can reduce cardiovascular disease, self blood glucose monitoring and drug compliance for type 1 diabetes patients.

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

**SECTION 1: INTERNAL VALIDITY**

**In a well conducted RCT study…**

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ■ No ☐</td>
</tr>
<tr>
<td>Can’t say ☐</td>
</tr>
</tbody>
</table>

| 1.1 | The study addresses an appropriate and clearly focused question. |
| --- | |
| Yes ■ No ☐ |
| Can’t say ☐ |

| 1.2 | The assignment of subjects to treatment groups is randomised. |
| --- | |
| Yes ■ No ☐ |
| Can’t say ☐ |

| 1.3 | An adequate concealment method is used. |
| --- | |
| Yes ☐ No ■ |
| Can’t say ☐ |

| 1.4 | The design keeps subjects and investigators ‘blind’ about treatment allocation. |
| --- | |
| Yes ☐ No ■ |
| Can’t say ☐ |

<p>| 1.5 | The treatment and control groups are similar at the start of the trial. |
| --- | |
| Yes ☐ No ■ |
| Can’t say ☐ |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
<th>Can’t say</th>
<th>Doesn’t apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
<td>Yes</td>
<td>No</td>
<td>Can’t say</td>
<td></td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes</td>
<td>No</td>
<td>Can’t say</td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Dropout rate: 3.2%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Yes</td>
<td>No</td>
<td>Can’t say</td>
<td>Doesn’t apply</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Yes</td>
<td>No</td>
<td>Can’t say</td>
<td>Doesn’t apply</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Code as follows</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias?</td>
<td>High quality (++)</td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Yes.</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes.</td>
</tr>
<tr>
<td>2.4</td>
<td>Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised.</td>
<td>It shows that intensive diabetes regimen is good for type 1 diabetes patients to have better disease management and drug compliance. However, this regimen needs a lot of manpower, money to involve in it. Besides, the age range between participants is too large and there are many factors to affect the occurrence of heart disease such as gene and there is not enough concealment methods.</td>
</tr>
</tbody>
</table>

72
25. Appendix 16: SIGN checklist (7)

Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Study identification</th>
<th>Include author, title, year of publication, journal title, pages</th>
</tr>
</thead>
</table>

Guideline topic: State how nurse phone follow up can improve medical adherence, self blood glucose monitoring and self reported health condition for diabetes patients.

<table>
<thead>
<tr>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lau Sin Ying</td>
<td></td>
</tr>
</tbody>
</table>

**Before** completing this checklist, consider:

3. Is the paper a *randomised controlled trial* or a *controlled clinical trial*? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a *controlled clinical trial* questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

4. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes ■ No □</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes ■ No □</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Yes ■ No □</td>
</tr>
<tr>
<td>1.4 The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
<td>Yes ■ Can’t say □</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes ■ No □</td>
</tr>
</tbody>
</table>

73
1.6 The only difference between groups is the treatment under investigation. Yes ■ No □ Can’t say □

1.7 All relevant outcomes are measured in a standard, valid and reliable way. Yes ■ No □ Can’t say □

1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? Dropout rate: 15.8% □

1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). Yes ■ No □ Can’t say □ Does not apply □

1.10 Where the study is carried out at more than one site, results are comparable for all sites. Yes ■ No □ Can’t say □ Does not apply □

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias? Code as follows:
- High quality (++■)
- Acceptable (+□)
- Low quality (-)□ Unacceptable – reject 0 □

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? Yes.

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline? Yes.

2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised.

It is good to have treatment integrated with realistic situations and change when patients’ conditions change such as unemployment, move to other places, etc. But it is better to enhance patient’s ability to have self monitoring because it is a life-long disease and it is impossible to have health workers following progress all the time.
### Appendix 17: A working plan of the proposed project

<table>
<thead>
<tr>
<th>Month</th>
<th>Nurses</th>
<th>1-3 months (preparation phrase)</th>
<th>4-6 months (Pilot test)</th>
<th>7-9 months (Implementation phrase)</th>
<th>10-12 months (Evaluation phrase)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 APN</td>
<td></td>
<td>Recruit participants in hospitals, invite 4 RNs to carry out this program and present program content and education content to RNs</td>
<td>Supervise the home visits, evaluate the test and amend the program when needed</td>
<td>Supervise the home visit services</td>
<td>Conclude and evaluate the data, present the result to DOM and WM</td>
</tr>
<tr>
<td>1 APN</td>
<td></td>
<td>Prepare education materials and hold a meeting to present this idea to DOM, WM</td>
<td>Supervise the home visits, evaluate the test and amend the program when needed</td>
<td>Supervise the home visit services</td>
<td>Conclude and evaluate the data, present the result to DOM and WM</td>
</tr>
<tr>
<td>4 CNS RNs</td>
<td></td>
<td>Will be taught about the education materials and program content</td>
<td>Regular home visits and evaluate the test</td>
<td>Regular home visits</td>
<td>Take participants’ blood test, collect the participants’ questionnaires in center and also finish staff’s questionnaire</td>
</tr>
</tbody>
</table>
### Appendix 18: The budget plan for the proposed innovation

<table>
<thead>
<tr>
<th>Items</th>
<th>Cost (HKD$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>APNs salary (each: $265x111) x2</td>
<td>58,830</td>
</tr>
<tr>
<td>RNs salary (each: $167x24) x4</td>
<td>16,032</td>
</tr>
<tr>
<td>Printing fees for education materials</td>
<td>0 (Available)</td>
</tr>
<tr>
<td>Computers</td>
<td>0 (Available)</td>
</tr>
<tr>
<td>Conference room for meeting</td>
<td>0 (Available)</td>
</tr>
<tr>
<td>Stationary</td>
<td>0 (Available)</td>
</tr>
<tr>
<td><strong>Total Cost</strong></td>
<td><strong>74,862</strong></td>
</tr>
</tbody>
</table>
### Appendix 19: Grade of Recommendation (Scottish Intercollegiate Guideline Network, 2012)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At least one systematic review or meta-analysis or rated 1++ RCT or a body of evidence consist of studies which are 1+ and it can be directly applied to the target population and shown consistent results.</td>
</tr>
<tr>
<td>B</td>
<td>The evidences including 2++ studies or extrapolated evidences from 1++ or 1+ studies and they can directly apply to the target population showing consistent results.</td>
</tr>
<tr>
<td>C</td>
<td>An evidence includes 2+ studies and it can directly apply to the target population.</td>
</tr>
<tr>
<td>D</td>
<td>An evidence which is level 3 or 4 or an extrapolated evidence from 2+ studies.</td>
</tr>
<tr>
<td>D (GTP)</td>
<td>Recommendations based on the experience in clinical setting by the development groups.</td>
</tr>
</tbody>
</table>
Title: An evidence-based guideline to improve disease management and develop healthy lifestyle for patients with Type I Diabetes Mellitus by community nurses.

Introduction:

After systematic review of journals and assessing the transferability and feasibility, it shows that home visit by community nurses is an effective and cost-saving methods to improve type 1 diabetes patients’ disease management and develop healthy lifestyle. However, when home visit program is implied, it is necessary to develop an evidence-based guideline so that community nurses can have a standard instruction to guide and support them during home visits such as the frequency of home visits, the content of education during home visits, etc.

Therefore, according to those seven high quality level RCTs found in systematic review, an evidence-based guideline is developed and seven recommendations are made for the home visit program by community nurses to improve type 1 diabetes patients’ disease management and develop a healthy lifestyle. Besides, the level of grading of these seven recommendations is assessed according to SIGN (2012) (Appendix 19) and one recommendation is in Grade A while the other six are in Grade B.

Objectives of the protocol:

1) To provide an evidence-based guideline to assist community nurses to give appropriate diabetes self management knowledge during home visits (Sayed et al., 2016; Chow et al., 2008; Nathan et al., 2005; Wong et al., 2004).
2) To provide an evidence-based guideline on frequency of home visits for community nurses (Sayed et al., 2016; Chow et al., 2008; Wong et al., 2004).

3) To provide an evidence-based guideline for community nurses on healthy lifestyle about diet control and regular exercise for type 1 diabetes patients (Sayed et al., 2016; Rothschild et al., 2014; Nathan et al., 2005).

- Recommendations:

**1. It should have at least one home visit per week by community nurses.**

(Grade A)

i) Undoubtedly home visit is able to improve physical and psychological well being of those chronic disease patients by enhancing and improving their quality of life and face-to-face education is better than phone consultation (Chow et al., 2008) (1++).  

ii) The community nurses serve as valuable resource people who provide ongoing problem identifications and related assessments for patients with chronic diseases and it is better when at least one home visit is provided per week (Chow et al., 2008) (1++).  

iii) The findings showed that the nurse follow-ups can improve participants’ glycaemic control which may improve their adherence to the health-related behaviors (Wong et al., 2004) (1+).
### 2. Community nurses should have tailor-made care plans according to patients’ habits. (Grade B)

i) Tailed made care coordination management is better than standard care for chronic disease patients, this can reduce their readmission rate (Rasjo et al., 2015) (1-).

### 3. Less sweet intake (less than two times per week) should be educated. (Grade B)

i) It is indicated poor glycemia control for type 1 diabetes patients is because of unhealthy lifestyle such as too much sweet and too little exercise (Sayed et al., 2016) (1+).

ii) Type 1 diabetes patients should restrict diet to 1500-1800 kcal per day and have regular exercise at least 30 minutes for three times per week (Sayed et al., 2016) (1+).

iii) Patients claimed that they have better glucose control when they intake less sugar less than 2 times per week and increase frequency of exercise at least 3 times per week (Nathan et al., 2005) (1-).

### 4. It is appropriate to have diary recording daily food intake and exercise (Grade B)

i) Type 1 diabetes patients should record the diet and have regular meal in regular time and with regular amount (Sayed et al., 2016) (1+).

ii) It is better in HbA1c result when type 1 diabetes patients can have strict diary record in their daily life (Nathan et al., 2005) (1-).
5. Regular exercise is important and it should be at least three times per week. (Grade B)
   i) Type 1 diabetes patients should restrict diet to 1500-1800 kcal per day and have regular exercise at least 30 minutes for three times per week (Sayed et al., 2016) (1+).
   ii) Patients claimed that they have better glucose control when they intake less sugar less than two times per week and increase frequency of exercise at least three times per week (Nathan et al., 2005) (1-).
   iii) The participants with intervention reported that better blood glucose control noted when they have increased physical activities from a baseline mean of 1.63 days per week to 2.64 days per week (Rothschild et al., 2014) (1+).
   iv) It is indicated poor glycemia control for type 1 diabetes patients is because of unhealthy lifestyle such as too much sweet and too little exercise (Sayed et al., 2016) (1+).

6. Regular self blood glucose monitoring is important and diabetes patients should record results. (Grade B)
   i) Poor glycaemic control, lower education level and female sex are linked with worse quality of life in our populations (Rothschild et al., 2014) (1++).
   ii) Type 1 diabetes is associated with at least 10-fold increases in cardiovascular diseases compared with nondiabetic population with same age so they should check blood glucose level by themselves regularly (Nathan et al., 2005) (1-).
iii) It shows that frequent self blood glucose monitoring can have better 
HbA1c level finally and doctors can adjust medication accurately 
according to blood glucose records done by patients (Chow et al., 
2008) (1+).

7. Hypoglycemia or hyperglycemia management should be educated, for 
example, they should take sweet immediately when hypoglycemia 
symptoms noted or eat less next meal and monitor blood sugar 
frequently when hyperglycemia is noted. (Grade B)

i) Type 1 diabetes patients should be educated to know what they should do 
when hypoglycemia attack or hyperglycemia noted in their daily life 
(Sayed et al., 2016) (1+).

ii) Type 1 diabetes patients should take sugars immediately when 
hypoglycemia symptoms such as dizziness, sweating noted (Sayed et al., 
2016) (1+).

iii) Type 1 diabetes is associated with at least 10-fold increases in 
cardiovascular diseases compared with nondiabetic population with same 
age because of severe hyperglycemia so they should check blood glucose 
level by themselves regularly and have appropriate management such as 
restrict diet when hyperglycemia noted. (Nathan et al., 2005) (1-).

Reference:


**Appendix 21: Flow of communication process**

1) Two APN will search high evidence based literatures about providing community nurses services to Type 1 diabetes patients and design the education materials.

2) APNs have a discussion with WM to get his support and expert opinions.

3) APNs have a formal presentation to CNS DOM.

4) APNs will invite 4 suitable RNs to run this innovation and explain the aims and purpose of this program clearly and reinforce that no extra workloads added to them to get their consensus.

5) During the implementation, when RNs and participants have questions or opinions, they can feel free to ask APNs and APNs will explain to them or seek WM advice to improve it.

6) Besides, WM and APNs would have regular meetings with RNs to evaluate the program.
### Appendix 22a: Questionnaire (1) (Participants) (English version)

Participants’ Satisfaction Questionnaires

Thank you your participants for 3 months’ community nurses’ home visits. Your feedback is valuable for us to improve patient care in the future.

Please circle the appropriate rating for the following aspect of the group
1=Totally disagree 2=Disagree 3=Neutral 4=Agree 5=Totally agree

<table>
<thead>
<tr>
<th>Questions</th>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) I have injected appropriate insulin dosage in appropriate time according to regimen.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(2) I have injected insulin every day according to regimen.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(3) I have at least 3 times exercise per week.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(4) I have less than 2 times sugar intake per week.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(5) I know how to manage hypo or hyperglycemia attack in daily life.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(6) I have attended follow up as scheduled.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(7) I have self monitored blood glucose every day.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(8) I am confidence in diabetes management and I don’t think I need nurses’ intervention.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(9) I think community nurses’ home visits can improve my condition.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Thank you for your help!
謝謝你參加是次社康護士改善一型糖尿病病友疾病管理及建立健康生活計劃。你的寶貴意見是很重要的，以便日後改善計劃。
麻煩完成此問卷，多謝你的參與和合作。

對於以下描述，請圈出你認為最合適的評價。
1=非常不認同 2=不認同 3=無意見 4=認同 5=非常認同

<table>
<thead>
<tr>
<th>描述</th>
<th>非常不認同</th>
<th>認同</th>
<th>無意見</th>
<th>認同</th>
<th>非常認同</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) 我會根據醫生開的處方在適當的時間自行注射適當份量的胰島素</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(2) 我每天都會根據醫生開的處方自行注射胰島素</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(3) 我每星期最少有三次運動</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(4) 我每星期會食少過兩次甜食</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(5) 我知道我點樣處理高血糖或低血糖徵狀</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(6) 我有準時去覆診</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(7) 我每天都有自行監察血糖</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(8) 我對自己的疾病管理很有信心，我覺得我不需要護士幫忙</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(9) 我覺得社康護士可改善我的疾病管理及建立健康生活</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

感謝你的幫忙!
Thank you for your involvement for 3 months’ home visits for type 1 diabetes patients. Your feedback is valuable for us to improve patient care in the future.

Please circle the appropriate rating for the following aspect of the group
1=Totally disagree 2=Disagree 3=Neutral 4=Agree 5=Totally agree

<table>
<thead>
<tr>
<th>Questions</th>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) The aim and objectives of this program are clear for me to understand.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(2) The content is organized and useful for me during providing relevant</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>education in home visits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(3) The content is easy for me to understand and follow.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(4) The duration of this program is appropriate.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>(5) I am confidence to provide appropriate diabetes knowledge during</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>home visits with that evidence-based guideline.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(6) I am confidence to provide appropriate healthy lifestyle knowledge</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>during home visits with that evidence-based guideline.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(7) I feel helpful for APNs’ support during facing difficulty in this</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>program.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thank you for your help!