School of Nursing LKS Faculty of Medicine

The University of Hong Kong

Title: Effectiveness of an Information-Motivation-Behavioral Skills Model-based intervention on adherence to domiciliary non-invasive ventilation of patients with chronic hypercapnic respiratory failure: A randomized controlled study

document date: 4 August 2021

School of Nursing, The University of Hong Kong
Department of Medicine & Geriatrics of United Christian Hospital

Effectiveness of an Information-Motivation-Behavioral Skills Model-based intervention on adherence to domiciliary non-invasive ventilation of patients with chronic hypercapnic respiratory failure: A randomized controlled study

Information Sheet

You are invited to participate in a research. This is a collaborative study conducted by United Christian Hospital and the School of Nursing, The University of Hong Kong. Before you decide, it is important that you understand why the research is done and how you will be involved. Please read the information carefully and discuss it with friends, relatives and your family doctor if you wish. Ask if there is anything unclear or if you wish to obtain more information. Take time to decide whether you wish to participate in the research.
A total number of 104 patients will be recruited from the wards of Department of Medicine and Geriatrics in United Christian Hospital (UCH). With referral from your primary doctor, you are cordially invited to participate in this study.

Purpose of the Study

This study aims to evaluate the effectiveness of an Information-Motivation-Behavioral skills (IMB) model-based intervention on adherence to domiciliary non-invasive ventilation (NIV) in patients with chronic hypercapnic respiratory failure (CHRF).

Participants Selection:

Patients who are suffering from CHRF for at least 4 weeks; using domiciliary NIV for >= 4 weeks and non-adherer (i.e., used domiciliary NIV for < 4 hours per night or < 70% of days or with a mean daily use < 5 hours in the last 2 weeks) will be invited to participate in this study.

Nature of Participation:

Your participation is absolutely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you refuse to participate, you don't have to give a reason. The treatment and care that you are receiving will not be affected. If you decide to take part in the study, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of treatment and care you receive in present and future. You will be updated timely of new information that may be relevant to your willingness to continue the participation in this study.

Data collection procedure

After obtaining informed consents, the research assistant will collect your socio-demographics (e.g. age, sex, education level etc.) and clinical characteristics (medical diagnosis and the related health history, NIV adherence record from the NIV machine, sleep quality and health quality) through a face-to-face interview which will

takes about 30 minutes. A doctor of the respiratory team will prescribe collection of your venous blood sample (3-5 ml) for bicarbonate (HCO_3^-). After collection of the above baseline data, you will be randomly assigned to two programs according to a computer generated sequences of equal opportunities (i.e. you will have half of the chance to be assigned to one of the plans named as Program A and Program B). After being assigned to either of the plan, you will not be able to request to change to another plan. Also if you could not attend/complete all visits, you are still treated as participants of the study and will not be terminated.

If you are assigned to Program A, you are invited to participate in this 6-week program in which you will be provided with behavioral and skill training as well as counselling in using the NIV machines by a research assistant trained by the medical officer and respiratory nurse of our research team. The telephone consultation hotline will be provided for information and motivation interventions according to the patient's needs during the program period.

1. First week--One hour face-to-face home visit

(i) to carry out a comprehensive assessment on the patient's needs for information, motivation and behavioral skill interventions,

(ii) to provide individualized interventions according to the assessment findings.

2. Second and third weeks--Twenty minutes telephone follow up (if you are unable to answer the phone, your relatives can answer it on behalf of you)

(i) to assess the patient's progress in domiciliary NIV adherence,

(ii) to deliver information and motivation interventions.

3. Sixth week--Half hour face-to-face follow-up at hospital (it will be conducted in the nurse-led clinic in the study ward of UCH)

(i) to provide information and behavioral skill training as needed, enhancing motivation and round off.

If you are assigned to Program B, you are invited to participate in this study in which you will be provided an one-hour face-to-face session to introduce the choices of domiciliary NIV and patient education or your family on how to operate and maintain the ventilator, interface and accessories, and also how to handle the common problems such as leakage and pressure sore in hospital before discharge. It will be conducted in the nurse-led clinic in the study ward of UCH. Commercial leaflet or booklet according to the choice of ventilator with information of the ventilator, interface, accessories and the ventilator company will be provided to the patient.

No matter you are in Program A or B, there will be three follow ups scheduled at 3-, 6-, 12-months after joining the program by the research assistant to assess the NIV adherence and knowledge. The RA will contact you by phone to arrange data collection (NIV adherence record from the NIV machine, sleep quality and health quality) with you at home according to the study timeline. It will takes about 30 minutes. At 3-month and 6-month, the doctor of the respiratory team will prescribe collection of your blood sample (3-5 ml) for venous bicarbonate (HCO_3^-) again. In addition, your venous blood result, number of unplanned hospital admission related to hypercapnic respiratory failure etc. will be retrieved from the Clinical Management System of the hospital by

the RA.

Alternative treatments if patient opts for not joining the study

All patients will receive appropriate and standardized treatment in the hospital. There will be no difference between study participants and other patients in terms of treatment arrangement. Your participation will not affect your present or future care and treatment received from the hospital or in the community.

Cost and payment of the study

Besides regular hospitalization fee, you will not be charged for participating in the study. Also you will not receive any rewards from this study.

Risk and Benefits:

The assessment will not cause any pain, discomfort or harm to you. The major potential benefit to evaluate the effectiveness of the program on improving adherence to domiciliary NIV in patients with CHRF. The results of this study will be used in prevention of premature death, promotion of physical well-being and reduction of health care cost in patients with CHRF using domiciliary NIV.

Compensation and treatment for study related injury

When there are any mental or physical discomfort raised during the study period, our research team will provide or refer appropriate treatment to you. You will not give up your legal rights by signing this form.

Anonymity and Confidentiality:

All the information which is collected about you during the course of the research will be kept strictly anonymous and confidential. The collected data will be locked up in a secure location and only the researcher can access to them. All the data will be destroyed within five years after the study.

Under the laws of Hong Kong [in particular the Personal Data (Privacy) Ordinance, Cap 486], you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By signing the written informed consent form, you are authorizing the Research Ethics Committee (REC) and the regulatory authority(ies) will be granted direct access to your study data for data verification.

Voluntary Participation/ Withdrawal

You are voluntary to participate in this study. Your decision to participate or not will be respected. You have the

right to ask any questions, refuse or withdraw from the study at any time and without giving a reason. Your decision of participating in this study will not affect the quality of present or future medical care you receive in the hospital and community. If you withdraw from the study, the data collected before withdrawal will be destroyed if we do not have your consent. You may also state in the consent to allow the researcher to continue using the data collected from you for your research purposes after your withdrawal. You will be given enough time to consider whether to participate in this study.

Please sign the attached consent form if you agree to participate in this study. After signing, a copy of this participant information sheet and signed consent form will be given to you for retention.

Inquiry:

For any questions or enquiries, please feel free to contact the research team:

Mr. Poon Chung-Leung, Henry, Senior Nursing Officer, Nursing Services Division, United Christian Hospital (Tel: 5215 6828).

Prof. YU Doris Sau-Fung , Professor, School of Nursing, The University of Hong Kong (Tel:3917 6319)

If you have questions related to your rights as a research participant, please contact the Research Ethics Committee (Kowloon Central/Kowloon East) at 35068888.

You are cordially invited to participate in this study.

Effectiveness of an Information-Motivation-Behavioral Skills Model-based intervention on adherence to domiciliary non-invasive ventilation of patients with chronic hypercapnic respiratory failure: A randomized controlled study

Informed Consent for Participation in a Research Study

This is to certify that I, _____, consent to participate in the above study. I understand that the information obtained from this study may be used in future research, and may be published. However, I will not be in any way identifiable. I have been given a detailed account of the project and have had opportunities to ask questions which have been explained to my satisfaction. I understand that my participation is entirely voluntary and I have the right to withdraw from the study at any time, and will not affect the quality of present or future clinical care I receive in the hospital.

If I request to withdraw from the study, I ☐ agree / ☐ disagree researcher to continue using the data collected from me for research purposes after my withdrawal.

I understand that my identity will be handled confidentially. I also agree the Research Ethics Committee and the relevant statutory bodies to directly review my research data to verify the relevant clinical research data, subject to the appropriate regulations and legislation and without infringing my privacy.

Name of Participant	Signature	Date
Name of Research Assistant	Signature	Date

** After signing, a copy of the participant information sheet and signed informed consent form will be given to me for retention.