Development and validation of educational pamphlet to prevent sleep apnea
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Abstract
Background. Obstructive sleep apnea (OSA) is characterized by recurrent complete (apneas) and partial (hypopneas) upper airway obstructive. The Obstructive Sleep Apnea is one of the leading risk factor for coronary heart diseases and heart failure.

Aim. The aim of the study was to develop and validate the educational pamphlet on Obstructive sleep apnea (OSA)

Design. A mixed method research design with quantitative research approach was adopted in this study.

Methods. Educational pamphlet was developed on prevention and control of Obstructive sleep apnea. The pamphlet was developed in three phases which includes review of content, design/layout of the pamphlet and validation with expert opinion. The pamphlet was validated using Item level content validity index (I-CVI) and Scale level Content Validity Index (S-CVI). individual items which ranged from 0.94 – 1. Scale level Content Validity Index (S-CVI) was 0.9120.

Methods AND MATERIALS
Ethical considerations
The study was initiated after obtained approval from the Principal, Faculty of Nursing, Institutional Ethics Committee, The Head of the Community Medicine, The Convener, Rural Health Training Centre & Research Institute, Sri Ramachandra Hospital. Participants were explained clearly about the study purpose and a written informed consent was obtained from all the participants before conducting the study. Confidentiality of the responses were assured and maintained throughout the study.

Research setting and design
A mixed method research design with quantitative research approach was adopted in this design.

Phases of Pamphlet Development
An in-depth literature review and focused group discussion with experts were conducted to formulate age, sex, central obesity, short structure and heavy neck circumference. The associated risk factors are stroke, Hypertension, Hypothyroidism, coronary he artery diseases.(Zarir et al., 2003). The untreated Obstructive Sleep Apnea may cause increased daytime sleep, Upper Respiratory Tract Infection, congestion, swelling of the throat, tonsillitis, increases in size of the lymphoid tissue, impairment in working memory and manipulating nonverbal information. The early clinical sign of sleep apnea are day time sleeping and snoring during sleeping. Hence people never consider those symptoms hence not faced much difficulty in their activity of daily living. A study done by Houts et al., showed that written information along with illustrations can be an effective teaching strategy for OSA high risk group especially from low literacy population [American Academy of sleep medicine(1999)], [Boyn ton et al.,(2013)]. Hence the need arises for such a service system which can be understood in local language and can be delivered in their home settings without much professional involvement. Keeping this into consideration, present study was aimed at development and validation of an educational pamphlet for the OSA high risk group in English as well as local (Tamil) Language. Its main purpose was to impart knowledge and educate high risk OSA.
and develop the content of education pamphlet to prevent sleep Apnea for people with high risk of developing sleep Apnea. The pamphlet have developed based on BALD (Backer Able Leaflet Design) method. The patient information pamphlet has validated for a layout and design, Item level content validity index (I-CVI) was calculated for individual items which ranged from 0.94 – 1. Scale level Content Validity Index (S-CVI) was calculated for complete nine items and it was found to be 0.9120.

Phase One
The development and validation of pamphlet on prevention of sleep Apnea has three stages. In initial stage the relevant content was gathered based on depth of literature review from text books, existing pamphlets and had discussion with endocrine medical, surgical experts, paramedical personnel about their experience in their specific field.

Phase Two
Literature review on pamphlet design reveals that the design of the pamphlet (pictorial representation, colour, organization of content) influence the memory and clear understanding about the preventive techniques. The pamphlet provided information about meaning and definition of sleep Apnea, risk factors, causes, clinical signs and preventive measures. The pamphlet fit on a two -sided sheet of paper for easy, inexpensive copying. Copies of the pamphlet and its subsequent translations was done into Tamil language also.

Phase Three
The printed pamphlet was validated by the experts with minimum 10 years of experience (Two general physician, Two endocrinologist, Ten Nursing teaching Faculties, Two physiotherapist, Five nursing administrators, Ten Intensive Care Staff nurse and Four post-operative staff nurses. Process of Development of educational pamphlet for prevention and treatment of sleep Apnea

Page I- Introduction
In this page general information about sleep Apnea, prevalence rate, definitions and types

Page II-Clinical Sign
This page explains clinical signs of OSA (snoring, insomnia, early morning headache, Restless Legs Syndrome & Sleep Hypoventilation) with proper illustrations.

Page III-Risk factors
This page views the risk factors of OSA with outline of pathological changes in specific organs. (Smoking, Alcoholism and Obesity)

Page IV-Risk factors
Page IV illustrates the preventive measures and home based simple treatment strategies explained with appropriate pictures. Treatment strategies which includes Tongue exercises, Breathing techniques and pursed lip breathing etc. Preventive measures which includes components of Mediterranean diet, yoga techniques, sleeping positions etc.

Experts validation
- Physician
- Nursing Faculties
- Icu staff Nurses
- Nursing Administrators
First draft of information pamphlet on prevention of OSA Prevention of sleep apnea
- Graphs
- Images
Obtained opinion for important domains from Expert review

Assessment of Content Validity
Assessment of Content Validity This pre-final draft was sent for content validity to experts. It was a two-stage process requiring validation in the developmental and judgment-quantification stages [Leininger (2002)]. During the developmental stage, a panel of four experts including two physiotherapists, general physicians and an endocrinologist validated the accuracy of information presented and ability to comprehend according to high risk group point of view. Judgment-quantification stage of content validation involved validation of both the content of the items and the entire instrument [Lynn(1986)]. Rating scales were sent to 34 validators. The panel of experts were having the relevant training, experience and qualification for this validation. Experts were selected from different fields to make the educational material more user friendly and to cater the needs of high risk groups. The panel received specific instructions to determine the content relevance of specific items and of the leaflet as a whole.
Validation was done through a questionnaire consisting of 10 items pertaining to completeness, understandability, legibility, clarity and utility of educational material for high risk groups and a section for comments. Questionnaire was distributed to 34 validators (Two general physician, Two endocrinologist, Ten Nursing teaching Faculties, Two physiotherapist, Five nursing administrators, Ten Intensive Care Staff nurse and Four post-operative staff nurses), along with a covering letter stating the purpose of this educational material, the reason why they have been chosen for validation and the importance of their participation in validating the educational material. Scoring was based on a 5 point likert scale. Results were quantified by applying the Content Validity Index (CVI) [Davis1992], Polit and Beck (2006)]. Translation & parallel back translation: Standard procedure was followed for translation into local language to enhance its utility and acceptability by local population [Beaton, Bombardier,Guillemin and Ferraz (2000)]. After completing the content validity, this leaflet was translated into local language (Tamil) by two independent persons with fluency in both the languages i.e., Tamil and 23 English. Both the versions were discussed with the involvement of third person with bilingual expertise to resolve any identified discrepancies or ambiguity of words. After reaching the final consensus, one single version was prepared. This final copy was sent to another person who was completely blinded for the study to translate it back to English (original language). Once parallel back translation was done, an expert committee meeting consisting of translators, language experts, physiotherapist and general physician and endocrinologist were held to consolidate the final form with equivalence in both the versions i.e., English and Tamil.

Experts in agreement of each items was calculated based on sum up the relevant rating provided by all experts for each item.

Table 1

<table>
<thead>
<tr>
<th>S. No</th>
<th>Q. No</th>
<th>Items</th>
<th>Level Content Validity</th>
<th>Index (I-CVI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Q1</td>
<td>Evaluate the appearance of the pamphlet</td>
<td>0.94</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Q2</td>
<td>The pamphlet is presented in a simple and understandable language</td>
<td>0.97</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Q3</td>
<td>The pamphlet provides information on prevention of sleep apnea</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Q4</td>
<td>The pamphlet provides information on risk factors of sleep apnea</td>
<td>0.97</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Q5</td>
<td>The pamphlet provides clear definition of sleep apnea</td>
<td>0.97</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Q6</td>
<td>The clinical signs of sleep apnea is relevant and understandable</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Q7</td>
<td>The pictures of breathing techniques assist to perform breathing techniques independently</td>
<td>0.97</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Q8</td>
<td>The pictures of tongue exercise assist to perform tongue exercise independently</td>
<td>0.97</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Q9</td>
<td>The Mediterranean diet and Their purposes are clearly understandable</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Q10</td>
<td>I would like to use this pamphlet to educate high risk groups to prevent sleep apnea</td>
<td>0.97</td>
<td></td>
</tr>
</tbody>
</table>

Scale Content Validity Index (S-CVI) = Average of I-CVI 9.76/10=0.97

Table 2

Validation of experts in agreement of an educational pamphlet on prevention and control of Sleep Apnea

| Q.NO | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | A.Ag |
|------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 1    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 33 |
| 2    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 34 |
| 3    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 35 |
| 4    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 35 |
| 5    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 35 |
| 6    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 35 |
| 7    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 35 |
| 8    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 34 |
| 9    | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 35 |
| 10   | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 34 |
Discussion

The objective of the present study was to develop and validate an educational pamphlet on prevention and control of OSA. Literature has reported that educating high risk groups and providing them with structured written information pamphlet can enhance the probability that important information will be better attended to, understood, accepted and recalled [Nicolette Bester et al., 2016]. The present study involved validators from different specialties and while selecting the panel of experts their qualification, training, experience, publication, presentations and research interests were taken into consideration. This was done in consensus with American Psychological Association guidelines which emphasize that these aspects should be considered to make the material more authenticated and operational for target population [Khurana, S et al. (2016)]. Content validation of our study showed I-CVI more than 0.97 for all the items in the questionnaire except item - 1 (I-CVI= 0.94). The I-CVI -0.94 value is acceptable level even though the least I-CVI in this study was taken in to the consideration and the overall app earance of the pamphlet was modified once again before pre final format of the pamphlets. Maximum number of validators found inadequacy and expressed their views to add a section on dietary management to prevent OSA. Therefore a table was added on the last page to provide information about the Mediterranean diet same in the educational pamphlet. This was done in line with previous studies which states that awareness of caregivers/parents about their child development is very crucial and it influences their expectations and interactions with their child [Reich(2005)].

Conclusion

The pamphlet on prevention of sleep OSA is an educational and interventional tool to prevent and control the OSA among people in high risk. It is very simple tool and it is available in English as well in local language of Tamilnadu (Tamil).People can able to use this pamphlet without medical professionals Guidance. Hence, an educational pamphlet covering information regarding the definition, causes, high risk, clinical sign and prevention of OSA.

References


