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Psychometric validation of Swedish and Arabic versions of two Health literacy questionnaires, eHEALS and HLS-EU-Q16, for use in a Swedish context: A study protocol

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Psychometric validation of Swedish and Arabic versions of two Health literacy questionnaires, eHEALS and HLS-EU-Q16, for use in a Swedish context: A study protocol

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ABSTRACT

Introduction

Equity in health and access to health care regardless of, gender, ethnicity or social position is a major political issue worldwide. Regardless of an individual's knowledge, motivation, and competence individuals are expected to be engaged and take responsibility of their own care. Migrants have been identified as a vulnerable population in health care and an explanation for the inequity in health, and in health care is limited health literacy. Further more, with increasing digitalization in health care, it puts demand on the individual to also have digital or electronic health (eHealth) literacy.

The overall aim of this study is to psychometric evaluate the Swedish and Arabic versions of HLS-EU-Q16 and eHEALS, and to compare Arabic and Swedish speakers' Health literacy and eHealth literacy levels in Sweden.

Methods and Analysis

This is a prospective, psychometric evaluation study with the intent of including 300 Arabic speaking and 300 Swedish speaking participants. Questionnaires: The Health Literacy Survey European Questionnaire (HLS-EU-Q16) including 16 items measuring perceived personal skills of finding, understanding, judging, and applying health information to maintain and improve their health. The eHealth literacy scale (eHEALS), an 8-item measuring health literacy skills in relation to online information and applications.

This study will be conducted in four phases. Phase 1: Translation of HLS-EU-Q16 and eHEALS from English to Swedish and Arabic following the principles of translation of questionnaires. Phase 2: Content validity testing of eHEALS, including face validity and interpretability conducted with five Arabic and five Swedish speaking participants. Phase 3: Psychometric testing including construct validity, reliability, feasibility and floor ceiling effects. Phase 4: Distribution and comparison of eHealth and HLS-EU-Q16 analysed with Chi square and Fisher's exact test as appropriate. To assess associations between HLS-EU-Q16, eHEALS and demographic variables binary logistic regression analyses will be performed.

Ethics and dissemination

The project has been approved by the regional ethical review board in Stockholm, Sweden (2019/5:1) and will follow the principles outlined in the 1964 Helsinki Declaration and its later amendments. Results from this study will be disseminated in peer-reviewed journals, scientific conferences and in social media.

ARTICLE SUMMARY

Strengths and limitations

- A Swedish and Arabic version of eHEALS and HLS-EU-Q16 have not yet been psychometric evaluated
- eHealth literacy has not previously been investigated in a Swedish population.
- This is the first study to compare eHealth literacy between Swedish and Arabic speaking citizens in Sweden.
- Although this study includes both Swedish and Arabic speaking participants from different contexts in the society the study is conducted in Sweden and may not be generalizable to other contexts.

INTRODUCTION

The importance of health literacy

Patients in today's health care system are expected to take part and be engaged in their own care. Consequently, they have to be able to read and understand health instructions on how to manage their own recovery at home ¹. Informed decision making requires people to have a certain level of health literacy when self-reporting measurements and health information. In this article we use the following definition of comprehensive health literacy:

Health literacy is linked to literacy and entails people's knowledge, motivation, and competence to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course².

Health literacy is regarded as a social determinant of health ³ and has a strong social gradient ⁴. Which means, health literacy can be an additional barrier to health for already disadvantaged and marginalised groups within societies. Limited health literacy is likely to affect patients' quality of care, resulting in lower satisfaction with care and lower understanding of their medical situation ⁵ and their safety, by decreasing the probability of an adverse medication due to misunderstanding instructions ^{5,6}. Health literacy is also associated with the extent to which people benefit from health examinations ⁷ and the quality of their postoperative recovery ⁸.

With increasing digitalisation of information and services, modern health care and health promotion have become increasingly challenging for both patients and health care staff⁹. This demands a range of digital competencies among users, and requires new ways to describe and evaluate users' digital capabilities and experiences in this rapidly changing health context ⁹. Consequently, the concept of digital or electronic health (eHealth) literacy has emerged ¹⁰⁻¹² and been described as 'the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem' ¹².

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3 Equity in health and access to health care regardless of social position, gender, race, or
4 ethnicity is a major political issue in the European Region and worldwide ¹³. The Swedish
5 Health and Medical Services Act ¹⁴ states that the goal of health care is to promote ‘good
6 health and care on equal terms for the entire population’ ^{6, 14}. Migrants, whether they are
7 labour migrants or refugees, have been identified as a vulnerable population, but there is
8 heterogeneity in the degree to which they are vulnerable to inadequate health care ^{5, 6, 15, 16}.
9 One explanatory factor for the inequity in health, and in health care is limited health literacy
10 on individual and organizational level ¹⁷. A Swedish study show for example that newly
11 arrived refugees with limited health literacy, to a higher degree experienced poor quality of
12 communication and benefited less from the health examination for asylum seekers than those
13 with higher health literacy ⁷. Another study show that newly arrived refugees with limited
14 comprehensive health literacy have poorer general health and do not seek needed care as often
15 as those with higher comprehensive health literacy ¹⁸.
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27 *HLS-EU-Q16*

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29 In 2011-2012, Sørensen et al. developed the Health Literacy Survey European Questionnaire,
30 HLS-EUQ47, a self-reporting instrument consisting of 47 items ¹⁹. The instrument is based on
31 a systematic literature review that derived an all-inclusive conceptual model and the definition
32 of comprehensive health literacy used in this study. In 2013, the instrument was used in a
33 large study including populations in 8 European countries ⁴. As a result of that study’s
34 analysis, the shorter 16-item version, HLS-EU-Q16, was developed ². Both the HLS-EUQ47
35 and HLS-EU-Q16 have been used frequently in many different countries and are available in
36 a range of languages ^{2, 18, 20-24}.
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44 The HLS-EU-Q16 aims to measure respondents’ perceived personal skills of finding,
45 understanding, judging, and applying health information to maintain and improve their health
46 ¹⁹. Each item in the instrument is answered on a 4-point Likert scale with response options
47 ranging from ‘very difficult’ to ‘very easy’. An overall HLS-EU-Q16 index will be calculated
48 in three steps according to the developer^{20, 25}. First, the response categories for the 16 items
49 will be dichotomized into easy (fairly easy and easy) giving the value of 1, and difficult
50 (difficult and very difficult) giving the value 0. Second, an overall sum score will be
51 calculated. Third, sum scores will be divided into three categories: inadequate (0-8 score
52 points), problematic (9-12 score points) and sufficient (13-16 score points) health literacy.
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3 . HLS-EUQ16 has been psychometrically tested and showed to be in some migrant
4 populations in which it was found to be reliable and valid ^{20, 26}.
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8 The Arabic and Swedish versions of HLS-EU-Q16 have been translated in line with
9 guidelines for the translation of instruments and tested for Face validity among migrants in
10 Sweden ²⁷. The Swedish and Arabic versions of the HLS-EU-Q16 have since been used in
11 several studies in Sweden ^{7, 18, 28} and Egypt ²³. However, the translated Swedish and Arabic
12 versions have not yet been tested for other aspects of validity and comprehensive health
13 literacy has not been compared between Swedish- and non-Swedish-speaking people.
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20 *eHEALS*

21 In 2006, Norman and Skinner developed the eHealth literacy scale, eHEALS. It aims to
22 measure a broad range of literacy skills, which might make it useful in assessing the effects of
23 strategies to deliver online information and applications. eHEALS is an 8-item instrument
24 with each item scored on a 5-point Likert scale with response options ranging from ‘strongly
25 agree’ to ‘strongly disagree’. Total scores on the eHEALS range from 8 to 40, with higher
26 scores representing higher self-perceived eHealth literacy.
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34 The eHEALS is available in a range of languages ^{11, 12, 29-33 34-36} and the English version has
35 been successfully administered digitally via telephone ³⁷. Tests of the validity of eHEALS
36 indicates that it is a reliable and valid instrument^{12, 30, 38-40} but also that the validity of if it
37 requires further investigation ¹¹. However, the eHEALS has not been tested for validity
38 among the general Swedish- or Arabic-speaking population in Sweden. eHealth literacy has
39 not been examined in Sweden nor compared between Swedish- and non-Swedish-speaking
40 people.
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48 **Aim**

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51 The overall aim of this study is to psychometric evaluate the Swedish and Arabic versions of
52 HLS-EU-Q16 and eHEALS, and to compare Arabic and Swedish speakers’ Health literacy
53 and eHealth literacy levels in Sweden.
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METHODS AND ANALYSIS

Study design

This is a prospective, psychometric and comparative evaluation divided into four different phases (Figure 1). Study recruitment will start in February 2019 and is planned to end in June 2019.

Phase 1: Translation process

The original English version of eHEALS will be translated into Swedish and Arabic. Arabic was selected as it is the most common native language spoken among refugees in Sweden ⁴¹. One independent translator each with either Swedish or Arabic as their native language will translate the English version of eHEALS to Swedish and Arabic. These translations should use plain language and be comprehensible to a 12-year-old speaker of the target language ⁴². Although it is important that the content of the items remain the same as in the original version, the wording or word order in the translated versions should be appropriate to the target language and understandable by speakers with various levels of education.

A translator group will consist of four professional translators, one for the forward translation into each of Swedish and Arabic and one for backward translations from each language. The translators will be recruited from translator associations found and through personal contacts. Previous experience in translating survey questions within the health domain will be a criterion for recruitment as a translator.

A committee to examine the quality of the translations will be recruited on the basis of criteria recommended for committees used in cross-cultural adaption projects ⁴³. The committee will consist of 12 members: 8 bilingual in English and Swedish and 4 multilingual in English, Arabic, and Swedish. The bilingual members should have experience in plain language and health literacy and/or health communication. Multilingual members should have experiences from data collections with Arabic speaking participants within the public health domain and previous experience of reviewing translated instruments.

The translation into Swedish will be completed first and reviewed by the researchers, who will compare it with the original English version, examine how well it fits the Swedish

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3 context, and check it for plain language. If necessary, adjustments will be made and the new
4 versions discussed with the bilingual members in the committee to ensure that the content of
5 the English and Swedish versions is the same and that plain language is used. The new
6 versions will also be discussed with four Swedish-speaking lay-people of different ages,
7 genders, and education levels to ensure the items are understandable. When the researchers
8 are satisfied with the Swedish version, based on the feedback from the bilingual and lay-
9 people, it will be back-translated into English and the researchers and the translator will
10 compare it with the English original version. If the back-translation does not match the
11 original eHEALS, the Swedish version will be adjusted and back-translated again as many
12 times as necessary to obtain a back-translation consistent with the original English version.
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22 Once the Swedish version is finalized, the translated Arabic version will be reviewed by the
23 four multilingual members in the committee, who together with the researchers, will discuss
24 how well the translated version fits the Swedish context, to what extent plain language has
25 been used, and how well the content of the translated version matches both the English
26 original and the final Swedish versions. If necessary, adjustments will be made and the new
27 versions discussed again with the multilingual members. When all are satisfied with the
28 translated version, it will be back-translated into English by one independent translator and
29 compared with the English original version by one of the multilingual members. If the back-
30 translation does not match the English original version, it will be adjusted and back-translated
31 again as many times as necessary to obtain a back-translation consistent with the original
32 English version.
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Phase 2: content validity testing of the Arabic and Swedish version of eHEALS

Content validity

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48 Content validity is the degree to which the content of an instrument is an adequate reflection
49 of the construct it is meant to measure⁴⁴. As the plan is to use the instruments in this study in
50 the general population, i.e. in study populations they have been used previously in, no greater
51 adaptations of the instruments are needed. Examination of the content of the instrument by an
52 expert committees will therefore not be conducted. However, the face validity – the degree to
53 which the items or the instrument as a whole appear to adequately reflect the construct to be
54 measured⁴⁴ – and the interpretability of the items⁴² will be examined.
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3 The face validity of the final Swedish and Arabic versions will be tested through qualitative
4 interviews with five people in each language group to check whether these people understand
5 the items as intended. Participants will be recruited purposively and through snowball
6 sampling ⁴⁵ either directly by the researchers or through the researchers' personal contacts
7 with key people in groups speaking Arabic. A mix of different ages, genders, and educational
8 levels will be sought. Information about the project and the meaning of informed consent will
9 be given orally and in writing to the participants. If the person agrees to attend, the time for
10 the interview will be booked.
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17 In the interview, participants will be asked 'What were you thinking of while you were
18 answering that question?' and if necessary, 'Why did you select that response?' Interviews
19 will be audio recorded and notes written by the interviewer into templates containing the two
20 predetermined questions. Participants will also be asked about their age, gender, highest level
21 of education, and years living in Sweden.
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27 The five Swedish-speaking participants will be interviewed by two of the researchers and the
28 five Arabic-speaking participants by a research assistant with Arabic as native language, who
29 will take notes in Swedish. Each interviewer will listen to the recorded audio files,
30 complemented by the notes (if any) written immediately after each interview. The researchers,
31 will then read all notes separately.
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38 If the analysis shows that any items are difficult to understand and major changes to either
39 translation are needed, the items concerned will be revised and tested again on five new
40 participants. This procedure will be repeated until all items are easy to understand.
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45 **Phase 3: Psychometric testing of the Arabic and Swedish version of eHEALS and HLS-** 46 **EU-Q16** 47

48 **Participants** 49

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51 Two different language groups will be recruited from different regions in Sweden to test the
52 translated instruments. The intention is to include one group of participants representative of
53 the general Swedish-born population (n = 300) and one group representative of Swedish
54 residents born in an Arabic-speaking country (n = 300). The chosen sample size was first
55 guided by the 10:1 ratio ⁴²: 16 items on the HLS-EU-Q16 × 10 = 160 participants. However, a
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3 general rule of thumb for factor analysis is 300 cases or the more lenient 50 participants per
4 factor ⁴⁶. HLS-EU-Q16 consists of only one factor ¹⁹, therefore a sample size of 300
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6 participants is considered most appropriate. Inclusion criteria for participation will be being
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8 an adult (≥ 18 years), having sufficient language skills to read, understand, and fill in a form in
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10 their native language (Swedish or Arabic), and being available on the days of data collection.
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12 Arabic speakers born outside of Sweden shall also have a Swedish resident's permit.
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15 Participants will be recruited from university courses, municipal adult education courses
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17 (Komvux), larger workplaces with both academic and non-academic staff, non-governmental
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19 organisations serving elderly people, migrant associations, courses in civic orientation, and
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21 supplementary academic courses for nurses with degrees from countries outside of Europe.
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23 These arenas are chosen because they attract many Swedish residents of different ages,
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25 genders, and levels of education who speak Swedish or Arabic as their first language. A mix
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27 of ages, genders, and educational levels will be sought in both groups. Upon recruitment of
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29 the participants, organizations manager or responsible person conducting group activities with
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31 potential study participants will be contacted and informed about the project.
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34 On the day of the data collection, a researcher will visit the various arenas to inform people
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36 both orally and in writing about the project and the meaning of informed consent. In groups
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38 with Arabic-speaking people, the Arabic-speaking research assistant will provide the oral and
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40 written information about the project and the meaning of informed consent in the potential
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42 participants' native language. People who agree to participate will be given a questionnaire
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44 and asked to fill it in directly onsite. By filling in the questionnaire, they also consent to take
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46 part in the study.
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49 The following questionnaires and study specific questions will be distributed in Swedish and
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51 Arabic respectively depending on native language.
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- 53 - the eHEALS instrument (8 items) assessing eHealth literacy;
- 54 - the HLS-EU-Q16 instrument (16 items) assessing comprehensive health literacy;
- 55 - one question about general self-perceived health;
- 56 - one question about use of internet and,
- 57 - descriptive background questions (age, gender, highest level of education, country of
58 birth).
- 59 - -number of years lived in Sweden. (Arabic-speaking group only).
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5 The questionnaire used in the Arabic-speaking group includes the same components, plus one
6 question about their number of years lived in Sweden.
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10 General self-perceived health will be measured by the questions ‘How do you assess your
11 overall health status?’ Response options are Very poor, Poor, Fair, Good, and Very good.^{7, 47}
12 Internet use will be measured by the question ‘How often do you use the internet?’ Response
13 options are Almost every day, Several days a week, About 1 day a week, Less than 1 day a
14 week, and Almost never¹¹.
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21 **Psychometric testing**

22 The psychometric testing will be guided by CONsensus-based Standards for the selection of
23 health Measurement INstruments (COSMIN)^{42, 44, 48}
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26 **Construct validity**

27 The construct validity⁴⁴ focus on evaluating tests of the hypotheses. This aspect of construct
28 validity can be described as the degree to which the scores of an instrument are consistent
29 with a hypothesis⁴⁴. The participants and questionnaire for collecting data, will be the same
30 as those described above.
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36 Based on previous studies on health literacy showing positive associations between limited
37 health literacy and high age^{4, 49-51}, low education level^{23, 51, 52}, poor health^{7, 8, 22, 50, 53} and
38 between eHEALS and low use of the Internet¹¹, several hypotheses will be used regarding
39 correlations between HLS-EU-Q16/eHEALS and; age, level of education, self-perceived
40 general health and quantity of Internet use. Moreover, hypothesis regarding correlations
41 between eHEALS and; HLS-EU-Q16 and certain HLS-EU-Q16 items will be used. All
42 hypothesis are presented in Figure 2.
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50 Spearman’s rank order correlation between total mean scores on eHEALS and HLS-EU-Q16,
51 self-perceived health, level of education, and age will be used to A coefficient magnitude of
52 >0.4 will be considered evidence of construct validity (i.e., moderate to strong correlations)⁴⁸.
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Reliability

Reliability can be used as a term for a domain and as a term for a measurement property⁴⁴. In this study we are analyse two aspects of reliability: internal consistency and test-retest reliability.

Internal consistency

Internal consistency describes the interrelatedness among items⁴⁴ and will be analysed for both eHEALS and HLS-EU-Q16.

- Exploratory factor analysis will be used to identify the underlying relationships between items on eHEALS and HLS-EU-Q16⁴².
- Cronbach's alpha will be calculated for each instrument to assess the average correlation of items within each scale. Cronbach's alpha in the range of 0.7–0.95 will be considered acceptable^{42, 54}.
- Split-half reliability will be used to measure the correlation between random split segments and to determine how much error in a test score is due to poor test construction⁵⁴. A Spearman-Brown coefficient of 0.70–0.90 will be considered acceptable^{55, 56}.

Test-retest reliability

Test-retest reliability can be described as the extent to which scores for the same patients are the same in measurements repeated over time⁴⁴. Intraclass correlation coefficient (ICC) will be used and an ICC value of ≥ 0.7 will be considered acceptable⁴². Because the sample size needed for test-retest is much smaller than for testing many other forms of validity, the sample size in the retest of 25 people per language category (total 50) is considered appropriate⁵⁷.

Participants in the test-retest groups will be invited to take part in the retest when they are recruited to participate in the main test. To minimise dropouts, participants in the test-retest groups will be recruited in the pre-existing groups having regular, at least weekly, meetings. A mix of different ages, genders, and education levels will be sought. To compare answers from the test and the retest, the participants will mark their questionnaires with their birth date or any other self-contained code if they do not wish to give their date of birth. If they use their

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3 own code, they will be asked to write it down in a list of codes the researcher will bring to the
4 second measurement in case they forget their code.
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8 **Feasibility**

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10 The feasibility of the clinical user-friendliness of the instruments will be assessed by their
11 successful response rate ⁴⁸.
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15 **Floor and ceiling effects**

16 Floor and ceiling effects (the number of respondents who achieve the lowest or highest
17 possible scores⁴² will be examined. Floor or ceiling effects are considered a problem if more
18 than 15% of a study population achieve the lowest or highest possible score⁴².
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26 **Phase 4. Distribution of eHEALS and HLS-EU-Q16 levels in the study population and** 27 **comparisons of levels in the two language groups**

28 The distribution of eHEALS and HLS-EU-Q16 levels in the study population as a whole and
29 within each language group will be examined. Chi-square tests – or Fisher’s exact tests as
30 appropriate – will be used to test for differences in eHEALS and HLS-EU-Q16 between
31 language groups. Binary logistic regression analyses will be performed to assess associations
32 between HLS-EU-Q16 and eHEALS as independent variables, and age, education level,
33 gender, country of birth, general self-perceived health, and internet use as dependent
34 variables.
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42 All data will be analysed using SPSS version 24.0 for Windows (IBM Corporation, Somers,
43 NY, USA). Two-tailed *P* values under .05 will be considered significant.
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50 **Discussion**

51 A considerable proportion of both the European population and newly arrived refugees in
52 Sweden have limited comprehensive health literacy ⁴. How this is distributed in the general
53 Swedish population and the eHealth literacy levels of Swedish- and Arabic-speaking people
54 living in Sweden are rather unknown. Knowledge about comprehensive health literacy (and
55 by extension, eHealth literacy) is important, though, as it is associated with people’s health
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3 status ¹⁷, use of health information and health care services ^{5, 6, 35, 49, 58}. Being regarded as an
4 important social determinant of health ³ and having a social gradient health literacy⁴ in
5 patients is important to consider in work to promote health, disease prevention, and health
6 care, in order to secure that people with various levels of health literacy benefit equally from
7 health efforts to reduce the risk of promote inequity in health and healthcare instead of vice
8 versa ¹⁷. However, in Sweden validated instruments to measure comprehensive health literacy
9 and eHealth literacy of Swedish-, and Arabic-speaking people are lacking, i.e. needs to be
10 developed.
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19 Our research team has developed and tested a digital monitoring system, Recovery
20 Assessment by Phone Points (RAPP), that enables day surgery patients to contact health care
21 easily and to report from home about how they feel ⁵⁹. It has been tested in studies with
22 Swedish-speaking patients, and proved to be cost-effective ⁶⁰, to help patients feel safer and
23 less bothered by symptoms, such as pain, nausea, anxiety, in their postoperative recovery ⁵⁹.
24 ⁶¹. Strong relationships between postoperative recovery, health, and mental health were also
25 found. However, so far RAPP is only available to Swedish-speaking patients. Next step is to
26 develop RAPP for non-Swedish-speakers, starting with Arabic, and to compare postoperative
27 recovery and unplanned medical contacts between non-Swedish-speaking Arabic patients and
28 Swedish-speaking patients. We will then also study differences in eHealth literacy, mental
29 health, and postoperative recovery between the groups, and describe their experiences of
30 postoperative recovery and using a digital tracking system such as RAPP. However, before
31 we can investigate these questions, we need to develop valid Arabic and Swedish version of
32 eHEALS to be able to assess eHealth literacy.
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45 **Ethics and dissemination**

46 The project has been approved by the regional ethical review board in Stockholm, Sweden
47 (number 2019/5:1) and will follow the principles outlined in the 1964 Helsinki Declaration
48 and its later amendments. Participants will receive written and verbal information about the
49 study, including the purpose and procedures, the voluntary nature of participation, and their
50 option to withdraw at any time. They will also be guaranteed confidentiality and secure data
51 storage.
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13 **Authors' contributions**

14 JW have contributed to the planning of the study, study design, the preparation of the
15 manuscript and approved of the final version.

16 KD have contributed to the planning of the study, study design, the preparation of the
17 manuscript and approved of the final version.

18 MJ have contributed to the planning of the study, study design, the preparation of the
19 manuscript and approved of the final version.

20 UN have contributed to the planning of the study, study design, the preparation of the
21 manuscript, led the calculation of sample size and approved of the final version.
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30 **Patient and Public Involvement**

31 No public involvement
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38 not-for-profit sectors
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43 **Competing interests**

44 None
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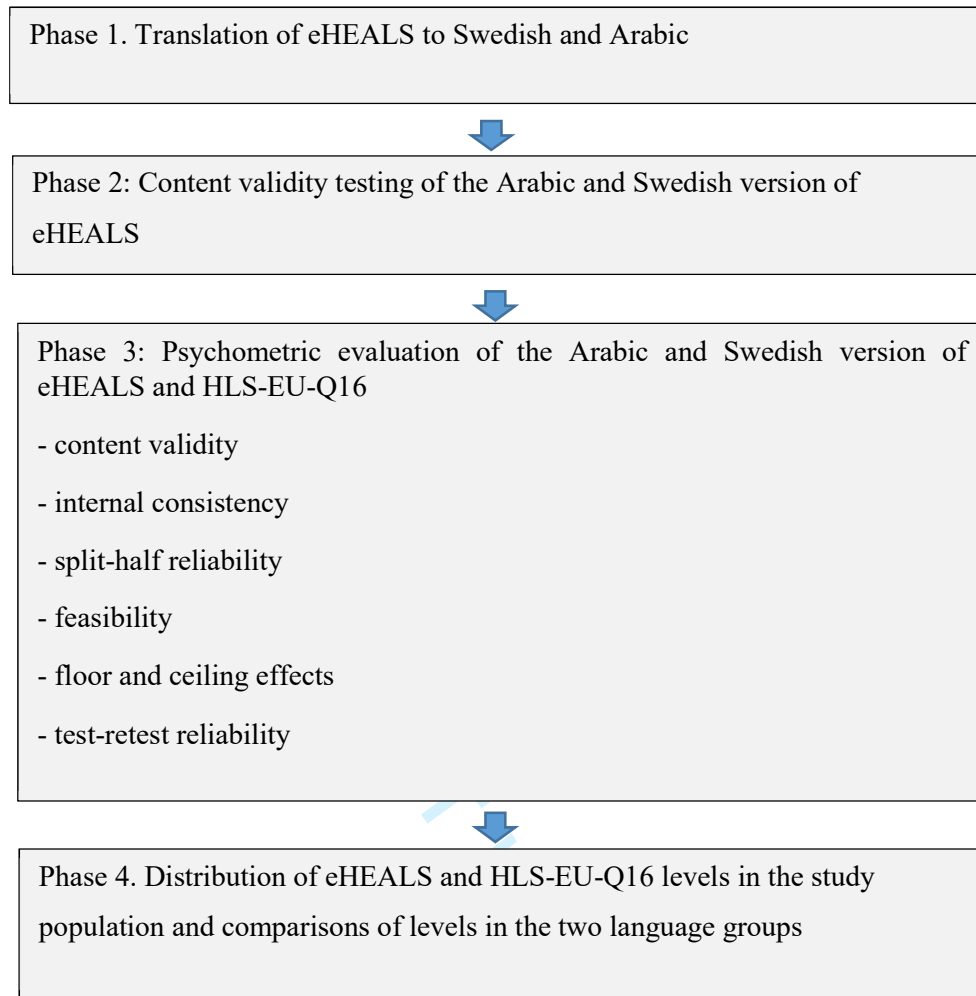


Figure 1. Overview of the research process.

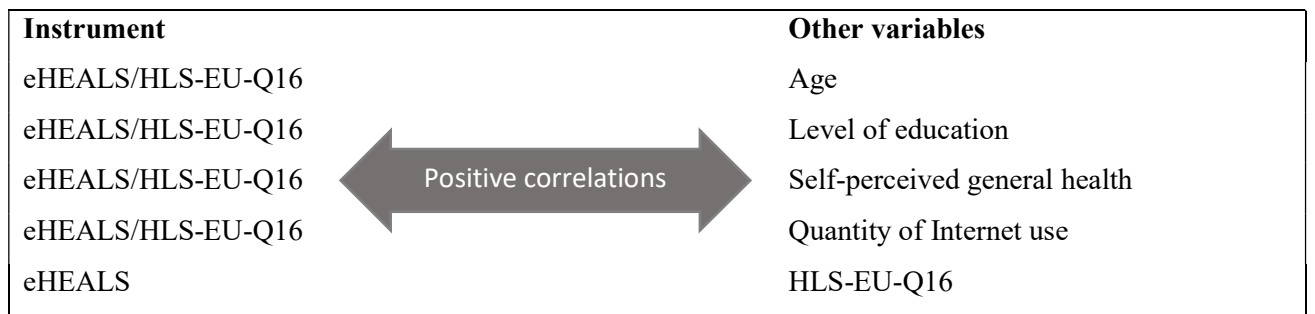


Figure 2. Hypothesis of correlations between eHEALS/HLS-EU-Q16 and various variables.

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Psychometric validation of Swedish and Arabic versions of two Health literacy questionnaires, eHEALS and HLS-EU-Q16, for use in a Swedish context: A study protocol

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Psychometric validation of Swedish and Arabic versions of two Health literacy questionnaires, eHEALS and HLS-EU-Q16, for use in a Swedish context: A study protocol

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ABSTRACT

Introduction

Equity in health and access to health care regardless of, gender, ethnicity or social position is a major political issue worldwide. Regardless of an individual's knowledge, motivation, and competence individuals are expected to be engaged and take responsibility of their own care. Migrants have been identified as a vulnerable population in health care and an explanation for the inequity in health, and in health care is limited health literacy. Further more, with increasing digitalization in health care, it puts demand on the individual to also have digital or electronic health (eHealth) literacy.

The overall aim of this study is to conduct a psychometric evaluation of the Swedish and Arabic versions of HLS-EU-Q16 and eHEALS, and to compare Arabic and Swedish speakers' Health literacy and eHealth literacy levels in Sweden.

Methods and Analysis

This is a prospective, psychometric evaluation study with the intent of including 300 Arabic speaking and 300 Swedish speaking participants. Questionnaires: The Health Literacy Survey European Questionnaire (HLS-EU-Q16) including 16 items measuring perceived personal skills of finding, understanding, judging, and applying health information to maintain and improve their health. The eHealth literacy scale (eHEALS), an 8-item measuring health literacy skills in relation to online information and applications.

This study will be conducted in four phases. Phase 1: Translation of HLS-EU-Q16 and eHEALS from English to Swedish and Arabic following the principles of translation of questionnaires. Phase 2: Content validity testing of eHEALS, including face validity and interpretability conducted with five Arabic and five Swedish speaking participants. Phase 3: Psychometric testing including construct validity, reliability, feasibility and floor ceiling effects. Phase 4: Distribution and comparison of eHealth and HLS-EU-Q16 analysed with Chi square and Fisher's exact test as appropriate. To assess associations between HLS-EU-Q16, eHEALS and demographic variables binary logistic regression analyses will be performed.

Ethics and dissemination

The project has been approved by the regional ethical review board in Stockholm, Sweden (2019/5:1) and will follow the principles outlined in the 1964 Helsinki Declaration and its later amendments. Results from this study will be disseminated in peer-reviewed journals, scientific conferences and in social media.

ARTICLE SUMMARY

Strengths and limitations

- A Swedish and Arabic version of eHEALS and HLS-EU-Q16 have not yet been psychometric evaluated
- eHealth literacy has not previously been investigated in a Swedish population.
- This is the first study to compare eHealth literacy between Swedish and Arabic speaking citizens in Sweden.
- Although this study includes both Swedish and Arabic speaking participants from different contexts in the society the study is conducted in Sweden and may not be generalizable to other contexts.

INTRODUCTION

The importance of health literacy

Patients in today's health care system are expected to take part and be engaged in their own care. Consequently, they have to be able to read and understand health instructions on how to manage their own recovery at home ¹. Informed decision making requires people to have a certain level of health literacy. In this article we use the following definition of comprehensive health literacy:

Health literacy is linked to literacy and entails people's knowledge, motivation, and competence to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course².

Health literacy is regarded as a social determinant of health ³ and has a strong social gradient ⁴. Which means, health literacy can be an additional barrier to health for already disadvantaged and marginalised groups within societies. Limited health literacy is likely to affect patients' quality of care, resulting in lower satisfaction with care and lower understanding of their medical situation ⁵ and their safety, by decreasing the probability of an adverse medication due to misunderstanding instructions ^{5,6}. Health literacy is also associated with the extent to which people benefit from health examinations ⁷ and the quality of their postoperative recovery ⁸.

With increasing digitalisation of information and services, modern health care and health promotion have become increasingly challenging for both patients and health care staff⁹. This demands a range of digital competencies among users, and requires new ways to describe and evaluate users' digital capabilities and experiences in this rapidly changing health context ⁹. Consequently, the concept of digital or electronic health (eHealth) literacy has emerged ¹⁰⁻¹² and been described as 'the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem' ¹².

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3 Equity in health and access to health care regardless of social position, gender, race, or
4 ethnicity is a major political issue in the European Region and worldwide ¹³. The Swedish
5 Health and Medical Services Act ¹⁴ states that the goal of health care is to promote ‘good
6 health and care on equal terms for the entire population’ ^{6, 14}. Migrants, whether they are
7 labour migrants or refugees, have been identified as a vulnerable population, but there is
8 heterogeneity in the degree to which they are vulnerable to inadequate health care ^{5, 6, 15, 16}.
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10 One explanatory factor for the inequity in health, and in health care is limited health literacy
11 on individual and organizational level ¹⁷. A Swedish study show for example that newly
12 arrived refugees with limited health literacy, to a higher degree experienced poor quality of
13 communication and benefited less from the health examination for asylum seekers than those
14 with higher health literacy ⁷. Another study show that newly arrived refugees with limited
15 comprehensive health literacy have poorer general health and do not seek needed care as often
16 as those with higher comprehensive health literacy ¹⁸.

27 *HLS-EU-Q16*

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29 In 2011-2012, Sørensen et al. developed the Health Literacy Survey European Questionnaire,
30 HLS-EUQ47, a self-reporting instrument consisting of 47 items ¹⁹. The instrument is based on
31 a systematic literature review that derived an all-inclusive conceptual model and the definition
32 of comprehensive health literacy used in this study. In 2013, the instrument was used in a
33 large study including populations in 8 European countries ⁴. As a result of that study’s
34 analysis, the shorter 16-item version, HLS-EU-Q16, was developed ². Both the HLS-EUQ47
35 and HLS-EU-Q16 have been used frequently in many different countries and are available in
36 a range of languages

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46 The HLS-EU-Q16 aims to measure respondents’ perceived personal skills of finding,
47 understanding, judging, and applying health information to maintain and improve their health
48 ¹⁹. Each item in the instrument is answered on a 4-point Likert scale with response options
49 ranging from ‘very difficult’ to ‘very easy’. An overall HLS-EU-Q16 index will be calculated
50 in three steps according to the developer ²³. First, the response categories for the 16 items will
51 be dichotomized into easy (fairly easy and easy) giving the value of 1, and difficult (difficult
52 and very difficult) giving the value 0. Second, an overall sum score will be calculated. Third,
53 sum scores will be divided into three categories: inadequate (0-8 score points), problematic
54 (9-12 score points) and sufficient (13-16 score points) health literacy. HLS-EUQ16 has been
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3 psychometrically tested and showed to be in some migrant populations in which it was found
4 to be reliable and valid ²⁴.
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8 The Arabic and Swedish versions of HLS-EU-Q16 have been translated in line with
9 guidelines for the translation of instruments and tested for Face validity among migrants in
10 Sweden ²⁵. The Swedish and Arabic versions of the HLS-EU-Q16 have since been used in
11 several studies in Sweden ^{7, 18, 26} and Egypt ²⁰. However, the translated Swedish and Arabic
12 versions have not yet been tested for other aspects of validity and comprehensive health
13 literacy has not been compared between Swedish- and non-Swedish-speaking people.
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20 *eHEALS*

21 In 2006, Norman and Skinner developed the eHealth literacy scale, eHEALS. It aims to
22 measure a broad range of literacy skills, which might make it useful in assessing the effects of
23 strategies to deliver online information and applications. eHEALS is an 8-item instrument
24 with each item scored on a 5-point Likert scale with response options ranging from ‘strongly
25 agree’ to ‘strongly disagree’. Total scores on the eHEALS range from 8 to 40, with higher
26 scores representing higher self-perceived eHealth literacy.
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34 The eHEALS is available in a range of languages ^{11, 12, 27-31 32-34} and the English version has
35 been successfully administered digitally via telephone ³⁵. Tests of the validity of eHEALS
36 indicates that it is a reliable and valid instrument^{12, 28, 36-38} but also that the validity of if it
37 requires further investigation ¹¹. However, the eHEALS has not been tested for validity
38 among the general Swedish- or Arabic-speaking population in Sweden. eHealth literacy has
39 not been examined in Sweden nor compared between Swedish- and non-Swedish-speaking
40 people.
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48 **Aim**

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51 The overall aim of this study is to psychometric evaluate the Swedish and Arabic versions of
52 HLS-EU-Q16 and eHEALS, and to compare Arabic and Swedish speakers’ Health literacy
53 and eHealth literacy levels in Sweden.
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METHODS AND ANALYSIS

Study design

This is a prospective, psychometric and comparative evaluation divided into four different phases (Figure 1). Study recruitment will start in February 2019 and is planned to end in June 2019.

Phase 1: Translation process

The original English version of eHEALS will be translated into Swedish and Arabic. Arabic was selected as it is the most common native language spoken among refugees in Sweden³⁹. One independent translator each with either Swedish or Arabic as their native language will translate the English version of eHEALS to Swedish and Arabic. These translations should use plain language and be comprehensible to a 12-year-old speaker of the target language⁴⁰. Although it is important that the content of the items remain the same as in the original version, the wording or word order in the translated versions should be appropriate to the target language and understandable by speakers with various levels of education.

A translator group will consist of four professional translators, one for the forward translation into each of Swedish and Arabic and one for backward translations from each language. The translators will be recruited from translator associations found and through personal contacts. Previous experience in translating survey questions within the health domain will be a criterion for recruitment as a translator.

A committee to examine the quality of the translations will be recruited on the basis of criteria recommended for committees used in cross-cultural adaption projects⁴¹. The committee will consist of 12 members: 8 bilingual in English and Swedish and 4 multilingual in English, Arabic, and Swedish. The bilingual members should have experience in plain language and health literacy and/or health communication. Multilingual members should have experiences from data collections with Arabic speaking participants within the public health domain and previous experience of reviewing translated instruments.

The translation into Swedish will be completed first and reviewed by the researchers, who will compare it with the original English version, examine how well it fits the Swedish

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3 context, and check it for plain language. If necessary, adjustments will be made and the new
4 versions discussed with the bilingual members in the committee to ensure that the content of
5 the English and Swedish versions is the same and that plain language is used. The new
6 versions will also be discussed with four Swedish-speaking lay-people of different ages,
7 genders, and education levels to ensure the items are understandable. When the researchers
8 are satisfied with the Swedish version, based on the feedback from the bilingual and lay-
9 people, it will be back-translated into English and the researchers and the translator will
10 compare it with the English original version. If the back-translation does not match the
11 original eHEALS, the Swedish version will be adjusted and back-translated again as many
12 times as necessary to obtain a back-translation consistent with the original English version.
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22 Once the Swedish version is finalized, the translated Arabic version will be reviewed by the
23 four multilingual members in the committee, who together with the researchers, will discuss
24 how well the translated version fits the Swedish context, to what extent plain language has
25 been used, and how well the content of the translated version matches both the English
26 original and the final Swedish versions. If necessary, adjustments will be made and the new
27 versions discussed again with the multilingual members. When all are satisfied with the
28 translated version, it will be back-translated into English by one independent translator and
29 compared with the English original version by one of the multilingual members. If the back-
30 translation does not match the English original version, it will be adjusted and back-translated
31 again as many times as necessary to obtain a back-translation consistent with the original
32 English version.
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Phase 2: content validity testing of the Arabic and Swedish version of eHEALS

Content validity

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46 Content validity is the degree to which the content of an instrument is an adequate reflection
47 of the construct it is meant to measure⁴². As the plan is to use the instruments in this study in
48 the general population, i.e. in study populations they have been used previously in, no greater
49 adaptations of the instruments are needed. Examination of the content of the instrument by an
50 expert committees will therefore not be conducted. However, the face validity – the degree to
51 which the items or the instrument as a whole appear to adequately reflect the construct to be
52 measured⁴² – and the interpretability of the items⁴⁰ will be examined.
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3 The face validity of the final Swedish and Arabic versions will be tested through qualitative
4 interviews with five people in each language group to check whether these people understand
5 the items as intended. Participants will be recruited purposively and through snowball
6 sampling ⁴³ either directly by the researchers or through the researchers' personal contacts
7 with key people in groups speaking Arabic. A mix of different ages, genders, and educational
8 levels will be sought. Information about the project and the meaning of informed consent will
9 be given orally and in writing to the participants. If the person agrees to attend, the time for
10 the interview will be booked.
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15 In the interview, participants will be asked 'What were you thinking of while you were
16 answering that question?' and if necessary, 'Why did you select that response?' Interviews
17 will be audio recorded and notes written by the interviewer into templates containing the two
18 predetermined questions. Participants will also be asked about their age, gender, highest level
19 of education, and years living in Sweden.
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23 The five Swedish-speaking participants will be interviewed by two of the researchers and the
24 five Arabic-speaking participants by a research assistant with Arabic as native language, who
25 will take notes in Swedish. Each interviewer will listen to the recorded audio files,
26 complemented by the notes (if any) written immediately after each interview. The researchers,
27 will then read all notes separately.
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31 If the analysis shows that any items are difficult to understand and major changes to either
32 translation are needed, the items concerned will be revised and tested again on five new
33 participants. This procedure will be repeated until all items are easy to understand.
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37 38 39 40 41 42 43 44 45 **Phase 3: Psychometric testing of the Arabic and Swedish version of eHEALS and HLS-** 46 **EU-Q16** 47

48 49 50 **Participants**

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52 Two different language groups will be recruited from different regions in Sweden to test the
53 translated instruments. The intention is to include one group of participants representative of
54 the general Swedish-born population (n = 300) and one group representative of Swedish
55 residents born in an Arabic-speaking country (n = 300). The chosen sample size was first
56 guided by the 10:1 ratio ⁴⁰: 16 items on the HLS-EU-Q16 × 10 = 160 participants. However, a
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3 general rule of thumb for factor analysis is 300 cases or the more lenient 50 participants per
4 factor ⁴⁴. HLS-EU-Q16 consists of only one factor ¹⁹, therefore a sample size of 300
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6 participants is considered most appropriate. Inclusion criteria for participation will be being
7
8 an adult (≥ 18 years), having sufficient language skills to read, understand, and fill in a form in
9
10 their native language (Swedish or Arabic), and being available on the days of data collection.
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12 Arabic speakers born outside of Sweden shall also have a Swedish resident's permit.
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15 Participants will be recruited from university courses, municipal adult education courses
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17 (Komvux), larger workplaces with both academic and non-academic staff, non-governmental
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19 organisations serving elderly people, migrant associations, courses in civic orientation, and
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21 supplementary academic courses for nurses with degrees from countries outside of Europe.
22
23 These arenas are chosen because they attract many Swedish residents of different ages,
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25 genders, and levels of education who speak Swedish or Arabic as their first language. A mix
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27 of ages, genders, and educational levels will be sought in both groups. Upon recruitment of
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29 the participants, organizations manager or responsible person conducting group activities with
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31 potential study participants will be contacted and informed about the project.
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34 On the day of the data collection, a researcher will visit the various arenas to inform people
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36 both orally and in writing about the project and the meaning of informed consent. In groups
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38 with Arabic-speaking people, the Arabic-speaking research assistant will provide the oral and
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40 written information about the project and the meaning of informed consent in the potential
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42 participants' native language. People who agree to participate will be given a questionnaire
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44 and asked to fill it in directly onsite. By filling in the questionnaire, they also consent to take
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46 part in the study.
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49 The following questionnaires and study specific questions will be distributed in Swedish and
50
51 Arabic respectively depending on native language.

- 52 - the eHEALS instrument (8 items) assessing eHealth literacy;
- 53 - the HLS-EU-Q16 instrument (16 items) assessing comprehensive health literacy;
- 54 - one question about general self-perceived health;
- 55 - one question about use of internet and,
- 56 - descriptive background questions (age, gender, highest level of education, country of
57
58 birth).
- 59 - -number of years lived in Sweden. (Arabic-speaking group only).
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5 The questionnaire used in the Arabic-speaking group includes the same components, plus one
6 question about their number of years lived in Sweden.
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10 General self-perceived health will be measured by the questions ‘How do you assess your
11 overall health status?’ Response options are Very poor, Poor, Fair, Good, and Very good.^{7, 45}
12 Internet use will be measured by the question ‘How often do you use the internet?’ Response
13 options are Almost every day, Several days a week, About 1 day a week, Less than 1 day a
14 week, and Almost never¹¹.
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20 21 **Psychometric testing**

22 The psychometric testing will be guided by CONsensus-based Standards for the selection of
23 health Measurement INstruments (COSMIN)^{40, 42, 46}
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27 28 **Construct validity**

29 The construct validity⁴² focus on evaluating tests of the hypotheses. This aspect of construct
30 validity can be described as the degree to which the scores of an instrument are consistent
31 with a hypothesis⁴². The participants and questionnaire for collecting data, will be the same
32 as those described above.
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38 Based on previous studies on health literacy showing positive associations between limited
39 health literacy and high age^{4, 47-49}, low education level^{20, 49, 50}, poor health^{7, 8, 22, 48, 51} and
40 between eHEALS and low use of the Internet¹¹, several hypotheses will be used regarding
41 correlations between HLS-EU-Q16/eHEALS and; age, level of education, self-perceived
42 general health and quantity of Internet use. Moreover, hypothesis regarding correlations
43 between eHEALS and; HLS-EU-Q16 and certain HLS-EU-Q16 items will be used. All
44 hypothesis are presented in Figure 2.
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51 Spearman’s rank order correlation between total mean scores on eHEALS and HLS-EU-Q16,
52 self-perceived health, level of education, and age will be used to A coefficient magnitude of
53 >0.4 will be considered evidence of construct validity (i.e., moderate to strong correlations)⁴⁶.
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Reliability

Reliability can be used as a term for a domain and as a term for a measurement property⁴². In this study we are analyse two aspects of reliability: internal consistency and test-retest reliability.

Internal consistency

Internal consistency describes the interrelatedness among items⁴² and will be analysed for both eHEALS and HLS-EU-Q16.

- Exploratory factor analysis will be used to identify the underlying relationships between items on eHEALS and HLS-EU-Q16⁴⁰.
- Cronbach's alpha will be calculated for each instrument to assess the average correlation of items within each scale. Cronbach's alpha in the range of 0.7–0.95 will be considered acceptable^{40, 52}.
- Split-half reliability will be used to measure the correlation between random split segments and to determine how much error in a test score is due to poor test construction⁵². A Spearman-Brown coefficient of 0.70–0.90 will be considered acceptable^{53, 54}.

Test-retest reliability

Test-retest reliability can be described as the extent to which scores for the same patients are the same in measurements repeated over time⁴². Intraclass correlation coefficient (ICC) will be used and an ICC value of ≥ 0.7 will be considered acceptable⁴⁰. Because the sample size needed for test-retest is much smaller than for testing many other forms of validity, the sample size in the retest of 25 people per language category (total 50) is considered appropriate⁵⁵.

Participants in the test-retest groups will be invited to take part in the retest when they are recruited to participate in the main test. To minimise dropouts, participants in the test-retest groups will be recruited in the pre-existing groups having regular, at least weekly, meetings. A mix of different ages, genders, and education levels will be sought. To compare answers from the test and the retest, the participants will mark their questionnaires with their birth date or any other self-contained code if they do not wish to give their date of birth. If they use their

own code, they will be asked to write it down in a list of codes the researcher will bring to the second measurement in case they forget their code.

Feasibility

The feasibility of the clinical user-friendliness of the instruments will be assessed by their successful response rate ⁴⁶.

Floor and ceiling effects

Floor and ceiling effects (the number of respondents who achieve the lowest or highest possible scores⁴⁰ will be examined. Floor or ceiling effects are considered a problem if more than 15% of a study population achieve the lowest or highest possible score⁴⁰.

Phase 4. Distribution of eHEALS and HLS-EU-Q16 levels in the study population and comparisons of levels in the two language groups

The distribution of eHEALS and HLS-EU-Q16 levels in the study population as a whole and within each language group will be examined. Chi-square tests – or Fisher’s exact tests as appropriate – will be used to test for differences in eHEALS and HLS-EU-Q16 between language groups. Binary logistic regression analyses will be performed to assess associations between HLS-EU-Q16 and eHEALS as dependent variables, and age, education level, gender, country of birth, general self-perceived health, and internet use as independent variables.

All data will be analysed using SPSS version 24.0 for Windows (IBM Corporation, Somers, NY, USA). Two-tailed *P* values under .05 will be considered significant.

Patient and Public Involvement

No public involvement

Discussion

A considerable proportion of both the European population and newly arrived refugees in Sweden have limited comprehensive health literacy ⁴. How this is distributed in the general Swedish population and the eHealth literacy levels of Swedish- and Arabic-speaking people

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3 living in Sweden are rather unknown. Knowledge about comprehensive health literacy (and
4 by extension, eHealth literacy) is important, though, as it is associated with people's health
5 status¹⁷, use of health information and health care services^{5, 6, 33, 47, 56}. Being regarded as an
6 important social determinant of health³ and having a social gradient health literacy⁴ in
7 patients is important to consider in work to promote health, disease prevention, and health
8 care, in order to secure that people with various levels of health literacy benefit equally from
9 health efforts to reduce the risk of promote inequity in health and healthcare instead of vice
10 versa¹⁷. However, in Sweden validated instruments to measure comprehensive health literacy
11 and eHealth literacy of Swedish-, and Arabic-speaking people are lacking, i.e. needs to be
12 developed.

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15 Our research team has developed and tested a digital monitoring system, Recovery
16 Assessment by Phone Points (RAPP), that enables day surgery patients to contact health care
17 easily and to report from home about how they feel⁵⁷. It has been tested in studies with
18 Swedish-speaking patients, and proved to be cost-effective⁵⁸, to help patients feel safer and
19 less bothered by symptoms, such as pain, nausea, anxiety, in their postoperative recovery⁵⁷,
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Strong relationships between postoperative recovery, health, and mental health were also
found. However, so far RAPP is only available to Swedish-speaking patients. Next step is to
develop RAPP for non-Swedish-speakers, starting with Arabic, and to compare postoperative
recovery and unplanned medical contacts between non-Swedish-speaking Arabic patients and
Swedish-speaking patients. We will then also study differences in eHealth literacy, mental
health, and postoperative recovery between the groups, and describe their experiences of
postoperative recovery and using a digital tracking system such as RAPP. However, before
we can investigate these questions, we need to develop valid Arabic and Swedish version of
eHEALS to be able to assess eHealth literacy.

Ethics and dissemination

The project has been approved by the regional ethical review board in Stockholm, Sweden
(number 2019/5:1) and will follow the principles outlined in the 1964 Helsinki Declaration
and its later amendments. Participants will receive written and verbal information about the
study, including the purpose and procedures, the voluntary nature of participation, and their
option to withdraw at any time. They will also be guaranteed confidentiality and secure data
storage.

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15 **Authors' contributions**

16 JW have contributed to the planning of the study, study design, the preparation of the
17 manuscript and approved of the final version.

18 KD have contributed to the planning of the study, study design, the preparation of the
19 manuscript and approved of the final version.

20 MJ have contributed to the planning of the study, study design, the preparation of the
21 manuscript and approved of the final version.

22 UN have contributed to the planning of the study, study design, the preparation of the
23 manuscript, led the calculation of sample size and approved of the final version.
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34 not-for-profit sectors
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39 **Competing interests**

40 None
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44 **No figure legend**

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47 Figure 1. Overview of the research process.

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49 Figure 2. Hypothesis of correlations between eHEALS/HLS-EU-Q16 and various variables.
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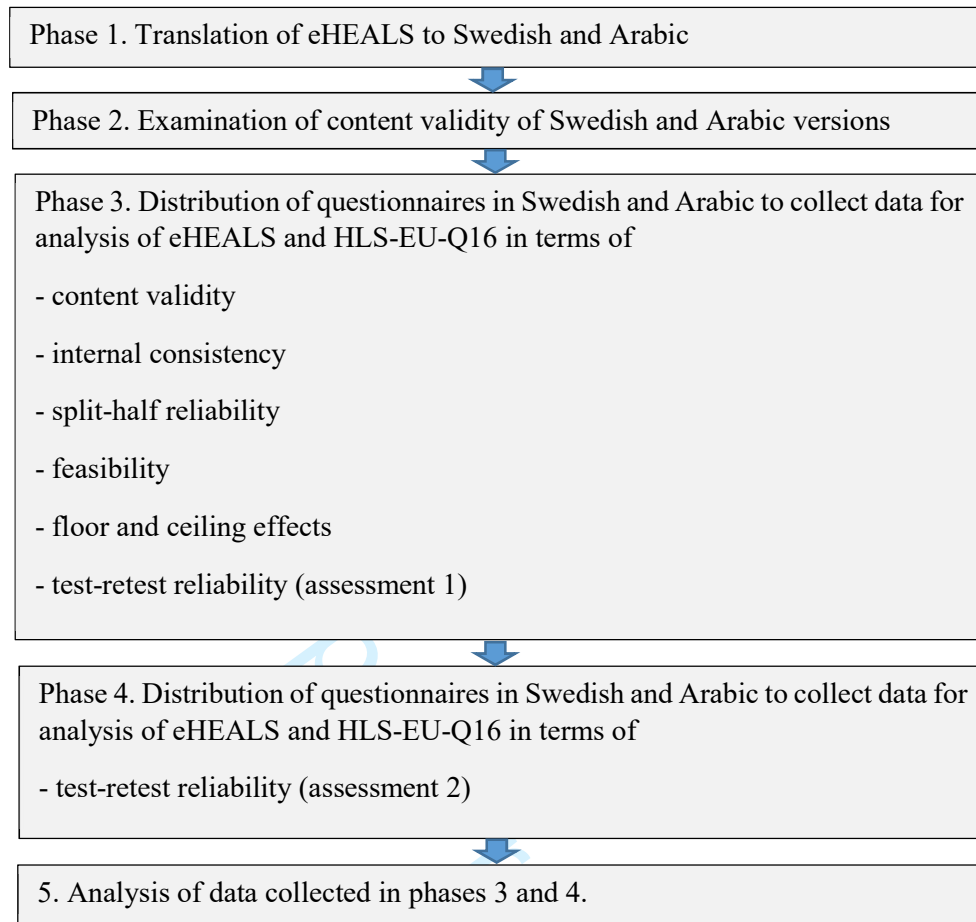


Figure 1. Overview of the research process.

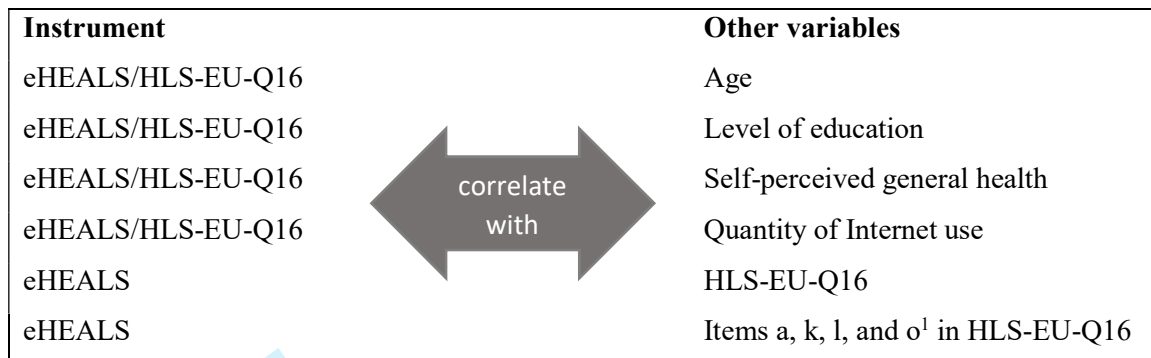


Figure 2. Hypothesis of correlations between eHEALS/HLS-EU-Q16 and various variables.

¹ Item a: How easy/difficult is it for you to find information on treatments of illnesses that concern you?

Item k: How easy/difficult is it for you to judge whether information on health risks in the media (e.g., on television or the internet) is reliable?

Item l: How easy/difficult is it for you to decide how you can protect yourself from illness based on information in media (e.g., in newspapers or leaflets or on the internet)?

Item o: How easy/difficult is it for you to understand information in the media (e.g., from the internet or daily or weekly magazines) on how improve your health?

BMJ Open

Psychometric validation of Swedish and Arabic versions of two Health literacy questionnaires, eHEALS and HLS-EU-Q16, for use in a Swedish context: A study protocol

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Psychometric validation of Swedish and Arabic versions of two Health literacy questionnaires, eHEALS and HLS-EU-Q16, for use in a Swedish context: A study protocol

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ABSTRACT

Introduction

Equity in health and access to health care regardless of, gender, ethnicity or social position is a major political issue worldwide. Regardless of an individual's knowledge, motivation, and competence individuals are expected to be engaged and take responsibility of their own care. Migrants have been identified as a vulnerable population in health care and an explanation for the inequity in health, and in health care is limited health literacy. Further more, with increasing digitalization in health care, it puts demand on the individual to also have digital or electronic health (eHealth) literacy.

The overall aim of this study is to conduct a psychometric evaluation of the Swedish and Arabic versions of HLS-EU-Q16 and eHEALS, and to compare Arabic and Swedish speakers' Health literacy and eHealth literacy levels in Sweden.

Methods and Analysis

This is a prospective, psychometric evaluation study with the intent of including 300 Arabic speaking and 300 Swedish speaking participants. Questionnaires: The Health Literacy Survey European Questionnaire (HLS-EU-Q16) including 16 items measuring perceived personal skills of finding, understanding, judging, and applying health information to maintain and improve their health. The eHealth literacy scale (eHEALS), an 8-item measuring health literacy skills in relation to online information and applications.

This study will be conducted in four phases. Phase 1: Translation of HLS-EU-Q16 and eHEALS from English to Swedish and Arabic following the principles of translation of questionnaires. Phase 2: Content validity testing of eHEALS, including face validity and interpretability conducted with five Arabic and five Swedish speaking participants. Phase 3: Psychometric testing including construct validity, reliability, feasibility and floor ceiling effects. Phase 4: Distribution and comparison of eHealth and HLS-EU-Q16 analysed with Chi square and Fisher's exact test as appropriate. To assess associations between HLS-EU-Q16, eHEALS and demographic variables binary logistic regression analyses will be performed.

Ethics and dissemination

The project has been approved by the regional ethical review board in Stockholm, Sweden (2019/5:1) and will follow the principles outlined in the 1964 Helsinki Declaration and its later amendments. Results from this study will be disseminated in peer-reviewed journals, scientific conferences and in social media.

ARTICLE SUMMARY

Strengths and limitations

- A Swedish and Arabic version of eHEALS and HLS-EU-Q16 have not yet been psychometric evaluated
- eHealth literacy has not previously been investigated in a Swedish population.
- This is the first study to compare eHealth literacy between Swedish and Arabic speaking citizens in Sweden.
- Although this study includes both Swedish and Arabic speaking participants from different contexts in the society the study is conducted in Sweden and may not be generalizable to other contexts.

INTRODUCTION

The importance of health literacy

Patients in today's health care system are expected to take part and be engaged in their own care. Consequently, they have to be able to read and understand health instructions on how to manage their own recovery at home ¹. As such, a patient's health literacy also influences their ability to take part in informed decision-making. In this article we use a comprehensive definition of health literacy:

Health literacy is linked to literacy and entails people's knowledge, motivation, and competence to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course².

Health literacy is regarded as a social determinant of health ³ and has a strong social gradient ⁴. Which means, health literacy can be an additional barrier to health for already disadvantaged and marginalised groups within societies. Limited health literacy is likely to affect patients' quality of care, resulting in lower satisfaction with care and lower understanding of their medical situation ⁵ and their safety, by decreasing the probability of an adverse medication due to misunderstanding instructions ^{5,6}. Health literacy is also associated with the extent to which people benefit from health examinations ⁷ and the quality of their postoperative recovery ⁸.

With increasing digitalisation of information and services, modern health care and health promotion have become increasingly challenging for both patients and health care staff ⁹. This demands a range of digital competencies among users, and requires new ways to describe and evaluate users' digital capabilities and experiences in this rapidly changing health context ⁹. Consequently, the concept of digital or electronic health (eHealth) literacy has emerged ¹⁰⁻¹² and been described as 'the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem' ¹².

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3 Equity in health and access to health care regardless of social position, gender, race, or
4 ethnicity is a major political issue in the European Region and worldwide ¹³. The Swedish
5 Health and Medical Services Act ¹⁴ states that the goal of health care is to promote ‘good
6 health and care on equal terms for the entire population’ ^{6, 14}. Migrants, whether they are
7 labour migrants or refugees, have been identified as a vulnerable population, but there is
8 heterogeneity in the degree to which they are vulnerable to inadequate health care ^{5, 6, 15, 16}.
9
10 One explanatory factor for the inequity in health, and in health care is limited health literacy
11 on individual and organizational level ¹⁷. A Swedish study show for example that newly
12 arrived refugees with limited health literacy, to a higher degree experienced poor quality of
13 communication and benefited less from the health examination for asylum seekers than those
14 with higher health literacy ⁷. Another study show that newly arrived refugees with limited
15 comprehensive health literacy have poorer general health and do not seek needed care as often
16 as those with higher comprehensive health literacy ¹⁸.

27 *HLS-EU-Q16*

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29 In 2011-2012, Sørensen et al. developed the Health Literacy Survey European Questionnaire,
30 HLS-EUQ47, a self-reporting instrument consisting of 47 items ¹⁹. The instrument is based on
31 a systematic literature review that derived an all-inclusive conceptual model and the definition
32 of comprehensive health literacy used in this study. In 2013, the instrument was used in a
33 large study including populations in 8 European countries ⁴. As a result of that study’s
34 analysis, the shorter 16-item version, HLS-EU-Q16, was developed ². Both the HLS-EUQ47
35 and HLS-EU-Q16 have been used frequently in many different countries and are available in
36 a range of languages

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46 The HLS-EU-Q16 aims to measure respondents’ perceived personal skills of finding,
47 understanding, judging, and applying health information to maintain and improve their health
48 ¹⁹. Each item in the instrument is answered on a 4-point Likert scale with response options
49 ranging from ‘very difficult’ to ‘very easy’. An overall HLS-EU-Q16 index will be calculated
50 in three steps according to the developer ²³. First, the response categories for the 16 items will
51 be dichotomized into easy (fairly easy and easy) giving the value of 1, and difficult (difficult
52 and very difficult) giving the value 0. Second, an overall sum score will be calculated. Third,
53 sum scores will be divided into three categories: inadequate (0-8 score points), problematic
54 (9-12 score points) and sufficient (13-16 score points) health literacy. HLS-EUQ16 has been
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3 psychometrically tested and showed to be in some migrant populations in which it was found
4 to be reliable and valid ²⁴.
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8 The Arabic and Swedish versions of HLS-EU-Q16 have been translated in line with
9 guidelines for the translation of instruments and tested for Face validity among migrants in
10 Sweden ²⁵. The Swedish and Arabic versions of the HLS-EU-Q16 have since been used in
11 several studies in Sweden ^{7, 18, 26} and Egypt ²⁰. However, the translated Swedish and Arabic
12 versions have not yet been tested for other aspects of validity and comprehensive health
13 literacy has not been compared between Swedish- and non-Swedish-speaking people.
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20 *eHEALS*

21 In 2006, Norman and Skinner developed the eHealth literacy scale, eHEALS. It aims to
22 measure a broad range of literacy skills, which might make it useful in assessing the effects of
23 strategies to deliver online information and applications. eHEALS is an 8-item instrument
24 with each item scored on a 5-point Likert scale with response options ranging from ‘strongly
25 agree’ to ‘strongly disagree’. Total scores on the eHEALS range from 8 to 40, with higher
26 scores representing higher self-perceived eHealth literacy.
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34 The eHEALS is available in a range of languages ^{11, 12, 27-31 32-34} and the English version has
35 been successfully administered digitally via telephone ³⁵. Tests of the validity of eHEALS
36 indicates that it is a reliable and valid instrument^{12, 28, 36-38} but also that the validity of if it
37 requires further investigation ¹¹. However, the eHEALS has not been tested for validity
38 among the general Swedish- or Arabic-speaking population in Sweden. eHealth literacy has
39 not been examined in Sweden nor compared between Swedish- and non-Swedish-speaking
40 people.
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48 **Aim**

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51 The overall aim of this study is to psychometric evaluate the Swedish and Arabic versions of
52 HLS-EU-Q16 and eHEALS, and to compare Arabic and Swedish speakers’ Health literacy
53 and eHealth literacy levels in Sweden.
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METHODS AND ANALYSIS

Study design

This is a prospective, psychometric and comparative evaluation divided into four different phases (Figure 1). Study recruitment will start in February 2019 and is planned to end in June 2019.

Phase 1: Translation process

The original English version of eHEALS will be translated into Swedish and Arabic. Arabic was selected as it is the most common native language spoken among refugees in Sweden³⁹. One independent translator each with either Swedish or Arabic as their native language will translate the English version of eHEALS to Swedish and Arabic. These translations should use plain language and be comprehensible to a 12-year-old speaker of the target language⁴⁰. Although it is important that the content of the items remain the same as in the original version, the wording or word order in the translated versions should be appropriate to the target language and understandable by speakers with various levels of education.

A translator group will consist of four professional translators, one for the forward translation into each of Swedish and Arabic and one for backward translations from each language. The translators will be recruited from translator associations found and through personal contacts. Previous experience in translating survey questions within the health domain will be a criterion for recruitment as a translator.

A committee to examine the quality of the translations will be recruited on the basis of criteria recommended for committees used in cross-cultural adaption projects⁴¹. The committee will consist of 12 members: 8 bilingual in English and Swedish and 4 multilingual in English, Arabic, and Swedish. The bilingual members should have experience in plain language and health literacy and/or health communication. Multilingual members should have experiences from data collections with Arabic speaking participants within the public health domain and previous experience of reviewing translated instruments.

The translation into Swedish will be completed first and reviewed by the researchers, who will compare it with the original English version, examine how well it fits the Swedish

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3 context, and check it for plain language. If necessary, adjustments will be made and the new
4 versions discussed with the bilingual members in the committee to ensure that the content of
5 the English and Swedish versions is the same and that plain language is used. The new
6 versions will also be discussed with four Swedish-speaking lay-people of different ages,
7 genders, and education levels to ensure the items are understandable. When the researchers
8 are satisfied with the Swedish version, based on the feedback from the bilingual and lay-
9 people, it will be back translated into English and the researchers and the translator will
10 compare it with the English original version. If the back-translation does not match the
11 original eHEALS, the Swedish version will be adjusted and back translated again as many
12 times as necessary to obtain a back-translation consistent with the original English version.
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22 Once the Swedish version is finalized, the translated Arabic version will be reviewed by the
23 four multilingual members in the committee, who together with the researchers, will discuss
24 how well the translated version fits the Swedish context, to what extent plain language has
25 been used, and how well the content of the translated version matches both the English
26 original and the final Swedish versions. If necessary, adjustments will be made and the new
27 versions discussed again with the multilingual members. When all are satisfied with the
28 translated version, it will be back translated into English by one independent translator and
29 compared with the English original version by one of the multilingual members. If the back-
30 translation does not match the English original version, it will be adjusted and back translated
31 again as many times as necessary to obtain a back-translation consistent with the original
32 English version.
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Phase 2: content validity testing of the Arabic and Swedish version of eHEALS

Content validity

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48 Content validity is the degree to which the content of an instrument is an adequate reflection
49 of the construct it is meant to measure⁴². As the plan is to use the instruments in this study in
50 the general population, i.e. in study populations they have been used previously in, no greater
51 adaptations of the instruments are needed. Examination of the content of the instrument by an
52 expert committee will therefore not be conducted. However, the face validity – the degree to
53 which the items or the instrument as a whole appear to adequately reflect the construct to be
54 measured⁴² – and the interpretability of the items⁴⁰ will be examined.
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3 The face validity of the final Swedish and Arabic versions will be tested through qualitative
4 interviews with five people in each language group to check whether these people understand
5 the items as intended. Participants will be recruited purposively and through snowball
6 sampling ⁴³ either directly by the researchers or through the researchers' personal contacts
7 with key people in groups speaking Arabic. A mix of different ages, genders, and educational
8 levels will be sought. Information about the project and the meaning of informed consent will
9 be given orally and in writing to the participants. If the person agrees to attend, the time for
10 the interview will be booked.
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15 In the interview, participants will be asked 'What were you thinking of while you were
16 answering that question?' and if necessary, 'Why did you select that response?' Interviews
17 will be audio recorded and notes written by the interviewer into templates containing the two
18 predetermined questions. Participants will also be asked about their age, gender, highest level
19 of education, and years living in Sweden.
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23 The five Swedish-speaking participants will be interviewed by two of the researchers and the
24 five Arabic-speaking participants by a research assistant with Arabic as native language, who
25 will take notes in Swedish. Each interviewer will listen to the recorded audio files,
26 complemented by the notes (if any) written immediately after each interview. The researchers,
27 will then read all notes separately.
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31 If the analysis shows that any items are difficult to understand and major changes to either
32 translation are needed, the items concerned will be revised and tested again on five new
33 participants. This procedure will be repeated until all items are easy to understand.
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37 38 39 40 41 42 43 44 45 **Phase 3: Psychometric testing of the Arabic and Swedish version of eHEALS and HLS-** 46 **EU-Q16** 47

48 49 50 **Participants**

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52 Two different language groups will be recruited from different regions in Sweden to test the
53 translated instruments. The intention is to include one group of participants representative of
54 the general Swedish-born population (n = 300) and one group representative of Swedish
55 residents born in an Arabic-speaking country (n = 300). The chosen sample size was first
56 guided by the 10:1 ratio ⁴⁰: 16 items on the HLS-EU-Q16 \times 10 = 160 participants. However, a
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3 general rule of thumb for factor analysis is 300 cases or the more lenient 50 participants per
4 factor ⁴⁴. HLS-EU-Q16 consists of only one factor ¹⁹, therefore a sample size of 300
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6 participants is considered most appropriate. Inclusion criteria for participation will be being
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8 an adult (≥ 18 years), having sufficient language skills to read, understand, and fill in a form in
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10 their native language (Swedish or Arabic), and being available on the days of data collection.
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12 Arabic speakers born outside of Sweden shall also have a Swedish resident's permit.
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15 Participants will be recruited from university courses, municipal adult education courses
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17 (Komvux), larger workplaces with both academic and non-academic staff, non-governmental
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19 organisations serving elderly people, migrant associations, courses in civic orientation, and
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21 supplementary academic courses for nurses with degrees from countries outside of Europe.
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23 These arenas are chosen because they attract many Swedish residents of different ages,
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25 genders, and levels of education who speak Swedish or Arabic as their first language. A mix
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27 of ages, genders, and educational levels will be sought in both groups. Upon recruitment of
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29 the participants, organizations manager or responsible person conducting group activities with
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31 potential study participants will be contacted and informed about the project.
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34 On the day of the data collection, a researcher will visit the various arenas to inform people
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36 both orally and in writing about the project and the meaning of informed consent. In groups
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38 with Arabic-speaking people, the Arabic-speaking research assistant will provide the oral and
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40 written information about the project and the meaning of informed consent in the potential
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42 participants' native language. People who agree to participate will be given a questionnaire
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44 and asked to fill it in directly onsite. By filling in the questionnaire, they also consent to take
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46 part in the study.
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49 The following questionnaires and study specific questions will be distributed in Swedish and
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51 Arabic respectively depending on native language.
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- 53 - the eHEALS instrument (8 items) assessing eHealth literacy;
- 54 - the HLS-EU-Q16 instrument (16 items) assessing comprehensive health literacy;
- 55 - one question about general self-perceived health;
- 56 - one question about use of internet and,
- 57 - descriptive background questions (age, gender, highest level of education, country of
58 birth).
- 59 - -number of years lived in Sweden. (Arabic-speaking group only).
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5 The questionnaire used in the Arabic-speaking group includes the same components, plus one
6 question about their number of years lived in Sweden.
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10 General self-perceived health will be measured by the questions ‘How do you assess your
11 overall health status?’ Response options are Very poor, Poor, Fair, Good, and Very good.^{7, 45}
12 Internet use will be measured by the question ‘How often do you use the internet?’ Response
13 options are Almost every day, Several days a week, About 1 day a week, Less than 1 day a
14 week, and Almost never¹¹.
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21 **Psychometric testing**

22 The psychometric testing will be guided by CONsensus-based Standards for the selection of
23 health Measurement INstruments (COSMIN)^{40, 42, 46}
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28 **Construct validity**

29 The construct validity⁴² focus on evaluating tests of the hypotheses. This aspect of construct
30 validity can be described as the degree to which the scores of an instrument are consistent
31 with a hypothesis⁴². The participants and questionnaire for collecting data, will be the same
32 as those described above.
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38 Based on previous studies on health literacy showing positive associations between limited
39 health literacy and high age^{4, 47-49}, low education level^{20, 49, 50}, poor health^{7, 8, 22, 48, 51} and
40 between eHEALS and low use of the Internet¹¹, several hypotheses will be used regarding
41 correlations between HLS-EU-Q16/eHEALS and; age, level of education, self-perceived
42 general health and quantity of Internet use. Moreover, hypothesis regarding correlations
43 between eHEALS and; HLS-EU-Q16 and certain HLS-EU-Q16 items will be used. All
44 hypothesis are presented in Figure 2.
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51 Spearman’s rank order correlation between total mean scores on eHEALS and HLS-EU-Q16,
52 self-perceived health, level of education, and age will be used to A coefficient magnitude of
53 >0.4 will be considered evidence of construct validity (i.e., moderate to strong correlations)⁴⁶.
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Reliability

Reliability can be used as a term for a domain and as a term for a measurement property⁴². In this study we are analyse two aspects of reliability: internal consistency and test-retest reliability.

Internal consistency

Internal consistency describes the interrelatedness among items⁴² and will be analysed for both eHEALS and HLS-EU-Q16.

- Exploratory factor analysis will be used to identify the underlying relationships between items on eHEALS and HLS-EU-Q16⁴⁰.
- Cronbach's alpha will be calculated for each instrument to assess the average correlation of items within each scale. Cronbach's alpha in the range of 0.7–0.95 will be considered acceptable^{40, 52}.
- Split-half reliability will be used to measure the correlation between random split segments and to determine how much error in a test score is due to poor test construction⁵². A Spearman-Brown coefficient of 0.70–0.90 will be considered acceptable^{53, 54}.

Test-retest reliability

Test-retest reliability can be described as the extent to which scores for the same patients are the same in measurements repeated over time⁴². Intraclass correlation coefficient (ICC) will be used and an ICC value of ≥ 0.7 will be considered acceptable⁴⁰. Because the sample size needed for test-retest is much smaller than for testing many other forms of validity, the sample size in the retest of 25 people per language category (total 50) is considered appropriate⁵⁵.

Participants in the test-retest groups will be invited to take part in the retest when they are recruited to participate in the main test. To minimise dropouts, participants in the test-retest groups will be recruited in the pre-existing groups having regular, at least weekly, meetings. A mix of different ages, genders, and education levels will be sought. To compare answers from the test and the retest, the participants will mark their questionnaires with their birth date or any other self-contained code if they do not wish to give their date of birth. If they use their

own code, they will be asked to write it down in a list of codes the researcher will bring to the second measurement in case they forget their code.

Feasibility

The feasibility of the clinical user-friendliness of the instruments will be assessed by their successful response rate⁴⁶.

Floor and ceiling effects

Floor and ceiling effects (the number of respondents who achieve the lowest or highest possible scores⁴⁰ will be examined. Floor or ceiling effects are considered a problem if more than 15% of a study population achieve the lowest or highest possible score⁴⁰.

Phase 4. Distribution of eHEALS and HLS-EU-Q16 levels in the study population and comparisons of levels in the two language groups

The distribution of eHEALS and HLS-EU-Q16 levels in the study population as a whole and within each language group will be examined. Chi-square tests – or Fisher’s exact tests as appropriate – will be used to test for differences in eHEALS and HLS-EU-Q16 between language groups. Binary logistic regression analyses will be performed to assess associations. We hypothesise that there will be positive correlations between HLS-EU-Q16/eHEALS and level of education, self-perceived general health and quantity of Internet use; and negative correlations between HLS-EU-Q16/eHEALS and age. Moreover, we hypothesise positive correlations between eHEALS, HLS-EU-Q16 and certain HLS-EU-Q16 items (Figure 2).

All data will be analysed using SPSS version 24.0 for Windows (IBM Corporation, Somers, NY, USA). Two-tailed *P* values under .05 will be considered significant.

Patient and Public Involvement

No public involvement

Discussion

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3 A considerable proportion of both the European population and newly arrived refugees in
4 Sweden have limited comprehensive health literacy⁴. How this is distributed in the general
5 Swedish population and the eHealth literacy levels of Swedish- and Arabic-speaking people
6 living in Sweden are rather unknown. Knowledge about comprehensive health literacy (and
7 by extension, eHealth literacy) is important, though, as it is associated with people's health
8 status¹⁷, use of health information and health care services^{5, 6, 33, 47, 56}. Being regarded as an
9 important social determinant of health³ and having a social gradient health literacy⁴ in
10 patients is important to consider in work to promote health, disease prevention, and health
11 care, in order to secure that people with various levels of health literacy benefit equally from
12 health efforts to reduce the risk of promote inequity in health and healthcare instead of vice
13 versa¹⁷. However, in Sweden validated instruments to measure comprehensive health literacy
14 and eHealth literacy of Swedish-, and Arabic-speaking people are lacking, i.e. needs to be
15 developed.

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27 Our research team has developed and tested a digital monitoring system, Recovery
28 Assessment by Phone Points (RAPP), that enables day surgery patients to contact health care
29 easily and to report from home about how they feel⁵⁷. It has been tested in studies with
30 Swedish-speaking patients, and proved to be cost-effective⁵⁸, to help patients feel safer and
31 less bothered by symptoms, such as pain, nausea, anxiety, in their postoperative recovery⁵⁷,
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59. Strong relationships between postoperative recovery, health, and mental health were also
found. However, so far RAPP is only available to Swedish-speaking patients. Next step is to
develop RAPP for non-Swedish-speakers, starting with Arabic, and to compare postoperative
recovery and unplanned medical contacts between non-Swedish-speaking Arabic patients and
Swedish-speaking patients. We will then also study differences in eHealth literacy, mental
health, and postoperative recovery between the groups, and describe their experiences of
postoperative recovery and using a digital tracking system such as RAPP. However, before
we can investigate these questions, we need to develop valid Arabic and Swedish version of
eHEALS to be able to assess eHealth literacy.

Ethics and dissemination

The project has been approved by the regional ethical review board in Stockholm, Sweden
(number 2019/5:1) and will follow the principles outlined in the 1964 Helsinki Declaration
and its later amendments. Participants will receive written and verbal information about the

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3 study, including the purpose and procedures, the voluntary nature of participation, and their
4 option to withdraw at any time. They will also be guaranteed confidentiality and secure data
5 storage.
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13 otherwise in compliance with the license. See: <http://creativecommons.org/licenses/by-nc/2.0/> and <http://creativecommons.org/licenses/by-nc/2.0/legalcode>.
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20 **Authors' contributions**

21 JW have contributed to the planning of the study, study design, the preparation of the
22 manuscript and approved of the final version.
23

24 KD have contributed to the planning of the study, study design, the preparation of the
25 manuscript and approved of the final version.
26
27

28 MJ have contributed to the planning of the study, study design, the preparation of the
29 manuscript and approved of the final version.
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32 UN have contributed to the planning of the study, study design, the preparation of the
33 manuscript, led the calculation of sample size and approved of the final version.
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38 This research received no specific grant from any funding agency in the public, commercial or
39 not-for-profit sectors
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44 **Competing interests**

45 None
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50 **No figure legend**

51 Figure 1. Overview of the research process.
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53 Figure 2. Hypothesis of correlations between eHEALS/HLS-EU-Q16 and various variables.
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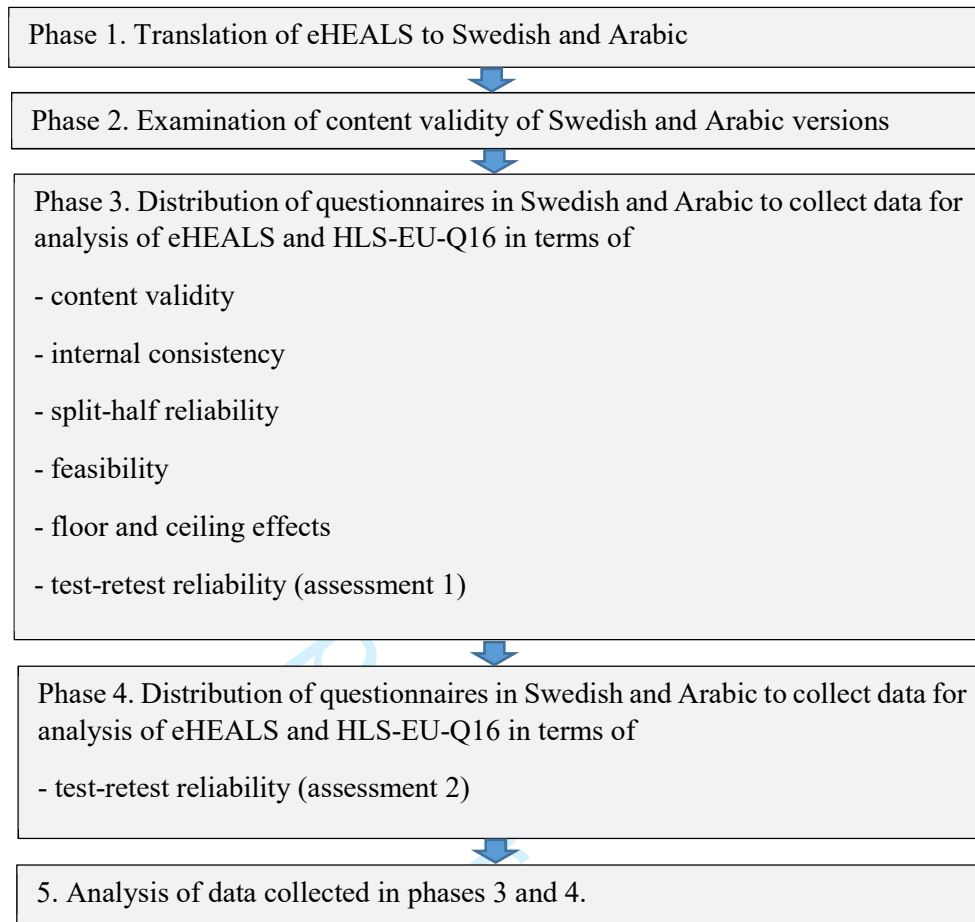


Figure 1. Overview of the research process.

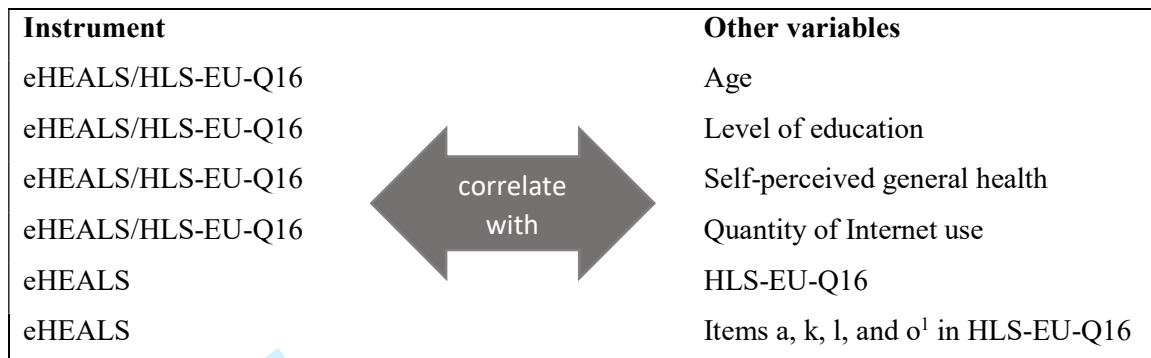


Figure 2. Hypothesis of correlations between eHEALS/HLS-EU-Q16 and various variables.

¹ Item a: How easy/difficult is it for you to find information on treatments of illnesses that concern you?

Item k: How easy/difficult is it for you to judge whether information on health risks in the media (e.g., on television or the internet) is reliable?

Item l: How easy/difficult is it for you to decide how you can protect yourself from illness based on information in media (e.g., in newspapers or leaflets or on the internet)?

Item o: How easy/difficult is it for you to understand information in the media (e.g., from the internet or daily or weekly magazines) on how improve your health?