CHRIS Study

Touchscreen – Restless Legs Syndrome Diagnosis and Rating Scale

Version 1.1

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1. Introduction

This module stores information related to the symptoms suggestive of restless legs syndrome of the participants, that was collected with the self-assessment questionnaire on a touchscreen.

Participants book a morning appointment at the CHRIS study center, ranging from 7.45 to 8.45 a.m. Each study participant is assigned a workflow at the reception. If there are ten study participants (maximum capacity), there are ten different workflows, marked with the letters from “A“ to “K“. The current workflow is as follows: A-B-C-D-E-F-G-H-I-K. All the workflows can be found in the documentation of CHRIS Baseline/General information/Administrative data, in the file named “Workflows at baseline assessment”. The self-administered questionnaire is filled in always after the blood draw, for most before the interview (workflows B, C, E, F, H, I, L). For the remainder, the self-administered questionnaire is filled in just after the interview (workflows A, G) or after the interview and the ECG measurement (workflow D).

The Restless Legs Syndrome - Diagnosis instrument was developed by Dr. Heine Benes of the somni bene Institute for Medical Research and Sleep Medicine Ltd., Schwerin Germany. The version used in the CHRIS study is the Version 1.1, of May 2004. This instrument was developed to diagnose an actual and persistently present Restless Legs Syndrome (RLS) in a sleep lab population. It consists of six items that cover the most prominent clinical features of RLS, i.e. its occurrence mainly at night and at rest, the urge to move the legs or arms, the tingling, its improvement thanks to physical activity like walking or stretching. The questionnaire was originally developed and validated in German, whereas the Italian version was translated by IfB researchers.

The Restless Legs Syndrome - Rating Scale instrument was developed by the International Restless Legs Syndrome Study Group to measure disease severity on patients already diagnosed with RLS. The instrument consists of ten questions, all with a similar format and a similar polarity. Each question has a set of five response options graded from no RLS or impact (score = 0) to very severe RLS or impact (score = 4). The total scale produced summing the answers has a range from 0 to 40. Since the instrument was validated in Germany, Ireland, Italy, Spain, Sweden, and the United States of America, the questionnaire was already available both in German and in Italian.

The self-assessment questionnaires and the guide for RLS-RS evaluation are available, respectively, at CHRIS Baseline/Self-Assessment/Touchscreen, CHRIS Baseline/Self-Assessment/Touchscreen/Restless Legs Syndrome Rating Scale, and online (see References section).

2. History version changes

Version 1 of this module was in use since August 24th,2011 and it has never been changed.

The cleaning process added the variables x0rd08, x0rd09, x0rd10, x0rr11, x0rr11a, x0rr12, and x0rr12a.

3. Data cleaning

1. The main CHRIS dataset was loaded.
2. The variable on leg pain combined with the urge to move them, x0rd01, had its missing observations set to “Unexpected missing”.

3. The variable on frequency of RLS, x0rd05, had its missing observations transformed into:
    a) "Don't know" (-88) if the chosen option was "I do not know",
    b) "Missing by design" (-99) if no leg pain with urge to move was experienced (x0rd01 was "Missing by design" or "No"),
    c) "Unexpected missing" (-89) if x0rd01 was "Unexpected missing" or "Yes".
4. The other symptom variables of the RLS-D instrument, x0rd02-x0rd04, had their missing observations set to:
    a) "Missing by design" (-99) if x0rd01 was "Missing by design" or "No",
    b) "Unexpected missing" (-89) if x0rd01 was "Unexpected missing" or "Yes".
5. The other RLS duration variables, x0rd06 and x0rd07, had their missing observations set to:
    a) "Missing by design" (-99) if no leg pain with urge to move was experienced (x0rd01 was "Missing by design" or "No"),
    b) "Unexpected missing" (-89) if both x0rd06 and x0rd07 were missing and x0rd01 was "Unexpected missing" or "Yes",
    c) "Unexpected missing" otherwise.
6. A new RLD duration variable was created as the sum of x0rd06 and 0rd07 (in years), with values:
    a) $x0rd06$ if x0rd07 was missing,
    b) $x0rd06 + \frac{x0rd07}{12}$ if both x0rd06 and x0rd07 were positive and $x0rd06 \neq \frac{x0rd07}{12}$,
    c) $x0rd07$ otherwise.

    It was saved as x0rd08. Furthermore, it was assigned the value "Out of range" (-86) if x0rd08=99 or x0rd08 was higher than the rounded age x0_ager plus 1.

7. The RLS diagnosis score variable was created and assigned the values:
    a) The sum of "Yes" among x0rd01-x0rd04,
    b) "Missing by design" if no leg pain with urge to move was experienced (x0rd01 was "Missing by design" or "No"),
    c) "Unexpected missing" if any among x0rd01-x0rd04 was "Unexpected missing".

    It was saved as x0rd09.
8. The frequency of missing values among the RLS-RS instrument, x0rr01-x0rr10, was investigated.
9. All the item variables of the RLS-RS instrument, x0rr01-x0rr10, had their missing observations set to:
    a) "Missing by design" (-99) if x0rd01 was "Missing by design" or "No",
    b) "Unexpected missing" (-89) if x0rd01 was "Unexpected missing" or "Yes".
10. Each RLS-RS item was assigned a subscore for each of its answers, from 0 (None/No RLS) to 4 (Very severe/No relief). The RLS rating scale score variable was created and assigned the values:
    a) The sum of each item's subscore,
    b) "Missing by design" if x0rd01 was "No",
    c) "Unexpected missing" if any of the item x0rr01-x0rr10 was "Unexpected missing".

    It was saved as x0rr11.
11. A severity score was derived from x0rr11, with the following values:
    a) "None" if x0rr11 was 0,
    b) "Mild" if x0rr11 was in the range 1-10,
    c) "Moderate" if x0rr11 was in the range 11-20,
    d) "Severe" if x0rr11 was in the range 21-30,

e) "Very severe" if x0rr11 was in the range 31-40,
f) "Unexpected missing" if x0rr11 was "Unexpected missing",
g) "Missing by design" if x0rr11 was "Missing by design".

It was saved as x0rr12.

12. If all the four symptoms of RLS-D were reported, the participant was said to be positive at restless leg syndrome, this was captured by the variable x0rd10, with values:
    a) "Unexpected missing" if x0rd01 was "Unexpected missing",
    b) "Yes" if the sum of the "Yes" among x0rd01-x0rd04 was 4,
    c) "No" otherwise.
13. The baseline dataset was saved.

4. Advices for the analysis

Additional information related to RLS can be found in the following variables:

- x0sq22 within Pittsburgh Sleep Quality Index, on the partner reporting legs twitching during sleep,
- x0rb04, of the REM Sleep Behavior Disorder instrument, on arms or legs moving during sleep,
- self-reported RLS can also appear in x0ne21 or x0ne22, in the neurology section of the Interview.

5. References

Benes H, Hening W, Högl B, Peglau I, Schüler P, Stiasny K, Trenkwalder C, Voderholzer U. Das Syndrom der ruhelosen Beine (Restless-Legs). Leitlinien zur Diagnose und Therapie [Restless legs syndrome. Guidelines for diagnosis and therapy]. MMW Fortschr Med. 2001 Nov 8;143(45):50-1.

The International Restless Legs Syndrome Study Group. Validation of the International Restless Legs Syndrome Study Group Rating Scale for restless legs syndrome. *Sleep Med* 2003;4(2):121-132. DOI: 10.1016/S1389-9457(02)00258-7

Restless Legs Syndrome Rating Scale scoring guidelines: https://biolincc.nhlbi.nih.gov/media/studies/masm/IRLS.pdf