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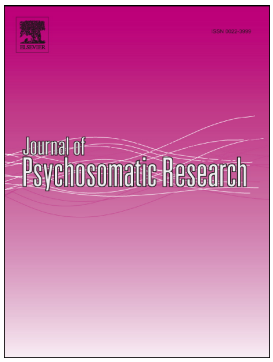

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Running head
RIFD – The Research Interview for Functional somatic Disorders

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Abstract

Objective: Epidemiological research in functional somatic disorders such as irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, and bodily distress syndrome and related conditions such as health (illness) anxiety is often based on self-reported questionnaires or layman interviews. This study presents and describes the Research Interview for Functional somatic Disorders (RIFD) and provides first data regarding RIFD's ability to identify cases with functional somatic disorders and health anxiety in a two-phase design following self-reported symptom questionnaires. **Methods:** RIFD was performed by phone by trained family physicians on a stratified subsample of 1590 adults from a Danish general population cohort (n=7493). Criterion validity was tested in a small preliminary test including 25 RIFD participants using Schedules of Clinical Assessment in Neuropsychiatry (SCAN), performed by a specialist in functional somatic disorders, as gold standard. Interrater reliability between interviewers was tested in 15 participants. **Results:** Compared with the comprehensive SCAN, preparation and conduction of RIFD were feasible and prompt. RIFD was well accepted by both interviewers and interviewees. RIFD identified cases with significantly more impairment than identified non-cases. Based on small preliminary tests, RIFD showed promising psychometric properties. **Conclusion:** RIFD was a feasible, well-accepted and promising instrument for use in large epidemiological studies. However, larger studies investigating its psychometric properties are needed.

Keywords: functional somatic syndromes, functional somatic disorders, bodily distress, health anxiety, illness anxiety, schedules of clinical assessment in neuropsychiatry.

1. Introduction

Persistent physical symptoms contribute greatly to the burden of disease worldwide (1,2). In cases where all or at least the vast majority of those symptoms are not attributable to any known conventionally-defined medical condition, patients may be diagnosed with a so-called functional somatic syndrome, e.g. irritable bowel syndrome (IBS), fibromyalgia (FM), and chronic fatigue syndrome (CFS) (2). Many other diagnostic labels are used, and recently the unifying research diagnosis bodily distress syndrome (BDS) has been introduced (2,3). The impairing conditions may be subsumed under the umbrella term "functional somatic disorders" having in common that we do not have any objective clinical or paraclinical tests to verify the diagnoses. Hence, the diagnoses are based on subjective symptom reports only combined with ruling out differential diagnoses with concurrent symptom patterns (1,4,5).

The various diagnostic constructs under the heading of functional somatic disorders are based on three basic principles: 1) a focus on somatic symptoms or symptom patterns (e.g. IBS or BDS), 2) a focus on cognitions, emotions and behaviours related to the symptoms (e.g. Somatic Symptom Disorder in the Diagnostic and Statistical Manual for Mental Disorders (DSM-5)), and 3) a focus on an assumed cause of the symptoms (e.g. whiplash associated disorders (WAD) or multiple chemical sensitivity (MCS) (5).

The approaches to identify individuals with functional somatic disorders in epidemiological reseach are several. First, an often used approach is to use questionnaires for case identification (6-11). Questionnaires have the advantage of being cost-effective, easy to distribute, having high reliability, and they are not influenced by an intermediary's understanding of disease. However, questionnaires may have a low validity as to distinguishing between functional somatic disorders and medical diseases with a concurrent symptom pattern, i.e. it is difficult – or even impossible – to rule out relevant differential diagnoses. An additional challenge is to delimitate individuals with clinically

relevant disorders from individuals with normal bodily reactions. This distinction is rather arbitrary when based on self-reported questionnaires only and makes identification of clinically relevant cases and the establishment of a research diagnosis uncertain (12). A second approach is simply to ask a patient or study participant whether or not they have received a diagnosis of a functional somatic disorder by a doctor (13). However, clinical diagnoses have shown to be biased as regarding sex ratio (14) and general understanding of classification and conceptualization of disease (15). Structured diagnostic interviews conducted by trained layman or physicans constitute a third approach (16). Layman interviews may carry the same problems as questionnaires as medical knowledge is necessary to differentiate between medical conditions. Some studies have tried to overcome this by having physicians review the layman interviews and make the final diagnoses (17). Diagnostic interviews conducted by physicians seem more reliable due to their medical knowledge. A final and most optimal approach would be to combine a physician-rated interview with a clinical examination and review of medical records. While this may be a practical procedure in clinical studies, this approach is too expensive and time-consuming in epidemiological research. Moreover, it raises ethical questions regarding the deep knowledge the interviewer gets about a participant's medical history.

The psychiatric interview Schedules of Clinical Assessment in Neuropsychiatry (SCAN) (18) is a comprehensive diagnostic interview developed for the assessment of mental disorders. In collaboration with the SCAN World Health Organization (WHO) working group, the Research Clinic for Functional Disorders and Psychosomatics at Aarhus University Hospital, Denmark, has refined the section on physical health and functional somatic disorders. This version has been used in daily clinic and in research (19-25). However, SCAN is time-consuming and requires interviewers with both medical background and special training in SCAN interviewing (typically at least one week of training, followed by at least ten individual diagnostic interviews that are checked

for interrater reliability). Hence, to use SCAN in large-scale epidemiological studies would be a prohibitive task in terms of time spent, economy, and personnel. A shorter version of SCAN has been developed for clinical use and clinical studies, but this version does not cover functional somatic disorders (26).

A condition associated with the functional somatic disorders is health (illness) anxiety (27) which constitutes individuals with long-lasting and interfering preoccupation of having a serious illness despite repeated medical reassurance (28). As part of establishing a study on functional somatic disorders and related conditions such as health anxiety in the general Danish population, the DanFunD study (13), a new brief interview inspired from SCAN was developed: The Research Interview for Functional somatic Disorders (RIFD). RIFD introduces a two-step approach where self-reported symptom questionnaires are followed by e.g. clinical interviews or clinical examination. This has been done in population-based studies including single functional somatic disorders such as IBS and FM (29-31) but never in studies including definitions of various functional somatic disorders.

The primary objective of this paper was to present and describe the development and feasibility of RIFD. As a secondary objective, we conducted a small preliminary study on the criterion validity and interrater reliability in identifying cases with functional somatic disorders and cases with health anxiety.

2. Methods

2.1. Study population

A subsample from the Danish Study of Functional Disorders (DanFunD) part II cohort (n=7493) was included in the study (Figure 1) (13). Participants answered symptom questionnaires with symptom scales for BDS (3) and the Whiteley-7 scale for health anxiety (32) among others.

Questionnaire answers formed the basis for a stratified sample of random participants and high score participants to be selected for RIFD (n=2450). RIFD was performed parallel with conduction of the symptom questionnaires within the period of December 2012 to August 2015.

In a small preliminary test of the criterion validity and interrater reliability of RIFD, 49 randomly selected consecutive RIFD participants were invited to participate in a full face-to-face SCAN interview, and 15 randomly selected RIFD interviews were rated simultaneously by at least two interviewers.

Figure 1 about here

2.2. Instruments

2.2.1. SCAN

The modified version of the face-to-face SCAN 2.1 with the 10th edition of the Present State Examination (PSE-10) (18) was used. Section two holds a section on physical diseases and symptoms, a section on health anxiety, and a section on dissociative or conversion disorders. Based on diagnostic algorithms, SCAN can identify, among others, somatoform and dissociative disorders and bodily distress.

The basic principle in SCAN is the interviewer's assessment of whether or not a symptom or symptom pattern is present and which diagnosis can account for this. The semi-structured form secures that the interviewer asks for all relevant symptoms, while being free to use any available additional information to qualify the judgment regarding differential diagnostics.

2.2.2. Research Interview for Functional somatic Disorders (RIFD)

RIFD is a semi-structured interview designed to be conducted by telephone. It encompasses symptoms inspired from the modified SCAN with items for diagnosing a range of functional somatic syndromes, i.e. IBS (33), FM (34), CFS (35), BDS (3,36), and health anxiety (28), among

others. It also covers anxiety, depression, and somatoform disorders from DSM-IV, DSM-5, and the draft of the 11th version of the International Classification of Diseases (ICD-11), which, however, are beyond the scope of this paper (Appendix A). During RIFD, the interviewer rates each symptom directly in a computer-based programme from where the entered data can be exported and analysed as quantitative data.

As in SCAN, the basic principle in RIFD is the interviewer's assessment of whether or not a symptom or symptom pattern is present, the severity of symptoms and impairment, and whether or not the participant has another medical condition that may account for their symptoms.

First, the interviewer is instructed to browse the participant's responses to the symptom questionnaires (Appendix B). In case of no health-related troubles, the interviewers are instructed to ask "I can see that you have not indicated any symptoms or discomfort in the questionnaire. Does that mean that, in the past year, you have not had any physical diseases, symptoms, injuries, pains, or other disorders that have limited you in your daily life?". If the participant confirms, the interview is ended. If the participant confirms to have symptoms, the interviewer is instructed to ask "Have you seen a doctor because of the symptoms? Did he/she find an explanation for them?". The interviewer can explore the case by additional questions if deemed necessary. In the beginning of the interview, a range of physical conditions are listed to assess whether the participant has one or more diseases that could cause any of the symptoms identified later on in the interview.

Second, functional somatic disorders are assessed. These sections are divided into symptom clusters defined by the BDS construct; i.e. cardiopulmonary, gastrointestinal, musculoskeletal, and general symptoms clusters (3). In addition, other symptoms are briefly assessed such as genital problems, MCS (37,38), WAD (39), and conversion/dissociative disorders. The symptoms listed in each cluster are largely identical with the corresponding symptoms in the questionnaires, and the interviewer can use the participant's answers from the questionnaires as a base for the interview. For

each symptom cluster, the interviewer, depending on the participant's questionnaire answers, asks: If negative response to e.g. musculoskeletal symptoms: "According to the questionnaire, you have not had any musculoskeletal problems in the past year. Have I understood this correctly?" If this is confirmed, the interviewer moves on to the next symptom cluster. If positive response: "In the questionnaire, you have indicated that you have suffered from (the symptoms indicated in the questionnaire are mentioned) within the past year. What is that about?" The interviewer can further explore the complaints if deemed necessary and register the positive symptoms in the interview.

After each section of symptom clusters, the interviewer assesses whether the symptoms are attributed to a conventionally-defined physical disease such as cancer or rheumatoid arthritis.

Finally, the interviewer assesses how impaired the participant is due to the symptoms. This is done by one item stating "How much have the mentioned symptoms all in all disturbed your regular daily activities?". The item is scored on a four-point Likert scale with options "Not at all", "Only small impact or discomfort", "Moderate or intermittent impact or discomfort", "Severe or incapacitating impact or discomfort", and it also includes the option "Uncertain/unknown/don't now".

In the next section, health anxiety is assessed. As diagnostic aid, the interviewer has access to the participant's answers from the symptom questionnaires, but the symptoms asked for in the RIFD stem from the original version of the modified SCAN (18).

Hereafter follow the sections for major depressive disorder and anxiety disorders. The interviewer is aided by the Symptom Checklist-90 (SCL-90) depression and anxiety subscales (40). Only symptoms included in the diagnostic criteria (ICD-10 and DSM-IV) for depression and anxiety are explored (41). The anxiety section encompasses single items concerning generalised anxiety, panic attacks, agoraphobia, and social anxiety.

Finally, the participants are asked if they have another mental disorder not already identified.

2.3. RIFD procedure

All RIFDs were conducted telephonically by three family physicians, all with at least 12 years of practise in family medicine and trained in both RIFD and SCAN. During two meetings, the interviewers were introduced to RIFD, and they pilot-tested the interview procedure on two study participants.

The interviewers were seated at The Research Clinic for Functional Disorders and Psychosomatics at Aarhus University Hospital, Denmark, and they could get supervision from other physicians and specialists at the clinic or, if necessary, ask any medical specialist at Aarhus University Hospital. Hence, during the interview period, continued clinical education and supervision took place.

The interviewees were seated in their own homes in the Western part of Copenhagen.

Each participant was given two time slots where the interviewer could contact them, and they further received a contact number to a secretary if they were hindered during the assigned times. If so, they were assigned a new time for the interview.

Sixty minutes were allotted for each interview and if exceeded, the next participant was allocated the next time slot he/she had been given. This could be the case if a participant had numerous symptoms and complaints which required a more thorough assessment.

Feasibility and acceptance of RIFD was assessed by independent unstructured interviews with the three interviewers.

2.4. Comparison of cases and non-cases

Data from the symptom questionnaires were used to investigate differences between identified individuals with a functional somatic disorder or health anxiety and individuals without these disorders. Self-perceived health and limitations in daily activities were obtained through single items from the 12-item Short Form Health Survey (42). Presence of physical and mental comorbid conditions was obtained through a list of 17 conventionally-defined conditions such as cancer,

myocardial infarction, asthma, and diabetes and two mental disorders; depression and anxiety (10). Difference in scores for health anxiety was measured on the 7-item Whiteley Index (32), normalized to a 0-100 scale.

2.5. Preliminary test of psychometric properties

For considering criterion validity, a random selection of participants for the SCAN interview went on during three time periods during the three-year period where RIFD was conducted. Individuals agreeing to participate in SCAN received a time to meet at the Center for Clinical Research and Prevention, the Capital Region, for the interview. A psychiatrist and family medicine specialist with great experience in SCAN was responsible for conducting the interviews. She had no knowledge of the answers given by the participants in neither the symptom questionnaires nor RIFD. Two hours were assigned for each SCAN interview.

For measuring interrater reliability, RIFDs were consecutively rated by two or three raters as follows: One interview in January 2014, ten interviews in July 2014, and four interviews in April 2015. For each test, the raters were located in separate rooms during the interview. One of the raters conducted the interview, while the other raters overheard the interview and made their own assessment at the same time.

In each case, the participants were informed about the procedure and gave their consent for their interview to be overheard by several raters.

2.6. Statistical analysis

All analyses were performed in Stata 15.0 for Windows (StataCorp LLC, College Station, USA). Difference in prevalence of functional somatic disorders and health anxiety between SCAN and RIFD was evaluated with McNemar's test for paired binominal data. Identified cases were compared to non-cases regarding different self-reported covariates from the symptom

questionnaires such as sex, poor self-perceived health, limitation in daily activities, and comorbidity. Relative risks were calculated with generalized linear models with binominal family and log link. For criterion validity, unweighted Kappa coefficients were calculated with 95% confidence intervals (CI) for the assignment of participants into cases and non-cases of functional somatic disorders and health anxiety. Sensitivity, specificity, positive predictive value (PPV), and negative predicted value (NPV) were also calculated with 95% CI. Interrater reliability was measured and interpreted with unweighted Kappa coefficients with 95% CI. Landis and Koch's division into classes of agreement was used for interpretation of both criterion validity and interrater reliability (43): 0.0–0.20, slight agreement; 0.21-0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, substantial agreement; 0.81–1.00, near perfect agreement.

2.7. Ethical considerations

Written informed consent was obtained from each participant before participation. The study was approved by the Ethical Committee of Copenhagen County (Ethics Committee: KA-2006-0011; H-3-2011-081; H-3-2012-0015) and the Danish Data Protection Agency (Jnl No.: 2012-58-006).

3. Results

The final sample of RIFD participants consisted of 1590 (64.9%) individuals with a median age of 54 years (Interquartile range (IQR: 44-63); 942 (59.3%) were women. Most of them (67.9%) had more than three years of vocational training and most of them were currently employed (63.5%).

3.1. Feasibility of RIFD

All three interviewers revealed the interview to be feasible to conduct. It was easy to get hold of the participants, i.e. in less than 20 cases, the interviewers could not get through to the participants. When initiated, all interviews were carried out without any dropouts indicating a good adherence to the procedure and acceptability of the interview.

In general, completion of each interview varied from five minutes for participants with no symptoms or complaints to 45 minutes for participants with multiple symptoms and complaints (a few participants with heavy symptom loads deviated with interviews lasting well over an hour). Preparation time for RIFD was 5-10 minutes to go through the symptom questionnaires.

Very few interviews revealed problems requiring the interviewer to intervene for ethical reasons: One case had serious alcohol abuse and revealed suicidal intentions during the interview. Other interviews revealed clear suspicion of serious disease, e.g. undiscovered cancer and ischemic heart disease. In these cases, the interviewers contacted the participants' general practitioner, with the participants' permission, and secured the further course. These participants were not excluded from the study.

The interviewers reported to have good contact with the participants and felt a trust on the participants' part that allowed for confiding their symptoms and complaints similar to a face-to-face consultation.

Participants were satisfied with the interview and showed great interest in talking about their health and symptoms. Neither the interviewers nor the DanFunD study contact personnel received complaints from the participants, and there were no reports on interviews ending in a bad manner, i.e. discussion or dissatisfaction.

3.2. Characteristics of cases from the RIFD interview

RIFD identified individuals with functional somatic disorders or health anxiety that differed significantly from individuals without these disorders (Table 1). Cases of functional somatic disorders were more often women, and they had significantly higher risk of having a poor self-perceived health, limitations in daily activities, and comorbid physical and mental disease. Cases of health anxiety were also more often women, had higher risk of mental comorbidity, and scored significantly higher on the Whiteley-7 scale for health anxiety.

Table 1 about here

3.3. Preliminary test of psychometric properties

Of the 49 participants invited to a SCAN interview, 38 (77.5%) agreed to participate, and a total of 25 (51.0%) full SCAN interviews were completed (Figure 1).

It took around 25 minutes to complete a SCAN interview for participants with no notable symptoms and around two hours for a participant with many symptoms. No differences in prevalence of functional somatic disorders ($p=0.29$) and health anxiety ($p>0.99$) between RIFD and SCAN were seen (Table 2).

Table 2 about here

With regard to criterion validity, a fair agreement was seen for functional somatic disorders, and a moderate agreement was seen for health anxiety (Table 3).

As to interrater analysis, 13 participants were rated by three raters, and two were rated by two raters. The interrater agreement for functional somatic disorders was moderate (κ=0.47, 95% CI, 0.10-0.77), while it was near perfect (κ=0.83, 95% CI 0.31-0.97) for health anxiety.

Table 3 about here

3.2.1. Discrepancies between RIFD and SCAN

Discrepancy between RIFD and SCAN was caused by eight cases of RIFD false negatives and three cases of RIFD false positives (Table 4). The false negatives were caused by 1) symptoms identified in SCAN but not in RIFD, or 2) symptoms identified in both interviews but assessed to be caused by a conventionally-defined disease in RIFD. The false positives were caused by RIFD reporting higher number or more impairing symptoms than SCAN.

Table 4 around here

4. Discussion

4.1. Principal findings

This paper presents the newly developed RIFD and reports results on its feasibility and acceptance. To our knowledge, RIFD is the first brief, clinical research interview for functional somatic disorders and health anxiety for use in large epidemiological studies. The study showed that RIFD was feasible to perform and well accepted by both interviewees and interviewers. RIFD identified cases that differed significantly from non-cases on different covariates, indicating poorer life quality. The RIFD also showed promising criterion validity and interrater reliability in a small preliminary test.

4.2. Discrepancies between RIFD and SCAN

Discrepancies between RIFD and SCAN may be caused by the complicated nature of functional somatic disorders making it difficult to differentiate them from comorbid disease.

Also, the difference in the interviewers' background, "culture" within medical specialty, and understanding of disease could induce rater bias (44). Besides being a specialist in primary care and psychiatry, the SCAN interviewer had long-time experience conducting SCAN on heavily

invalidated patients with multiple functional somatic disorders in a highly specialized setting. In that setting, the presence of one or two conventionally-defined physical diseases would not explain the patient's whole symptom pattern, hence, they would still be assessed to have a functional somatic disorder. The SCAN interviewer might have overstated the presence and severity of symptoms in this population-based (and therefore presumably less impaired) sample, overdiagnosing functional somatic disorders. On the other hand, the RIFD interviewers were specialists within family medicine with large experience from primary care dealing with patients presenting with unexplained and presumably less incapacitating symptoms. They did not have the routine of assigning diagnoses of functional somatic disorders, and they may tend to rate more conservatively giving diagnoses of conventionally-defined disease as reason for symptom patterns. However, since all RIFD interviewers were also SCAN trained, it is reasonable to assume that the interviewers' basic understanding of establishing diagnoses of functional somatic disorders and health anxiety was adequate for this study's purpose. Also, when SCAN is used for diagnosing at the Research Clinic for Functional Disorders and Psychosomatics, every interview is conducted following a review of the patient's medical records and self-report on symptom questionnaires; an approach largely resembling the RIFD procedure in this study. However, the SCAN interviews in this study were conducted with the SCAN interviewer having no knowledge about the participant's symptom questionnaires, medical records, or other preparatory information. The different preparatory material might also have influenced on the shown discrepancies.

4.3. Comparison with other studies

4.3.1. Feasibility and criterion validity

Other comparison studies on shorter diagnostic interviews and SCAN have been performed, but they focused on ICD-10 psychiatric diagnoses. Concerning feasibility, studies report short form interviews to be acceptable and feasible compared to SCAN (26,45,46). However, in one of the

studies, the interviewer reported suspicion about the interviewees having problems understanding the wording in some parts of the short form interview (45) contrary to our study, where unstructured interviews with the three RIFD interviewers revealed all parts of RIFD to be understandable and manageable to go through for both interviewers and interviewees. Population-based studies found measures of agreement consistent with this study when comparing the Composite International Diagnostic Interview (CIDI) (47), the Diagnostic Interview Schedule (DIS) (12), and the Clinical Interview Schedule Revised (CIS-R) (45) with SCAN ICD-10 psychiatric diagnoses.

Studies including patient samples also find results comparable with ours: One used public health doctors as interviewers when comparing CIDI and CIS-R with SCAN ICD-10 neurotic disorders given by a SCAN trained psychiatrist (48), and another compared the shortened version of SCAN with SCAN (26) obtaining very good agreement in almost all diagnostic categories.

4.3.2. Face-to-face interviews vs. telephone interviews

In all the above mentioned studies, interviews were conducted as face-to-face interviews as opposed to our study, where only SCAN was conducted face-to-face and RIFD was performed over telephone. This might have influenced the obtained agreement and raise the question if telephone interviews are just as valid as diagnostic face-to-face interviews. A review reported insufficient evidence for telephone-conducted diagnostic interviews being as valid as face-to-face diagnostic interviews (49). However, since we reported properties regarding criterion validity comparable with other studies, we assume that this issue has minor influence.

4.3.3. Studies within other medical fields

Within neurology and pain research, diagnostic research interviews have shown to be beneficial. Studies in migraine have shown similar results of interview agreement as in our study (50,51), and a headache study points out that diagnostic interviews are superior in assigning correct diagnoses when comparing to questionnaires alone (52). Also, one study showed interviews to be even more

precise and accurate when used in combination with a self-reported headache diary (53) which supports the use of symptom questionnaires before RIFD.

4.4. Strengths and limitations

This study has several strengths. First, the large sample of 1590 participants is a major strength giving high power in the comparison analyses of cases and non-cases. Second, the participants were sampled from an unbiased general population sample in contrary to patients from more selected clinical samples. Third, the study's two-phase design secured a more cost-effective and targeted procedure where only relevant participants were identified for RIFD. In this study, specific symptom scales were used in the questionnaires, but since the purpose of the questionnaires is to establish an overview of the participants' symptoms, future studies may not have to use the exact same symptom scales. Furthermore, since family physicians in general are unsure of how to diagnose and examine patients for functional somatic disorders, the two-step approach using the combined technique of symptom questionnaires and interviews may pave the way for improved diagnostics by non-specialists.

However, the results from this study also have to be seen in the light of some study limitations. First, the participation rate in RIFD was only 64.9%, but since the flow of RIFD participants increased during the recruitment period, the participation rate was more likely to be caused by the recruitment method and not the RIFD interview itself. Second, the majority (92.5%) of the RIFD decliners constituted high scores on the symptom questionnaires. Two-phase designs have the general limitation of losing some of the phase one participants in the second phase (54), and it would be reasonable to assume that these participants had a higher burden of symptoms than completers. We therefore believe this limitation to be linked to the overall study design more than to RIFD itself. Third, the workload and time spent on performing SCAN interviews and interrater

reliability tests carry important limitations in the form of small study samples causing low power to the statistical analyses. A final but important limitation is that no participants were further examined with diagnostic or paraclinical tests. Hence, from this study, we cannot conclusively determine which interview was correct in the cases of discrepancies, but it is clear that these discrepancies emerged because of different assessments of whether or not conventionally-defined disease caused the symptoms. Doing further clinical examinations would be the final step in clarifying this and getting closer to a "true" diagnosis.

5. Conclusion

Compared to SCAN, RIFD was feasible and affordable to conduct. It was a promising tool for identifying cases of functional somatic disorders and health anxiety in large epidemiological studies. A small preliminary test on some of its psychometric properties showed fair to near perfect agreement. Further studies are needed on RIFD before using it as a standard tool for assessing functional somatic disorders and health anxiety in large epidemiological studies.

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Conflicts of interest

None.

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Figure legends

Figure 1: Flowchart. Flow of participants' inclusion in the DanFunD study, procedure of establishing a stratified subsample for the Research Interview for Functional somatic Disorders (RIFD), and selection of participants for testing criterion validity and interrater reliability. Randomly selected=one tenths of all consecutive participants from the self-reported symptom questionnaires; High scores=all cases of bodily distress syndrome (3) or health anxiety (32) from the self-reported symptom questionnaires. SCAN=Schedules of Clinical Assessment in Neuropsychiatry

Tables

Table 1

	FSD N=435	HA N=99
Sex; Women vs. men, RR (95% CI)	**1.3 (1.2-1.4)**	**1.2 (1.1-1.4)**
Poor self-perceived health[a], RR (95% CI)	**2.5 (2.1-3.0)**	1.3 (0.9-1.8)
Limitations in daily activities[a], RR (95% CI)	**2.2 (1.9-2.6)**	1.0 (0.7-1.4)
Mental comorbidity, RR (95% CI)	**2.1 (1.8-2.5)**	**2.0 (1.5-2.5)**
Physical comorbidity, RR (95% CI)	**1.1 (1.0-1.1)**	1.0 (0.9-1.1)
Whiteley-7 score difference[b] (0-100) (95% CI)	**13.5 (11.3-15.7)**	**29.5 (25.4-33.5)**

Table 1: Characteristics of cases of functional somatic disorders (FSD) and health anxiety (HA) compared to non-cases. [a]Single items from the 12-item Short Form Health Survey (12). [b](32). RR=relative risk; CI=confidence interval. **Bold:** Significantly different from non-cases ($p<0.05$). Number of FSD non-cases=1150. Number of HA non-cases=1491. Total N=1590.

Table 2

	Concordance SCAN/RIFD				Prevalence	
	Both interviews negative (n) -/-	**Only RIFD positive (n)** -/+	**Only SCAN positive (n)** +/-	**Both interviews positive (n)** +/+	**SCAN** **% (95% CI)**	**RIFD** **% (95% CI)**
Functional somatic disorders	9	2	6	8	56.0 (34.9-75.6)	40.0[°] (21.1-61.3)
Health anxiety	19	1	2	3	20.0 (6.8-40.7)	16.0[°] (4.5-36.1)

Table 2: Concordance between Schedules of Clinical Assessment in Neuropsychiatry (SCAN) and the Research Interview for Functional somatic Disorders (RIFD). Functional somatic disorders: Bodily distress syndrome or functional somatic syndrome. CI=confidence interval. No significant differences in prevalences between SCAN and the RIFD interview ([°]$p=0.29$. [°]$p>0.99$). N=25

Table 3

	Observed agreement % (95% CI)	**Cohen's Kappa** (95% CI)	**Sensitivity** % (95% CI)	**Specificity** % (95% CI)	**PPV** % (95% CI)	**NPV** % (95% CI)
Functional somatic disorders	68.0 (46.5-85.1)	0.38 (-0.03-0.7)	57.1 (28.9-82.3)	81.8 (48.2-97.7)	80.0 (44.4-97.5)	60.0 (32.3-83.7)
Health anxiety	88.0 (68.8-97.5)	0.59 (0.1-0.9)	60.0 (14.7-94.7)	95.0 (75.1-99.9)	75.0 (19.4-99.4)	90.5 (69.6-98.8)

Table 3: Criterion validity of the Research Interview for Functional Somatic Disorders using Schedules of Clinical Assessment in Neuropsychiatry as gold standard. Functional somatic disorders: Bodily distress syndrome or functional somatic syndrome; PPV=positive predictive value; NPG=negative predictive value; CI=confidence interval. N=25

Table 4

Discrepancies between interviews on functional somatic disorders

Discrepancy	N participants	SCAN outcome	RIFD outcome	Notes
RIFD false-positive	2	-	+	Both interviews report symptoms but in SCAN they are stated to be caused by conventionally-defined organic disease. Hence, the participants were identified as non-case in SCAN
RIFD false-negative	2	+	-	RIFD does not report sufficient number or severity of symptoms to fulfill any criteria of functional somatic disorder. Hence, the participants were identified as non-case in RIFD
	4	+	-	RIFD does not report sufficient number or severity of symptoms to fulfill any criteria of functional somatic disorder and reported symptoms were assessed as having conventionally-defined organic disease as cause. Hence, the participants were identified as non-case in RIFD

Discrepancies between interviews on health anxiety

Discrepancy	N participants	SCAN outcome	RIFD outcome	Notes
RIFD false-positive	1	-	+	RIFD reports sufficient number and severity of symptoms enough for fulfilling criteria of health anxiety but this was not the case in SCAN
RIFD false-negative	2	+	-	RIFD does not report any symptoms. In SCAN, some mild symptoms of health anxiety are reported

Table 4: Description of participants with discrepancy in outcome between Schedules of Clinical Assessment in Neuropsychiatry (SCAN) and the Research Interview for Functional somatic Disorders (RIFD). Outcome=non-case (-) or case (+). N=25

Highlights

- RIFD assesses functional somatic disorders and health anxiety
- RIFD was feasible and affordable to perform in a large population-based study
- RIFD was well accepted by both interviewers and interviewees
- RIFD clearly identified cases with poorer health and quality of life than non-cases
- RIFD showed promising psychometric properties, but larger studies are needed

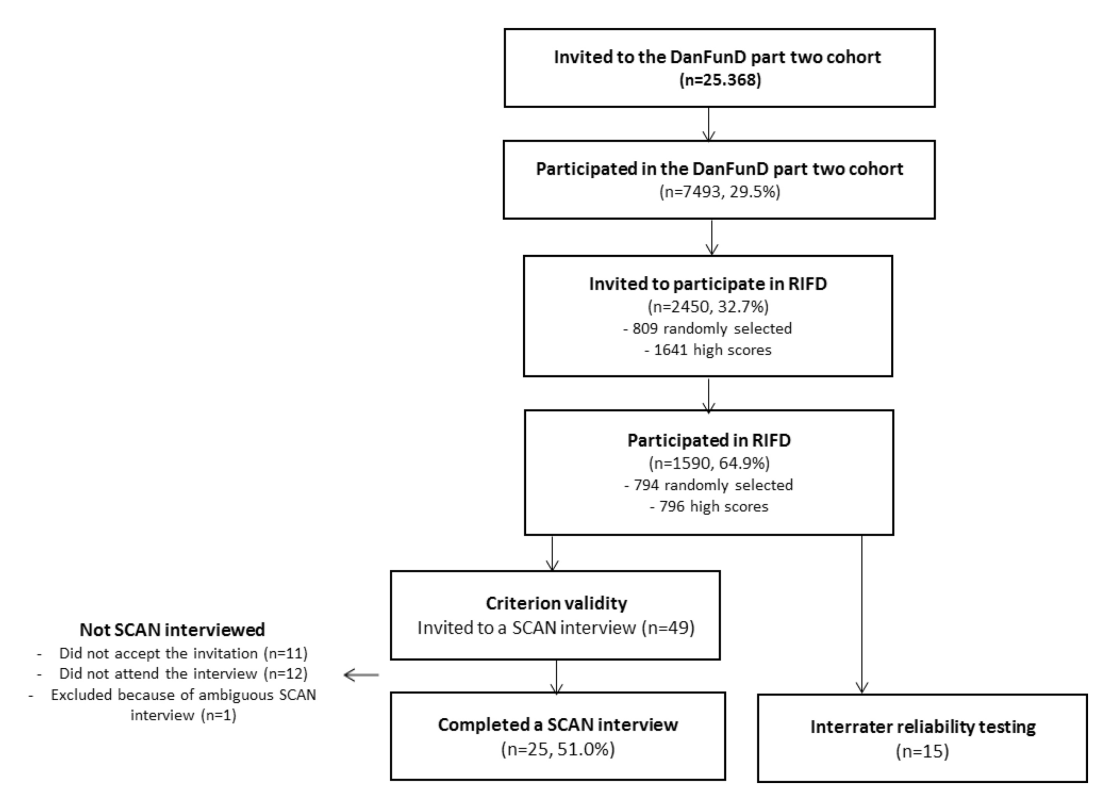
Invited to the DanFunD part two cohort
(n=25.368)
Participated in the DanFunD part two cohort
(n=7493, 29.5%)
Invited to participate in RIFD
(n=2450, 32.7%)
- 809 randomly selected
- 1641 high scores
Participated in RIFD
(n=1590, 64.9%)
- 794 randomly selected
- 796 high scores
Criterion validity
Invited to a SCAN interview (n=49)
Not SCAN interviewed
- Did not accept the invitation (n=11)
- Did not attend the interview (n=12)
- Excluded because of ambiguous SCAN interview (n=1)
Completed a SCAN interview
(n=25, 51.0%)
Interrater reliability testing
(n=15)

Figure 1