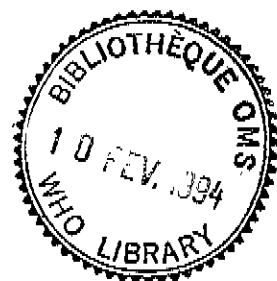


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WHO INTERNATIONAL STUDY OF
SOMATIFORM DISORDERS
STUDY PROTOCOL AND INSTRUMENTS



DIVISION OF MENTAL HEALTH

WORLD HEALTH ORGANIZATION

GENEVA

WHO INTERNATIONAL STUDY OF SOMATOFORM DISORDERS

STUDY PROTOCOL AND INSTRUMENTS

June 1993 version

The major objective of this study is an understanding of the somatic presentation of psychological disorders in different cultures. Relying on an interdisciplinary approach which draws from anthropology and linguistics as well as psychiatry and epidemiology, it will examine the cross-cultural applicability of symptoms and diagnostic criteria of Somatoform Disorders and will develop a set of diagnostic instruments for the assessment of Somatoform Disorders in different cultures. The study consists of two main phases. In the first phase, instruments for the assessment of Somatoform Disorders have been developed and are being tested for cross-cultural applicability, inter-rater and test-retest reliability and validity. In the second phase, using the instruments, the prevalence of Somatoform Disorders and their characteristics in different cultures will be assessed.



DIVISION OF MENTAL HEALTH
WORLD HEALTH ORGANIZATION
GENEVA
1994

The WHO International Study of Somatoform Disorders has been carried out by the Division of Mental Health, WHO. The responsible WHO officer is Dr A. Janca.

The plans for this study have been developed in collaboration with many experts and it is impossible to list all their names here. However, the advice and technical contributions of Dr A.C. Altamura, Institute of Psychiatry, Cagliari; Dr L. Bennett, Department of Anthropology, Memphis State University; Dr J. Burke, Department of Psychiatry, Texas A. and M. University; Dr A. Forgione, Ravizza Farmaceutici Spa., Muggio; Dr M. Isaac, National Institute of Mental Health and Neurosciences, Bangalore; Dr L. Robins, Department of Psychiatry, Washington University School of Medicine in St. Louis; Dr G. Tacchini, Department of Psychiatry, University of Milan and Dr T.B. Üstün, Division of Mental Health, WHO, have been particularly helpful. Dr N. Sartorius inspired the development of this project from its inception and has provided valuable advice in all its stages.

The study is supported by Ravizza Farmaceutici Spa., and it is a pleasure to acknowledge their donation.

The field centres collaborating investigators in Phase I of this project are: Dr S.W. Acuda, Department of Psychiatry, University of Zimbabwe, Harare; Dr A.C. Altamura, Institute of Psychiatry, Cagliari; Dr J. Burke, Department of Psychiatry, Texas A. and M. University, Temple; Dr C.R. Chandrashekar, National Institute of Mental Health and Neurosciences, Bangalore; Dr G. Tacchini, Department of Psychiatry, University of Milan, Milan and Dr C. Torres de Miranda, Department of Psychiatry, Escola Paulista de Medicina, Sao Paulo.

Three more centres will join Phase II of the project.

Further information can be obtained from Dr A. Janca, Medical Officer, Division of Mental Health, World Health Organization, CH-1211 Geneva 27, Switzerland.

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WHO INTERNATIONAL STUDY OF SOMATOFORM DISORDERS

STUDY PROTOCOL

INTRODUCTION

The development of diagnostic criteria for mental disorders has been one of the major goals of the WHO Mental Health Programme. Through the past decade the Division of Mental Health, WHO, has supported the development of *Clinical Descriptions and Diagnostic Guidelines*⁽¹⁾ and of *Diagnostic Criteria for Research of The ICD-10 Classification of Mental and Behavioural Disorders*⁽²⁾. These parts of the ICD-10 system have been extensively field-tested to assess their clinical and cultural suitability, acceptability and reliability.

A related goal of WHO has been the development of instruments for the reliable and valid assessment of mental disorders in cross-cultural studies. This goal has been expressed in the ongoing WHO/NIH Joint Project on Diagnosis and Classification of Mental Disorders, Alcohol- and Drug-Related Problems. Closely tied to the ICD-10 and related classification systems have been several new diagnostic instruments. The Composite International Diagnostic Interview (CIDI)⁽³⁾ is a member of the family of instruments developed within the WHO/NIH Joint Project, and its primary application is in epidemiological research in psychiatry⁽⁴⁾. Over the past several years CIDI was field-tested in more than 20 centres worldwide, and it was found to be acceptable and appropriate for use across cultures and to have excellent inter-rater reliability⁽⁵⁾. Other WHO instruments include the Schedule for Clinical Assessment in Neuropsychiatry (SCAN)⁽⁶⁾ and the International Personality Disorder Examination (IPDE)⁽⁷⁾. Both SCAN and IPDE have also been extensively tested and found to be applicable and reliable diagnostic tools in different cultures^(8,9).

Somatoform disorders

Psychological problems are a frequent reason for contact with health services. These disorders often appear with somatic symptoms. Among these disorders, Somatoform Disorders comprise an important part of the burden created by psychological illness in general practice. People with these disorders have a high rate of help-seeking and present with complex patterns of symptoms that defy standard medical categories. They are often given a variety of tests in an effort to explain their complaints, and frequently receive unnecessary exploratory surgery⁽¹⁰⁾.

Special difficulties arise for Somatoform Disorders in cross-cultural studies. In different cultures, patients with Somatoform Disorders may present with different somatic symptoms. The ability of subjects to distinguish psychogenic from medical symptoms may be strongly influenced by the practices of local physicians with respect to conducting biological tests and communicating their findings to their patients. Another complication

arises out of using native healers, who may believe that physical disorders have supernatural causes, and yet another from culturally supported theories for the etiology of physical disease. It is necessary to learn whether there are characteristic patterns of symptoms and course that distinguish Somatoform Disorders from physically explained symptoms independently of such cultural differences.

These problems apply especially to Undifferentiated Somatoform Disorder. This category is intended to be used for patients who do not meet the diagnostic threshold for Somatization Disorder, but for whom the presenting symptoms, severity level, co-existing disorders and prognosis are not established. The category is thought to be widely applicable in primary care settings and to apply in many different cultures, but little research has been conducted on it⁽¹¹⁾.

STUDY GOALS

The WHO International Study of Somatoform Disorders builds on two areas of work - the improvement of diagnostic criteria and the development of associated assessment instruments - by investigating the nature of Somatoform Disorders in different settings and cultures. As part of the study, a set of new assessment instruments will be developed and tested to permit future research studies on a cross-cultural basis and to provide the basis for creating diagnostic tools particularly useful to primary care physicians.

The specific goals of the study are:

- a) To test the criteria in ICD-10 and DSM-IV for Somatoform Disorders, especially Somatization Disorder and Undifferentiated Somatoform Disorder, in different cultures.
- b) To develop a set of instruments for the assessment of Somatoform Disorders and test their cross-cultural applicability, reliability and validity in different cultures.
- c) To assess rates and characteristics of Somatoform Disorders in different cultures.
- d) To develop a set of educational tools (manual, slides, videos, etc.,) for teaching physicians about the characteristics of Somatoform Disorders in different cultures and their management.

As an outcome of the study, the nature of Somatoform Disorders will be better characterized. Particularly for Undifferentiated Somatoform Disorder, the study will examine patterns of somatic symptoms, factors relevant to their development, their course, cessation and relation to other disorders such as Neurasthenia and Mixed Anxiety-Depression. In this effort, the investigation will employ a longitudinal view of the disorders.

STUDY METHODS

The study will be carried out in the following two phases.

Phase I

Phase I of the study consists of the following components:

1. *Review of concepts and existing literature*

An extensive review of literature was carried out initially, with special emphasis on the evolution of various concepts related to somatization and its current nosological status. The review also focused on areas of interest for future cross-cultural research on Somatoform Disorders. It will be published as a separate paper, a draft copy of which may be obtained from WHO.

2. *Mail questionnaire survey*

As a preliminary step, a somatic symptoms questionnaire was drafted at WHO headquarters and mailed to experts from many different cultures in the fields of psychiatry, psychology, primary care, medical anthropology and sociology. This survey was undertaken to obtain expert opinion on the ICD-10 definitions of Somatization Disorder and Undifferentiated Somatoform Disorder, the symptoms related to these conditions, and on the appropriateness of questioning on the presence of these symptoms in different cultural and health-care settings. Suggestions were also solicited for additional or culture-specific symptoms of Somatoform Disorders that should be included in their descriptions.

The results of this survey will be used to refine the study protocol and study instruments.

3. *Development of study instruments*

3.1 **Somatoform Disorders Schedule (SDS)**

The main instrument developed for the assessment of Somatoform Disorders is the Somatoform Disorders Schedule (SDS), based on the CIDI section on Somatoform Disorders. Several new questions have been added to fully operationalize the criteria for all the categories of ICD-10 and DSM-IV Somatoform Disorders, Hypochondriasis and Neurasthenia. A new section on symptom summary has been added to assess the severity, frequency, duration and variability of the symptoms, precipitating events, care-seeking pattern, effectiveness of treatment and satisfaction with care. Certain alterations have been made to the Probe Flow Chart to simplify probing of the positive answers. The SDS is highly structured and suitable for administration by lay interviewers. An earlier version of the instrument was tested on a sample of 120 inpatients in various hospital units at Milan University and was shown to have a high reliability (inter-rater reliability: kappa = .87, test-retest diagnostic reliability: kappa = .72). The draft version of the SDS is given in Appendix I.

3.2 **Screeener for Somatoform Disorders (SSD)**

The 12-item Screeener for Somatoform Disorders (SSD) has been developed to

identify patients likely to be presenting with Somatoform Disorders. The symptoms in the Screener are based on the responses and suggestions made by experts in different cultures during the Mail Questionnaire Survey. The Screener can be either self-administered or interviewer-administered in settings with illiterate or semi-literate respondents. The draft version of the Screener for Somatoform Disorders is given in Appendix II.

3.3 Somatoform Disorders Symptom Checklist

The Somatoform Disorders Symptom Checklist has been derived from the Somatoform Disorders Schedule (SDS) for use by clinicians, and basically consists of all the symptoms which appear in the SDS. In addition, the various criteria for the diagnosis of Somatoform Disorders - duration, number of symptoms, consultations and refusal to accept explanation - have also been operationalized to facilitate the clinician to arrive at an ICD-10 diagnosis. Initial trials by clinicians in a general psychiatric setting in Bangalore have shown the Checklist to be useful and applicable. The draft version of the Somatoform Disorders Symptom Checklist is given in Appendix III.

4. *Pilot test of the instruments*

The specific components of the pilot testing of the assessment instruments are as follows.

4.1 Sample size and recruitment of subjects

Each participating centre will use the Somatoform Disorders Schedule (SDS) to assess 40 patients; 20 patients from a general medical or primary care setting and 20 from a general psychiatric setting. About half of the patients will be expected to have Undifferentiated Somatoform Disorders. Some patients will be expected to have serious or persistent symptoms entirely or partly explained by a general medical condition. The Screener for Somatoform Disorders (SSD) will be administered to everyone who is contacted; those with three or more symptoms lasting for a period of three or more months will be chosen for detailed assessment using the SDS.

4.2 Interviewer-observer assessment using Somatoform Disorders Schedule

Recruits for detailed assessment will be interviewed by non-clinician (lay) interviewers using the Somatoform Disorders Schedule (SDS). One of the non-clinician interviewers will interview the patient while the other observes and rates the interview. The interviewer and observer will alternate their roles for the next respondent. Comments on every interview and specific difficulties, if any, will be noted. Reasons for discrepancy will also be recorded. A discrepancy sheet for that purpose has been developed. The Brief Disability Questionnaire, used in the WHO Collaborative Study on Psychological Problems in General Health Care, will be completed for everyone recruited for the assessment with SDS. Audiotaping of entire interviews is advisable.

4.3 Assessment by clinician

All those recruited for the study will be assessed by a clinician familiar with ICD-10 and DSM-IV within three days of the first interview, using initially the Somatoform Disorders Schedule (SDS) and later the ICD-10 Symptom Checklist⁽¹²⁾ and the Somatoform Disorders Symptom Checklist. Physical examinations and appropriate investigations, where necessary, will also be carried out. The goal of this assessment will be to examine the patient thoroughly for physical and/or psychiatric disorders. In addition to interviews and physical examinations, the clinician may also utilize medical records, results of previous investigations and information from family members.

4.4 Training

Before the beginning of the study, the instruments should be translated and back-translated. Interviewers will be trained by the chief investigator in the use of the instruments in the language of the centres. It is recommended that interviewers should have five to ten practice interviews before they start interviewing people recruited for the main sample. In addition to use of the instruments, training will focus also on the overall objectives of the study, editing and handling of data and data entry.

4.5 Data entry

Data entry will be undertaken by individual collaborating centres. A data entry programme will be produced and provided by WHO. Centres are also required to send copies of the raw data to WHO.

Phase II

1. *Field work*

During Phase II a general study of Somatoform Disorders, with particular emphasis on Undifferentiated Somatoform Disorder, will be undertaken in eight to ten centres. Each centre will interview at least 100 primary health care patients using the SDS, revised as necessary after the pilot test in Phase I. The exact number of subjects to be interviewed will be determined by power analysis using the expected rates of disorders based on Phase I experience. The efficacy of the screening procedure being tested in the pilot phase will be reviewed to determine its effectiveness in identifying people with somatoform disorders.

The different cultures represented by the centres will be contrasted with respect to symptom patterns, course, how symptoms are treated, which professionals or which types of healer take responsibility for these patients, types of care commonly offered and the outcome of this care. The cultures will also be compared with respect to typical age of onset, course of the disorder in terms of the succession of specific symptoms, speed of development and periods of remission. Analysis of symptom profiles and their relation to key sociodemographic variables will be undertaken, as well as analysis of frequency, rates and other epidemiological indicators. The data will also be compared with relevant data from prior WHO studies, such as the WHO Collaborative Study on Pathways to Psychiatric Care

and the WHO Collaborative Study on Psychological Problems in General Health Care.

Medical records will be collected and abstracted to document each subject's medical experience and interactions with clinicians. Physicians will be asked their opinion about each subject's diagnosis and the possible psychiatric basis of symptoms. All data will be entered into the data entry programme and scored. Hospital records and other sources of data will be used to estimate the prevalence and other epidemiological issues in relation to this group of disorders.

2. *Data analysis*

Each centre will enter its own data using the data entry programme developed in the preparatory phase of the study. Each centre will retain its own data, but will send a copy of the data disk to WHO Headquarters in Geneva so that cross-site analyses can be carried out centrally. WHO will be responsible for establishing the general approaches and methods of data analysis which will be disseminated to the sites to advance single site analytic work.

The different cultures represented by the centres will be contrasted with respect to the symptom patterns of Undifferentiated Somatoform Disorder, the possibility of distinguishing it from medical illnesses, its course, how it is treated, which professionals take responsibility for these patients, types of care commonly offered and the outcome of this care. The cultures will also be compared with respect to typical age of onset, the course of the disorder in terms of the succession of specific symptoms, speed of development and periods of remission.

Statistical analyses will use computer packages designed for qualitative and quantitative analysis. Analyses of symptom profiles and their relation to key socio-demographic variables will be undertaken, as well as analysis of frequency, rates and other epidemiological indicators.

3. *Development of educational tools*

As an outcome of the study, a set of tools for teaching purposes will be developed. It will comprise a manual, slides and videos about the characteristics of Somatoform Disorders in different cultures, as well as guidelines for their management. The teaching materials will also include the training curriculum and training materials for the administration of the assessment instruments developed within the framework of the study. Supplementary funds might be needed for this exercise.

SELECTION OF CENTRES

The following criteria will be used for selecting the centres:

- (i) Centres will be chosen from cultures that have been found to differ in their expression of psychological distress and provision of mental health care.
- (ii) The centres should between them cover most major languages, to ensure that the instruments can be used, after adaptation, all over the world.

- (iii) The centres should have had previous experience of participation in international research projects.
- (iv) The centres should have an interest in and experience of the application of CIDI and similar instruments.

STAFFING

The Head Office (WHO) will have a principal investigator/project coordinator. A secretary will provide administrative services to the project, communicate with the centres, receive and organize the protocols, prepare interviews, reports and publications. A biostatistician will be needed for Phase I and Phase II data analysis.

An expert advisory group will be established to provide expertise in various outstanding issues in the course of the study.

Each participating centre will have a chief centre investigator, a project coordinator, translators and at least two trained interviewers.

EQUIPMENT

Each centre will be expected to have a personal computer for data entry and a fax machine for rapid communications. Audiotaping should be available for recording and reviewing interviews to maintain high standards of consistency.

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Appendix I
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SOMATOFORM DISORDERS SCHEDULE

(SDS)

Version 1.1

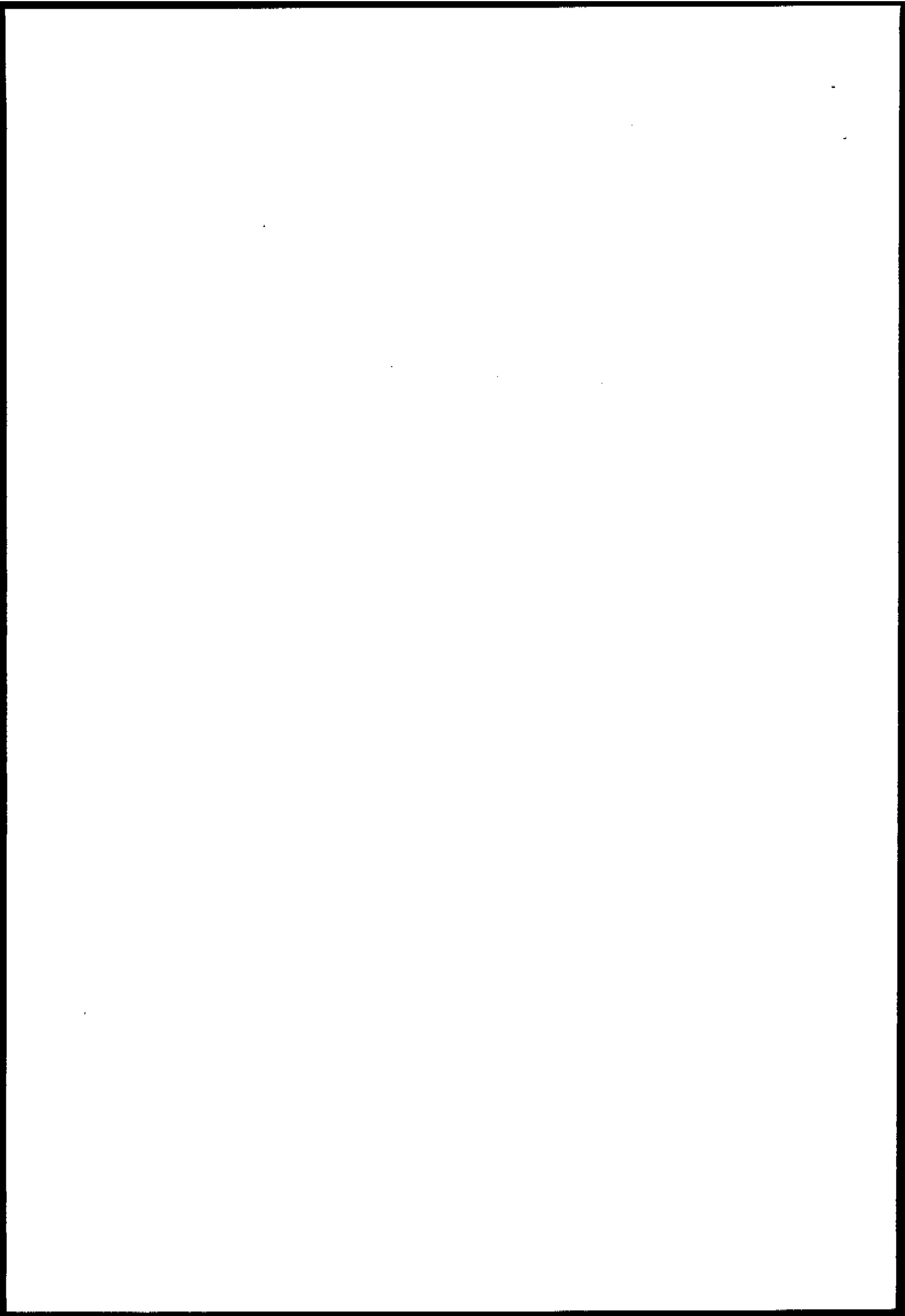
This instrument is based on the
CIDI 1.1 section on somatoform disorders
and has been developed for the
WHO International Study of Somatoform Disorders
by Dr G. Tacchini, Dr A. Janca and Dr M. Isaac.

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SOMPN3R B5 Have you ever had chest pains, or a feeling of pressure on
SOM3RB14 your chest?
PPICDA MD: _____ OTHER: _____ PRB: 1 5
SOMICDD8 2 4
SADICDC1

SOMPN3R B6 Have you ever had a lot of trouble with headaches?
PPICDA MD: _____ OTHER: _____
NAICDB3
IF ALL PROBES IN PFC BOX A ARE NEGATIVE
EXCEPT FOR MEDICATION, ASK: Did you ever take
nonprescription medication three or more times in a single
week for your headaches?
IF NO, ASK: Did you ever take prescription medication for
your headaches? PRB: 1 5
IF NO TO BOTH, CODE PRB 2. 2 4

SOM3RB32 B7 FOR WOMEN ONLY: Have you ever had a lot of trouble
SOMPN3R with excessively painful menstrual periods?
PPICDA
SOICDD10 IF ALL PROBES IN PFC BOX A ARE NEGATIVE
EXCEPT MEDICATION, ASK: Did you take prescription
medication? IF YES, CONTINUE PROBING. IF NO,
CODE PRB 2.
MD: _____ OTHER: _____ PRB: 1 5
2 4

SOM3RB10 B8 Have you ever had pain when you urinated (that is, passed
SOMPN3R your water)?
PPICDA MD: _____ OTHER: _____ PRB: 1 5
SADICDC6 2 4

SOMPN3R B9 Have you ever had a period of 24 hours or more when you
SOM3RB27 were completely unable to urinate (or pass water), or had
SOMICDD9 great difficulty urinating (other than after [childbirth] or
surgery)?
MD: _____ OTHER: _____ PRB: 1 5
4

SOM3RB28 B10 Have you ever had a burning pain around your private
SOMPN3R parts?
SOMICDD10 IF PAIN ONLY DURING URINATION OR
PPICDA DURING INTERCOURSE, CODE PRB 1.
MD: _____ OTHER: _____ PRB: 1 5
2 4

SOM3RB11 B11 Have you ever had pain anywhere else, other than in the
SOMP3R places we've already talked about?
PPICDA

Where ? _____

IF VOLUNTEERS PAIN ONLY IN SITES MENTIONED
IN B1-B10 OR DURING INTERCOURSE, CODE PRB 1.

MD: _____ OTHER: _____

PRB: 1 2 4 5

IF NO PRB 5 WAS CODED IN B1-B11, SKIP TO B15.

SOMP3RA B12 Have there ever been 6 months or more in your life when
PPICDA most of time you were bothered a great deal by (LIST
PAINS CODED 5 IN B1-B11)?

NO 1
YES 5

SOMP3RB B13 Did these pains keep you from working or seeing friends or
relatives for 6 months or more?

NO 1
YES 5

B14 ONS/REC: When was the (first/last) time that you were
bothered a great deal by the pain(s)?

ONS: 1 2 3 4 5 6
AGE ONS: _____/_____
REC: 1 2 3 4 5 6
AGE REC: _____/_____

SOM3RB1 B15 Have you ever had a lot of trouble with vomiting (when
SOMICDD5 you were not pregnant), or with regurgitation of food?

MD: _____ OTHER: _____

PRB: 1 2 4 5

SOM3RB35 IF R IS MALE, SKIP TO B17.
SOMICDD5

B16 During any pregnancy, did you vomit all through the
pregnancy? IF NEVER PREGNANT, CODE PRB 1 AND
SKIP TO B17. IF CODED 5, SKIP TO B17.

PRB: 1 5

A. Were you ever hospitalized during a pregnancy
because of vomiting?

PRB: 1 5

SOM3RB3 B17 Have you ever had a lot of trouble with nausea, that is,
SOMICDD5 feeling sick to your stomach but not actually vomiting?
MOTION SICKNESS IS COUNTED AS A PHYSICAL
CONDITION.

MD: _____ OTHER: _____

PRB: 1 2 4 5

SOM3RB5
SOMICDD6
SADICDC5

B18 Have you ever had a lot of problems with loose bowels or diarrhoea or overly frequent bowel movements?

MD: _____ OTHER: _____

PRB: 1 2 4 5

SOM3RB4
SOMICDD3

B19 Have you ever had a lot of trouble with excessive gas or bloating of your stomach or abdomen?

MD: _____ OTHER: _____

PRB: 1 2 4 5

SADICDC7

B20 Have you ever had a lot of trouble with belching or hiccups?

MD: _____ OTHER: _____

PRB: 1 2 4 5

SADICDB5

B21 Have you ever had a lot of trouble with churning, "butterflies" or discomfort in your stomach or abdomen?

MD: _____ OTHER: _____

PRB: 1 2 4 5

SOM3RB6

B22 Have you ever found there were different kinds of foods that you could not eat because they made you ill?

MD: _____ OTHER: _____

PRB: 1 4 5

SOM3RB22
DISICDG1
DISICDB6

B23 Have you ever been blind in one or both eyes when you were unable to see anything for a few seconds or more?

MD: _____ OTHER: _____

PRB: 1 4 5

SOM3RB21
DISICDA
DISICDG1
DISICDB6

B24 Has your vision ever been blurred, when it was not just due to needing glasses or changing glasses?

MD: _____ OTHER: _____

PRB: 1 2 4 5

SOM3RB19
DISICDA
DISICDG1
DISICDB6

B25 Have you ever been deaf, when you completely lost your hearing for a period of time?

MD: _____ OTHER: _____

PRB: 1 4 5

B26 Have you ever had a lot of trouble with ringing and buzzing (or screeching) in your ears or head?

MD: _____ OTHER: _____

PRB: 1 2 4 5

B35 Have you ever had spells or attacks lasting at least a few minutes when your whole body or parts of your body shook a lot, when you were not unconscious?

MD: _____ OTHER: _____

PRB: 1 2 3 4 5

SOM3RB16
DISICDA

B36 Have you ever had a period of amnesia - that is, a period of several hours or days where you could not remember anything afterwards about what happened during that time?

MD: _____ OTHER: _____

PRB: 1 2 3 4 5

IF ANY PRB 5 WAS CODED IN B15-B36, ASK B37. OTHERWISE SKIP TO B38.

B37 ONS/REC: When was the (first/last) time you were bothered a lot by (MENTION THE SYMPTOMS CODED PRB 5 IN B15-B36)?

ONS: 1 2 3 4 5 6
AGE ONS: _____/_____
REC: 1 2 3 4 5 6
AGE REC: _____/_____

SOM3RB20

B38 Have you ever had problems with double vision?

MD: _____ OTHER: _____

PRB: 1 2 3 4 5

SOM3RB12
SOMICDD7
SADICDC2

B39 Have you ever had shortness of breath when you had not been exerting yourself ?

MD: _____ OTHER: _____

PRB: 1 2 3 4 5

SADICDC2

B40 Have you ever had periods of heavy and fast breathing when you had not been exerting yourself?

MD: _____ OTHER: _____

PRB: 1 2 3 4 5

SOM3RB13

B41 Has your heart ever beaten so hard that you could feel it pound in your chest?

IF NO, CODE PRB 1. IF YES, ASK A.

PRB: 1 2 3 4 5

A. Has that happened only when you were exerting yourself or at other times too?

IF ONLY ON EXERTION, CODE PRB 1.
IF OTHER TIMES, CONTINUE PROBING.

MD: _____ OTHER: _____

- SOM3RB15
NAICDB2 B42 Have you ever been bothered by **dizziness or lightheadedness?**
MD: _____ OTHER: _____ PRB: 1 2 4 5
- SOM3RB26 B43 Have you ever been bothered by periods of **weakness**, that is, when you could not lift or move things you could normally lift or move?
MD: _____ OTHER: _____ PRB: 1 2 4 5
- SOMICDD12 B44 Have you ever been bothered a lot by **blotchiness or discoloration of the skin?**
MD: _____ OTHER: _____ PRB: 1 2 4 5
- SADICDB2 B45 Have you ever been bothered a lot by **hot or cold sweats?**
MD: _____ OTHER: _____ PRB: 1 2 4 5
- SADICDB4 B46 Have you ever been bothered a lot by **flushing or blushing?**
MD: _____ OTHER: _____ PRB: 1 2 4 5
- B47 Have you ever been bothered a lot by **feelings of heaviness or lightness** in some part of your body ?
MD: _____ OTHER: _____ PRB: 1 2 4 5
- SOMICDD4 B48 Did you ever have a lot of trouble with a **bad taste in your mouth** or an excessively coated tongue?
MD: _____ OTHER: _____ PRB: 1 2 4 5
- SADICDB3 B49 Did you ever have a lot of trouble with a **dry mouth?**
MD: _____ OTHER: _____ PRB: 1 2 4 5
- SOMICDD9
SADICDC6 B50 Did having to **urinate too frequently** ever cause you a lot of trouble?
MD: _____ OTHER: _____ PRB: 1 2 4 5

SOM3RB29 B59 Now I'm going to ask you about your sexual experience. In general has your sex life been important to you, or have you felt you could have got along as well without sex?

IMPORTANT 1
 COULD GET ALONG WITHOUT IT 5
 NO SEXUAL EXPERIENCE (SKIP TO B64) 8
 REFUSES TO ANSWER (SKIP TO B64) 9

SOM3RB30 B60 Has having sexual relations ever been physically painful for you?

MD: _____ OTHER: _____

PRB: 1 2 4 5

B61 Has there been a period of several months in your life when having sex was not pleasurable for you (even when it was not painful)?

MD: _____ OTHER: _____

PRB: 1 2 4 5

SOM3RB31 B62 Have you had any other kind of sexual difficulties (FOR MEN, such as a period of two months or more when you had trouble having an erection or lost semen while urinating)?

MD: _____ OTHER: _____

PRB: 1 2 4 5

IF NO 5 CODED IN B60-B62, SKIP TO C1.

B63 ONS/REC: When was the (first/last) time you had (that/any of those) sexual difficulties?

ONS: 1 2 3 4 5 6
 AGE ONS: _____/_____
 REC: 1 2 3 4 5 6
 AGE REC: _____/_____

SOM3RA B64 Has your physical health been pretty good or have you been sickly for the majority of your life?

ENTER ONLY ONE CODE.

PRETTY GOOD MOST OF LIFE 1
 EXPLAINED BY SINGLE LONG-TERM ILLNESS . 4
 SICKLY MOST OF LIFE . 5

SOMICDC B65 You have talked to doctors about several of these problems, such as (MENTION SOME PRB 5's, SINCE B1, WITH ENTRY ON MD LINE). Do you feel your doctor examined and handled your problems well, or were you dissatisfied with the way your problems were handled?

HANDLED WELL 1
 DISSATISFIED 5

SOMICDC B66 Did you often disagree with your doctor's diagnosis, or with what he told you to do for these problems? NO 1
YES 5

B67 What do you think is the cause of these SX?

RECORD: _____

HYPOCHONDRIASIS

HYICDA C1 In the last twelve months, was there a period of six months or more when you worried about having a serious physical illness or deformity most of the time? NO . . (SKIP TO D1) . 1
YES 5

ASK BEFORE PROBING:

A.What illness or deformity were you worried about? PRB: 1 5
ILLNESS _____ 2 4
SX = your worry about having (ILLNESS/DEFORMITY).
IF NOT PHYSICAL ILLNESS OR DEFORMITY, OR IF
THREE OR MORE PHYSICAL ILLNESSES,
CODE PRB 1.

MD: _____ OTHER: _____

C2 ONS/REC: When was the (first/last) time that you worried a lot about (ILLNESS OR DEFORMITY)? ONS: 1 2 3 4 5 6
AGE ONS: _____/_____
REC: 1 2 3 4 5 6
AGE REC: _____/_____

HYICDB C3 Did this worry about having (ILLNESS OR DEFORMITY) interfere with your life during that period (of six months)? NO 1
YES 5

HYICDB C4 Did you see your doctor several times or go to several doctors because of your worry about having (ILLNESS OR DEFORMITY)? NO 1
YES 5

HYICDB C5 Did you have several diagnostic tests or examinations to see if you had (ILLNESS OR DEFORMITY)? NO 1
YES 5

HYICDC	C6	Do you feel that your doctor(s) examined and handled your illness well or were you dissatisfied with the way it was examined or handled ?	HANDLED WELL . . . 1 DISSATISFIED 5
--------	----	---	--

HYICDC	C7	Did you often think that your doctors were mistaken about the cause or diagnosis of your illness, or what should be done about it?	NO 1 SOMETIMES 2 YES 5
--------	----	--	--

NEURASTHENIA

SADICDC3 NAICDA2	D1	Have there ever been periods when you felt tired all the time? MD: _____ OTHER: _____	PRB: 1 5 2 4
---------------------	----	--	--

NAICDA1	D2	Have you ever got easily tired (worn out, weak) while performing everyday tasks? MD: _____ OTHER: _____	PRB: 1 5 2 4
---------	----	--	--

NAICDA2	D3	Has even minimal physical effort ever caused you exhaustion? MD: _____ OTHER: _____	PRB: 1 5 2 4
---------	----	--	--

IF NO 5 CODED IN D1-D3, SKIP TO E1

NAICDC	D4	Have you ever found it difficult to recover from these periods of fatigue or exhaustion when you rested?	NO 1 YES 5
--------	----	--	-----------------------------------

NAICDB4	D5	During these periods of fatigue or exhaustion, did you also have trouble falling asleep, staying asleep or waking up too early?	NO 1 YES 5
---------	----	---	-----------------------------------

NAICDB6	D6	During these periods of fatigue or exhaustion, were you also more impatient or more irritable than usual?	NO 1 YES 5
---------	----	---	-----------------------------------

NAICDB5	D7	During these periods of fatigue or exhaustion, were you also unable to relax?	NO 1 YES 5
---------	----	---	-----------------------------------

COMORBIDITY

E1		NO	YES
	Now I'd like to ask you about some other problems you may have had. Have you ever had:		
PAN	1. Spells or attacks when all of a sudden you felt frightened, anxious or very uneasy in situations when most people would not be afraid or anxious?	1	5
GAD	2. Periods of a month or more when most of the time you felt tense, worried and anxious?	1	5
PHOB	3. Strong and unreasonable fears of certain things or situations in which most people would not be afraid?	1	5
DEP	4. Two weeks or more when nearly every day you felt sad, blue or depressed?	1	5
MAN	5. A period of two days when you were so happy or excited that you got into trouble, or your family or friends worried about it, or a doctor said you were manic?	1	5
SCH	6. An experience of seeing or hearing something or someone that others who were present could not see or hear, or having beliefs other people found strange?	1	5
E2			
You mentioned earlier that you had (LIST ALL PRB 5's IN B1-D6). Did these symptoms occur only when you had (LIST ALL 5's CODED IN E1)?		NO	1
		YES	5

SYMPTOM SUMMARY

F1 You have mentioned that you had (LIST ALL RPB 5's IN B1-D6). I would like to ask you some more questions about these problems.

SEV F2 Which three problems were the most severe?
(RECORD IN ORDER OF SEVERITY)

1. _____

2. _____

3. _____

FREQ F3 Which three problems were the most frequent?
(RECORD IN ORDER OF FREQUENCY)

1. _____

2. _____

3. _____

DUR F4 Which three problems were the most long lasting?
(RECORD IN ORDER OF DURATION)

1. _____

2. _____

3. _____

VAR F5 Have these problems changed over the time or stayed pretty
much the same? SAME 1
CHANGED 5

EVENT F6 Were any of these problems related to some terrible or
shocking experience or any other important event? NO 1
YES 5

IF YES, RECORD EVENT: _____

CARE F7 Have you consulted someone about any of these problems? NO . (SKIP TO F16) . 1
YES 5

F8 Have you consulted any of the following professionals?
(READ AND CIRCLE EACH YES)

Nurse 1

General practitioner 2

Psychiatrist 3

Other specialist 4

Psychologist 5

Pharmacist 6

Traditional healer 7

Religious healer 8

Other (SPECIFY) _____ 9

F9 How frequently have you consulted these people? Was it:
(READ AND CIRCLE ONLY ONE CATEGORY)

- once a week? 1
- once a month? 2
- once in six months? 3
- once a year? 4

F10 How many times have you consulted these people? # OF TIMES: /

F11 ONS/REC: When was the (first/last) time you saw someone about any of these problems?

ONS: 1 2 3 4 5 6
AGE ONS: /
REC: 1 2 3 4 5 6
AGE REC: /

F12 How frequently have you undergone tests, x-rays or investigations? Was it:
(READ AND CIRCLE ONLY ONE CATEGORY)

- once a week? 1
- once a month? 2
- once in six months? 3
- once a year? 4

TREAT

F13 Which kinds of treatment have you been provided with?
Was it:
(READ AND CIRCLE EACH YES)

- Medicine(s) 1
IF YES: Which one(s)? SPECIFY (IF KNOWN) _____

- Surgery 2
- Psychotherapy or counselling 3
- Acupuncture 4
- Other alternative treatment 5
- Ritual cure (e.g., talisman) 6
- Traditional healing 7
- No treatment 8
- Does not know 9
- Other treatment (SPECIFY) _____

F14 Was the effect of the treatment:
(READ AND CIRCLE ONLY ONE CATEGORY)

- complete improvement or recovery? 1
- partial improvement? 2
- temporary relief? 3
- worsening? 4
- no change? 5

F15 Were you satisfied with the way your symptoms were managed? NO 1
YES 2

F16 As you have seen, I have tried to ask you about many different kinds of problems that people might have. But of course everyone is different, and I might have skipped something that has been important to you.

Have you had any problems I should have covered, but didn't?

RECORD VERBATIM: _____

ENTER TIME:

HR ___/___ MIN ___/___

ASK QUESTION

NO → CODE PRB 1

YES → (1 5) → CODE PRB 5

Did you tell a doctor* about (SX)?

YES
NO

(12 5) → CODE PRB 5

(NO "2") → GO TO BOX B

Did you tell any other professional** about (SX)?
Did you take medication more than once for (SX)?
Did (SX) interfere with your life or activities a lot?

ALL NO → CODE PRB 2
FIRST YES →

Was (SX) ever the result of a physical illness or injury?

YES
NO

CODE PRB 5

D

When you told the doctor, what was the diagnosis? [What did he say was causing (SX)?]

- NERVES STRESS ANXIETY DEPRESSION MENTAL ILLNESS
RECORD DX AND CODE PRB 5
- MEDICATION DRUGS ALCOHOL
- PHYSICAL ILLNESS/ INJURY
- NO DEFINITE DIAGNOSIS

Did he find anything abnormal when he examined you or took tests or x-rays?

NO. NO EXAM. DK → RECORD DK AND CODE PRB 5
YES →

Was (SX) always the result of taking medication, drugs or alcohol?
NO → CODE PRB 5
YES → CODE PRB 4

Was (SX) always the result of a physical illness or injury (such as)?
YES → RECORD ILL./INJ AND CODE PRB 4
NO → CODE PRB 5

* Doctor includes psychiatrists, other medical doctors and osteopaths.
** Other professionals includes psychologists, social workers, counsellors, nurses, clergy, dentists, chiropractors, healers and podiatrists.

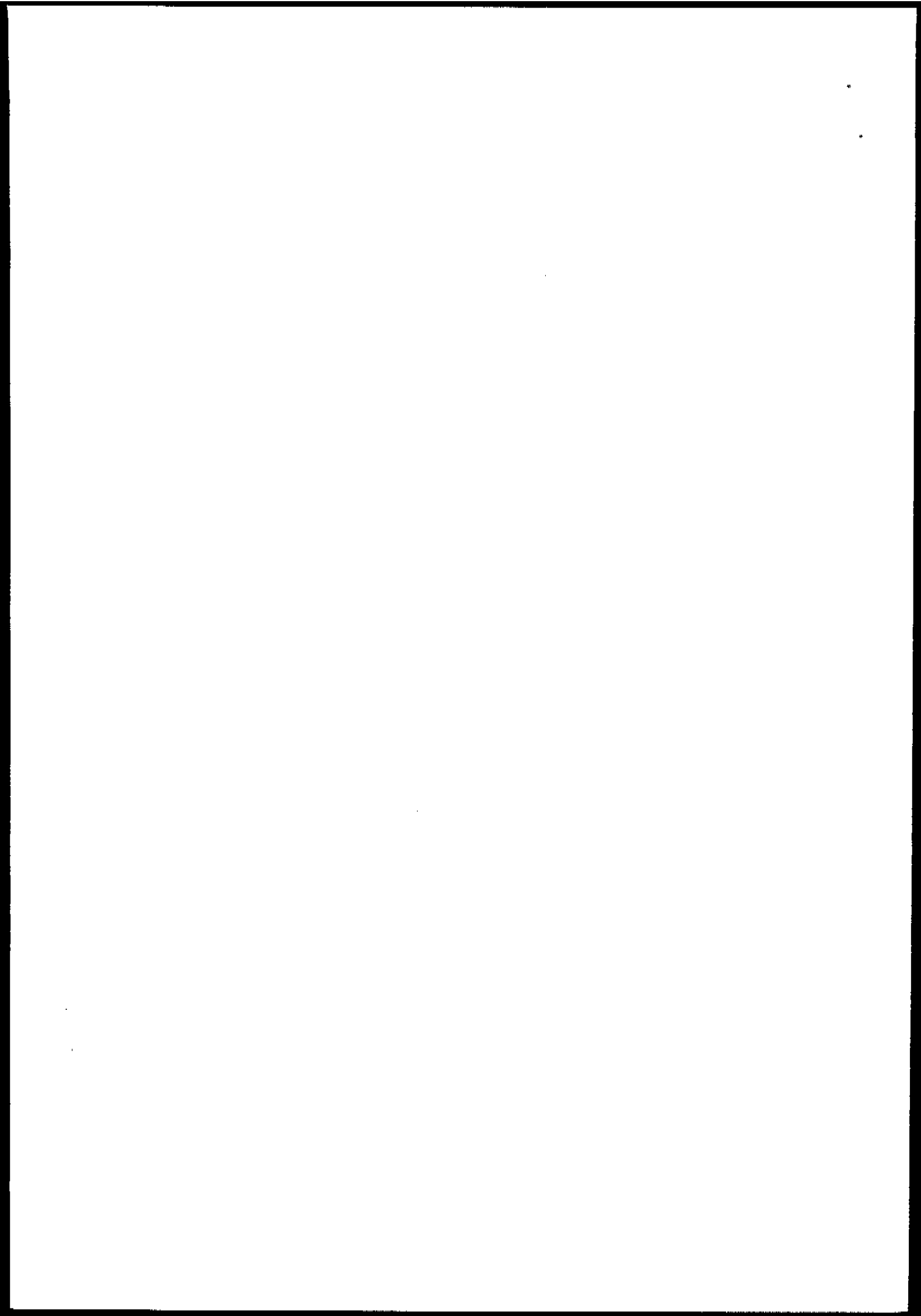
ONS/REC QUESTIONS

A. When was the (first/last) time You had (SX)?

IF DK, ASK BEFORE CODING: Was it in the last 12 months?

ONS/REC CODES:

- 1 = within last 2 weeks
- 2 = 2 weeks to less than 1 month ago
- 3 = 1 month to less than 6 months ago
- 4 = 6 months to less than 1 year ago
- 5 = In the last 12 months, DK WHEN
- 6 = more than 1 year ago. ASK ONS/AGE: How old were you the (first/last) time you had (SX)?





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Appendix II
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SOMATIFORM DISORDERS

SYMPTOM CHECKLIST

Version 1.0

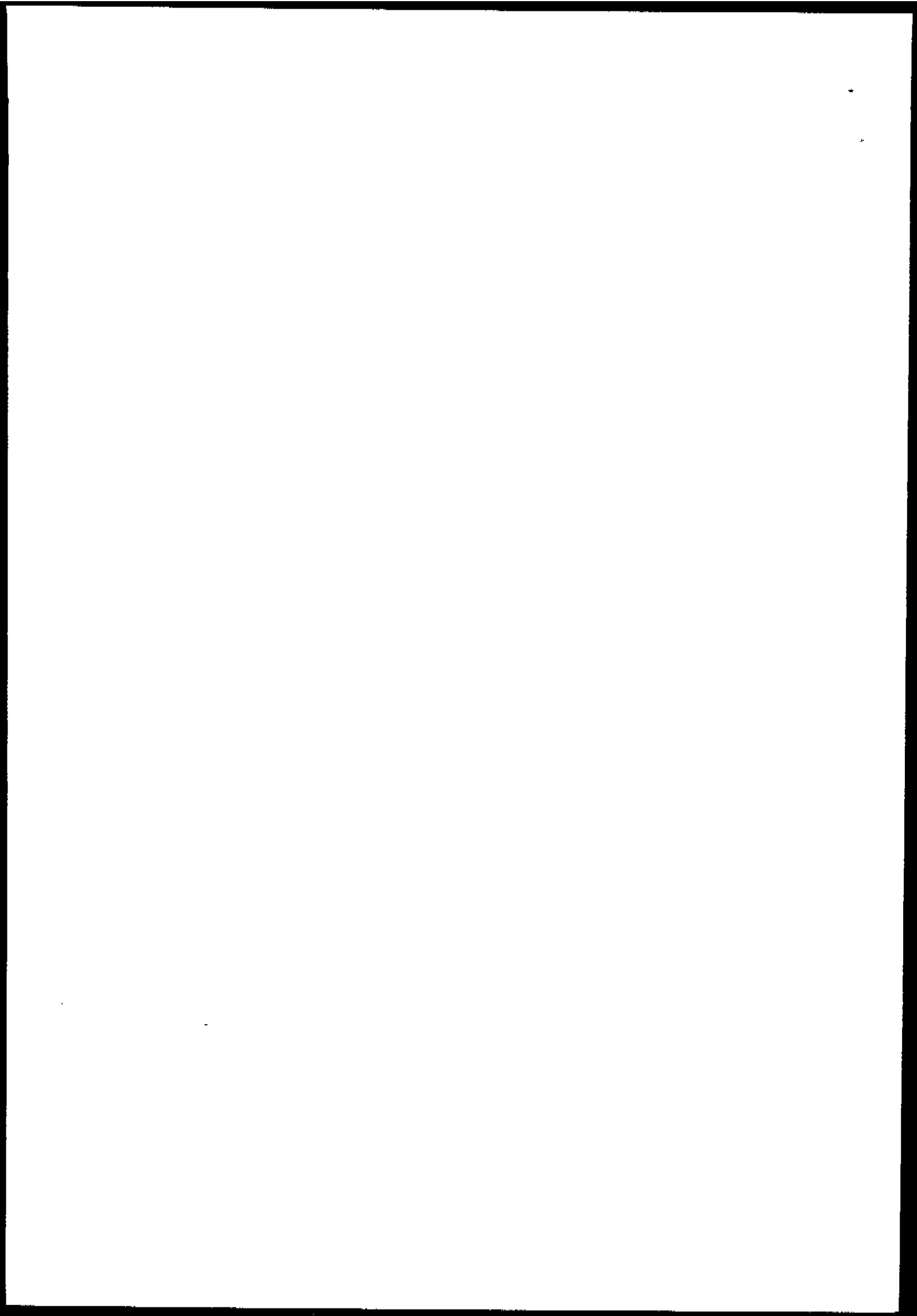
This instrument has been developed for the
WHO International Study of Somatoform Disorders
by Dr A. Janca, Dr M. Isaac and Dr G. Tacchini.

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CENTRE: _____

CODE: ____/____

INTERVIEWER'S NAME: _____

INTERVIEWER'S ID CODE: ____/____

RESPONDENT'S ID CODE: ____/____/____

DATE OF ASSESSMENT: ____/____/____/____/____

A. ASSESS AND CODE THE FOLLOWING SYMPTOMS:

NO YES*

(*YES = present and not due to physical disorder or condition, e.g., pregnancy)

1.	abdominal or belly pain	1	5
2.	back pain	1	5
3.	pains in the joints	1	5
4.	pains in the arms or legs	1	5
5.	chest pains	1	5
6.	headaches	1	5
7.	excessively painful menstrual periods	1	5
8.	pain when urinating	1	5
9.	inability to urinate	1	5
10.	burning pain around private parts	1	5
11.	vomiting or regurgitation of food	1	5
12.	vomiting throughout pregnancy	1	5
13.	nausea	1	5
14.	loose bowels or diarrhoea	1	5
15.	excessive gas or feeling bloated	1	5
16.	belching or hiccups	1	5
17.	churning, "butterflies" or discomfort in abdomen	1	5
18.	intolerance of several different foods	1	5

NO YES*

(*YES = present and not due to physical disorder or condition, e.g., pregnancy)

19.	blindness	1	5
20.	blurred vision	1	5
21.	deafness	1	5
22.	ringing and buzzing (or screeching) in ears or head	1	5
23.	trouble walking	1	5
24.	loss of feeling in arms or legs	1	5
25.	crawling or creeping sensations	1	5
26.	paralysis	1	5
27.	loss of voice	1	5
28.	seizure	1	5
29.	fainting	1	5
30.	unconsciousness	1	5
31.	spells or attacks of body shaking without unconsciousness	1	5
32.	amnesia	1	5
33.	double vision	1	5
34.	shortness of breath without exertion(ing)	1	5
35.	heavy and fast breathing	1	5
36.	heart beating hard or palpitations	1	5
37.	dizziness or lightheadedness	1	5
38.	weakness	1	5
39.	blotchiness or discoloration of skin	1	5
40.	hot or cold sweats	1	5
41.	flushing or blushing	1	5
42.	feelings of heaviness or lightness in head or body	1	5
43.	bad taste in mouth or coated tongue	1	5
44.	dry mouth	1	5
45.	frequent urination or dysuria	1	5

NO YES*

(*YES = present and not due to physical disorder or condition, e.g., pregnancy)

46.	numbness or tingling sensations	1	5
47.	lump in throat	1	5
48.	irregular menstrual periods	1	5
49.	excessive menstrual bleeding	1	5
50.	unusual or copious vaginal discharge	1	5
51.	painful sexual relations	1	5
52.	unpleasurable sex	1	5
53.	sexual difficulties	1	5
54.	tiredness all the time	1	5
55.	easily tired (worn out, weak)	1	5
56.	exhaustion caused by minimal physical effort	1	5
57.	inability to relax	1	5
58.	difficulty in recovering from exhaustion	1	5
59.	trouble in falling asleep, staying asleep or waking up too early	1	5
60.	more impatient or more irritable (than usual)	1	5

NO YES

B. IS THE TOTAL NUMBER OF POSITIVE SYMPTOMS:

1.	six or more from at least two symptom groups ¹ ?	1	5
2.	three or more (two autonomic and one other) ² ?	1	5
3.	at least one of the symptoms ³ plus A55 or A56?	1	5

C. HAVE THE SYMPTOMS OR THE SYNDROME PERSISTED FOR AT LEAST (code only one):

1.	three months ³ ?	1	5
2.	six months ⁴ ?	1	5
3.	two years ¹ ?	1	5

	NO	YES
D. CAN POSITIVE SYMPTOMS BE EXPLAINED BY ANY PHYSICAL DISORDER(S)?	1	5
E. HAVE THE SYMPTOMS CAUSED PERSISTENT DISTRESS AND LEAD TO THREE OR MORE CONSULTATIONS OR SETS OF INVESTIGATIONS?	1	5
F. HAS THERE BEEN PERSISTENT REFUSAL TO ACCEPT REASSURANCE THAT THERE IS NO PHYSICAL CAUSE FOR THE PHYSICAL SYMPTOMS?	1	5
G. ASSESS AND CODE ICD-10 DIAGNOSIS:		
1. Somatization Disorder	1	5
2. Undifferentiated Somatoform Disorder	1	5
3. Somatoform Autonomic Dysfunction	1	5
4. Persistent Somatoform Pain Disorder	1	5
5. Neurasthenia	1	5

H. RECORD YOUR CLINICAL DIAGNOSIS (IF DIFFERENT FROM ICD-10):

-
- 1 **Somatization Disorder:**
 Gastrointestinal symptoms: A1, A11, A13, A14, A15, A43
 Cardiovascular symptoms: A35, A5
 Genitourinary symptoms: A5, A34
 Skin and pain symptoms: A3, A4, A39, A46
 - 2 **Somatoform Autonomic Dysfunction:**
 Autonomic symptoms: A17, A36, A40, A41, A44
 Other symptoms: A5, A7, A14, A15, A16, A17, A45, A34, A35, A55, A56
 - 3 **Neurasthenia:**
 A4, A6, A37, A57, A58, A59
 - 4 **Persistent Somatoform Pain Disorder**
-



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Appendix III
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SCREENER FOR SOMATOFORM DISORDERS (SSD)

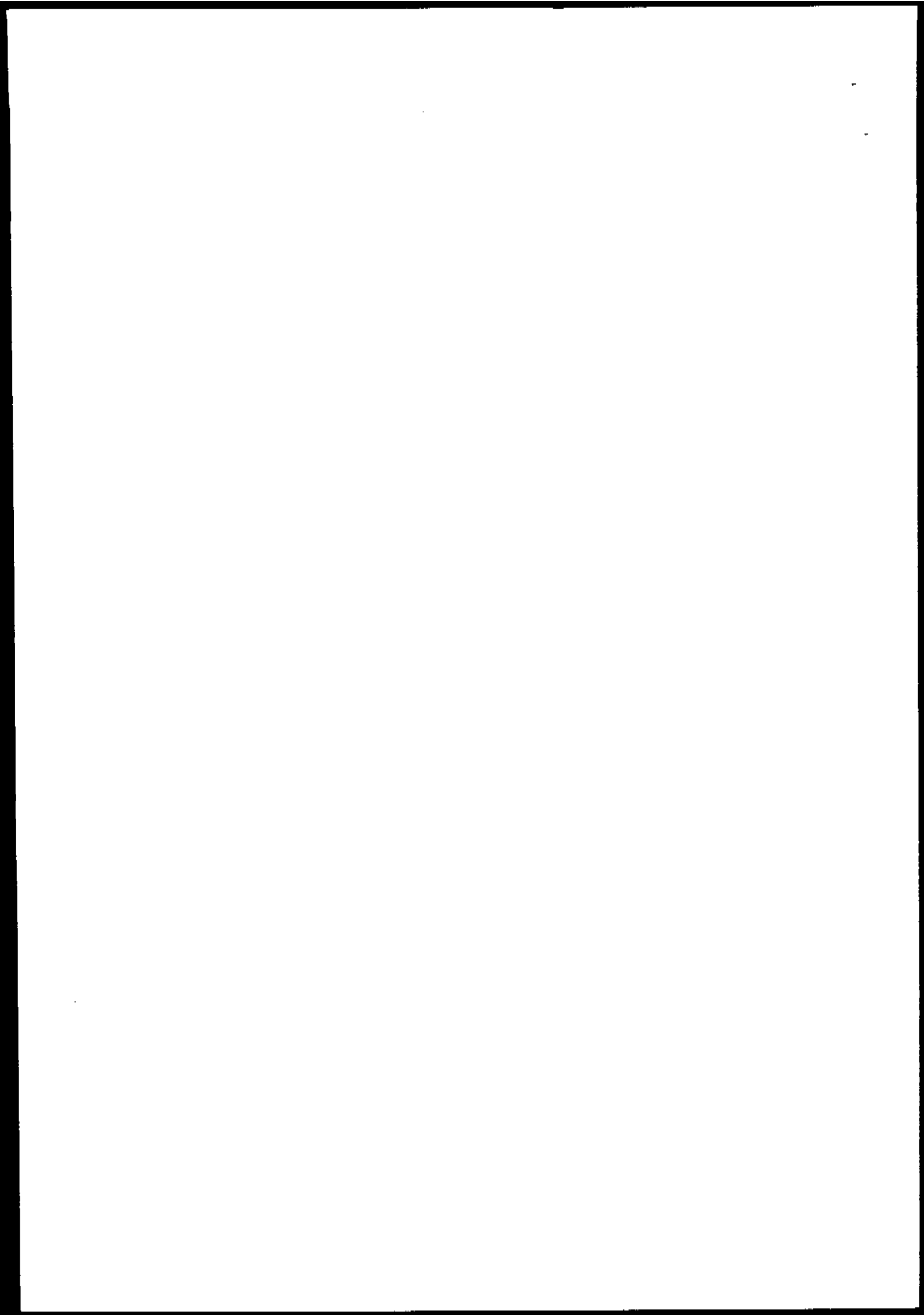
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CENTRE: _____ CODE: ___/___
INTERVIEWER'S NAME: _____ INTERVIEWER'S ID CODE: ___/___
RESPONDENT'S ID CODE: ___/___/___
DATE OF ASSESSMENT: ___/___/___/___/___

RESPONDENT'S SEX: MALE ... 1 FEMALE ... 2
AGE: ___/___

MARITAL STATUS: MARRIED 1
WIDOWED 2
SEPARATED 3
DIVORCED 4
NEVER MARRIED 5

EMPLOYED: NO ... 1 YES ... 2 IF YES: FULL-TIME 1
PART-TIME 2

YEARS OF SCHOOLING COMPLETED: _____

HEALTH CARE SETTING: _____

Have you ever had a lot of trouble because of one of the following problems:
(PLEASE CIRCLE YES OR NO FOR EACH ITEM.)

- | | | | |
|----|--|-----|----|
| 1 | Headache | YES | NO |
| 2 | Feeling your heart pounding in your chest | YES | NO |
| 3 | Discomfort in your stomach or abdomen | YES | NO |
| 4 | Back pain | YES | NO |
| 5 | Dizziness | YES | NO |
| 6 | Heaviness or lightness in your head | YES | NO |
| 7 | Difficulty swallowing | YES | NO |
| 8 | Feelings of muscular pains and aches | YES | NO |
| 9 | Persistent fatigue after minor mental or physical effort | YES | NO |
| 10 | Feelings of heaviness or lightness in your arms or legs | YES | NO |
| 11 | Crawling or creeping sensations in your body | YES | NO |
| 12 | Unpleasant numbness or tingling sensations | YES | NO |

Have at least three of these problems lasted three or more months? YES NO
(IF YES, INCLUDE RESPONDENT IN THE STUDY.)