Delstudie:

KARISMA 2

Karolinska Institutet

Karisma

Follow-up questionnaire

Contents

Reading the metadata

The survey is built up by questions, which are grouped into the following domains.

Domains

Name	Description
msa	General symptoms
fac	Specific and other symptoms
wom	Menstruation
med	Medication
mor	Tamoxifen use

Each question in the survey, when saved as database variables, is named in accordance with the above domain names. E.g., the variable "soc_education" is the variable for the education level question, which asks the study participant about his/her education level. All variables in the database concerning socio-demographic issues start with the three letters "soc_", which unifies all "socio-demographic" variables into one and same domain name space "soc_". Moreover, all variable domain names together define the full name space for the questionnaire.

Questionnaire items and variable names

a) Below questionnaire element shows a question with a single answer option. The corresponding variable in the dataset is "soc_education" having the predefined answer options "1", "2", "3", "4", "5", "6" and "998".

[soc_education] - Education level

bg5. Which is the highest level of education you completed / are working on?
 ○ Folkskola (up to 8 years) (5)   ○ University (3)

❍ Realskola (up to 10 years) (6)	❍ Other (please state) (4)_____
❍ Nine year school (1)	❍ Don't know / refuse (998)
❍ Gymnasium (2)	

b) Below questionnaire element shows a question with a multi answer option also including open text fields. The corresponding variables in the dataset are:

Dataset variable	values
soc_sibling_full	0, 1
soc_sibling_half	0, 1
soc_sibling_oth	0, 1
soc_sibling_no	0, 1
soc_sibling_998	0, 1
soc_sibling_full_other	Free text
soc_sibling_half_other	Free text
soc_sibling_oth_other	Free text

[soc_sibling]

Do you have siblings?

Yes

❑ Full siblings (number) [full]
_____ [full_other]

❑ Half siblings (number) [half]
_____ [half_other]

❑ Other siblings, e.g. step siblings_____ [oth_other]

❍ No [no]

❍ Don't know / refuse [998]

c) In below questionnaire element there is a question with grid answer options also having open text fields. The corresponding variables in the dataset are:

Dataset variable	value
soc_wrkpresent_pres_occ	Free text
soc_wrkpresent_pres_plc	Free text
soc_wrkpresent_pres_dur	Free text
soc_wrkpresent_pres_1	0, 1
soc_wrkpresent_pres_2	0, 1

[soc_wrkpresent]

What is your present occupation and place of work?

	Occupation (e.g. engineer, nurse) [occ]	Place of work (e.g. office, hospital) [plc]	Worked number of years [dur]	Full-time Part-time [int]	
				[1]	[2]
[pres]	_____	_____	_____	☐	☐

d) When questions are updated, the corresponding variable name will receive a version number. The number will be placed within the name after the domain name part, e.g.:

Variable in dataset
soc_wrkpresent_pres_occ
soc2_wrkpresent_pres_occ

Variable extensions

Extension is a central notion in the metadata design used to build up the name space in the questionnaire data. Besides the domain pre-extensions described above there are also in- and post-extensions. E.g., "eat_weight_kg" is the name for a question concerning weight measured in kilogram in the eating disorder domain of questions. The most common extensions are:

Extension	Meaning
cm	Centimeter
kg	Kilogram
cl, 33cl, 50cl	Centiliter
frq	Frequency
dur	Duration
tms	Times
nbr	Number
date	Date
yrs, yr	Years
mnts, mnt	Months
wks, wk	Weeks
days, day	Days
hrs	Hours
min	Minutes
sec	Seconds
whc	Which
amnt	Amount
oth, other	Other

sum	sum
isoxxx	ISO-code
icdxxx	ICD-code
dsmxxx	DSM-code

Variable values - answer options

The answer options, i.e. variable values, are free text or predefined values. The most common predefined values for the variables in the questionnaire dataset are:

Precode	Meaning
1	Yes
2	No
1	Male
2	Female
1	Checkbox checked in a multi answer option question
0	Checkbox not checked in a multi answer option question, but shown to the study participant
999	Refuse to answer
998	Don't know / refuse
997	Don't know
996	None of these. Multi answer option questions often also have this answer option so the study participant can choose to say that none of the other answer options applies.
995	Question has been shown to the study participant, which chose not to respond to the question.
null	The variable does not have a value registered, i.e. the corresponding questions in the survey was not shown or

	answered by the study participant. "null" is the symbolic expression for a missing value.

Missing by design

The Karisma 2 follow-up survey includes logic that distributes an individualized set of questions to the survey responders. This will result in a dataset which recorded value wherever the respondent responded to the distributed question. This also means that wherever there is a missing value in the dataset, the responder was not given that question or did not respond do that question. The latter case is only possible if the survey was not completed, because all questions are mandatory in the survey.

This phenomenon is called "missing by design" and is of interest in analysis situations.

Longitudinal data

At study entry, the Karisma 2 study participants respond to the baseline survey. This survey includes questions of "ever" character, e.g. what diseases the study participants ever had in their life. The study participants also respond to surveys at follow-ups, which occur at 1 month, 3 months and 6 months after study entry. Some of the participants respond to the "Exit" follow-up survey, this occurs when they interrupt their participation in the study. Some of the questions in the Karisma 2 follow-up surveys refer to the time "since last response" instead being of "ever" character. This is marked in the follow-up survey PDF-file. The following variables are available in the dataset to identify which questions were asked to the study participant at the different occasions.

Variable	Meaning
survey_name	Name of collecting survey, e.g. KARISMA S1 BASELINE, KARISMA S2 FOLLOWUP, KARISMA S3 FOLLOWUP, KARISMA S4 FOLLOWUP, KARISMA S20 EXIT
survey_version	Version of survey collecting data for study participant.

status	Whether survey respondent finished survey or not. "complete" means finished survey.
baseline_mode	Whether survey asked baseline questions or follow-up questions to the responder.
interview_lasttime	Time span which the questions of "since last response" character refers back to in the follow-up surveys.

Karisma Symptom

General Symptoms

msa – General Symptoms

SY1. Below is a list of 24 symptoms. Read each symptom carefully. Mark each symptom you have had in the last 30 days.

❑ Difficulty concentrating (con)

❑ Pain (pai)

❑ Lack of energy (ene)

❑ Cough (cou)

❑ Feeling nervous (ner)

❑ Dry mouth (mou)

❑ Nausea (nau)

❑ Feeling drowsy (dro)

❑ Numbness/tingling in the hands and feet (num)

❑ Difficulty sleeping (sle)

❑ Problems with urination (uri)

❑ Shortness of breath (bre)

❑ Feeling sad (sad)

❑ Worrying (wor)

❑ Itching (itc)

❑ Lack of appetite (app)

❑ Difficulty swallowing (swa)

❑ Change in the way food tastes (foo)

❑ Constipation (cos)

❑ Swelling of arms or legs (swe)

❑ "I don't look like myself" (loo)

○ None of these (996)

○ Don't know / refuse (998)

For each marked symptom in SY1, show corresponding symptom in SY1a, SY1b and SY1c

msa_frq – General symptoms, frequency.

SY1a. How often were you (did you have) {each symptom marked in SY1}?

○ Rarely (1)

○ Occasionally (2)

○ Frequently (3)

○ Almost constantly (4)

○ Don't know / refuse (998)

msa_difficulty - General symptoms, difficulty

SY1b. How hard was the symptom usually?

❍ Slight (1) ❍ Very severe (4)

❍ Moderate (2) ❍ Don't know / refuse (998)

❍ Severe (3)

msa_affected - General symptoms, affected

SY1c. How much, did it bother or worry you?

❍ Not at all (1) ❍ Quite a bit (4)

❍ A little bit (2) ❍ Very much (5)

❍ Somewhat (3) ❍ Don't know / refuse (998)

Specific Symptoms

fac1 – Tamoxifen specific side effects

TA1. Enter your answer for each question that concerns the last 30 days.

	Not at all (1)	A little bit (2)	Somewhat (3)	Quite a bit (4)	Very much (5)	Don't know / refuse (998)
I have hot flashes (fla)	❍	❍	❍	❍	❍	❍
I have cold sweats (swe)	❍	❍	❍	❍	❍	❍
I have night sweats (nig)	❍	❍	❍	❍	❍	❍
I have vaginal discharge (dis)	❍	❍	❍	❍	❍	❍
I have vaginal itching/irritation (itc)	❍	❍	❍	❍	❍	❍
I have vaginal bleeding or	❍	❍	❍	❍	❍	❍

	Not at all (1)	A little bit (2)	Somewhat (3)	Quite a bit (4)	Very much (5)	Don't know / refuse (998)
spotting (ble)						
I have vaginal dryness (dry)	❍	❍	❍	❍	❍	❍
I have pain or discomfort with intercourse (int)	❍	❍	❍	❍	❍	❍
I have lost interest in sex (sex)	❍	❍	❍	❍	❍	❍
I have gained weight (wei)	❍	❍	❍	❍	❍	❍

fac2 - Tamoxifen specific side effects

TA2. Enter your answer for each question that concerns the last 30 days.

	Not at all (1)	A little bit (2)	Somewhat (3)	Quite a bit (4)	Very much (5)	Don't know / refuse (998)
I feel lightheaded (dizzy) (diz)	❍	❍	❍	❍	❍	❍
I have been vomiting (vom)	❍	❍	❍	❍	❍	❍
I have diarrhea (dia)	❍	❍	❍	❍	❍	❍
I get headaches (hea)	❍	❍	❍	❍	❍	❍
I feel bloated (blo)	❍	❍	❍	❍	❍	❍
I have breast sensitivity/tenderness (bre)	❍	❍	❍	❍	❍	❍
I have mood swings (moo)	❍	❍	❍	❍	❍	❍
I am irritable (irr)	❍	❍	❍	❍	❍	❍
I have pain in my joints (pai)	❍	❍	❍	❍	❍	❍
I have fragile mucous membranes (mem)	❍	❍	❍	❍	❍	❍

fac3 - Tamoxifen specific side effects

TA3. Enter your answer for each question that concerns the last 30 days.

	Not at all (1)	A little bit (2)	Somewhat (3)	Quite a bit (4)	Very much (5)	Don't know / refuse (998)
I have rapid heart rate or palpitations (pal)	○	○	○	○	○	○
I have muscle cramps (e.g. in legs) (cra)	○	○	○	○	○	○
I have abdominal obesity (obe)	○	○	○	○	○	○
I have eyesight changes (eye)	○	○	○	○	○	○
I have dry eyes (dey)	○	○	○	○	○	○
I have hair loss (hai)	○	○	○	○	○	○
I have skin rashes (ras)	○	○	○	○	○	○
I feel quick (qui)	○	○	○	○	○	○

If fac1_nig is greater than 2, show fac1_nig_time

fac1_nig_time – Night sweats, most bothered on the day

TA1a. When on the day are you most bothered by hot flashes?

○ Daytime (1)   ○ Regardless of the time of day (3)

○ Nighttime (2)   ○ Don't know / refuse (998)

If fac3_pal is greater than 2, show fac2_pal_time

fac2_pal_time – Rapid heart rate or palpitations, most bothered on the day

TA1b. When on the day are you most bothered by rapid heart rate or palpitations?

○ Daytime (1)   ○ Regardless of the time of day (3)

○ Nighttime (2)   ○ Don't know / refuse (998)

If fac2_pai is greater than 2, show fac2_pai_time

fac2_pai_time - Pain in joints, most bothered on the day

TA1c. When on the day are you most bothered by pin in joints and hands?

○ Daytime (1)   ○ Regardless of the time of day (3)

○ Nighttime (2)   ○ Don't know / refuse (998)

Other Symptoms

fac2_other – Other Symptoms

TA2a. Have you had any other symptoms in the last 30 days (i.e. except: {each symptom marked in fac1, fac2 and fac3})?

○ No (0)

○ Yes, 1 symptom (1)

○ Yes, 2 symptoms (2)

○ Yes, 3 symptoms (3)

○ Yes, 4 symptoms (4)

○ Yes, 5 or more symptoms (5)

○ Don't know / refuse (998)

fac2_other_oth - Other symptom, describe

TA2b. Describe your {first, second, third …} symptom.

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fac2_other_affect - Other symptom, affect

TA2c. How much did the symptom bother you?

○ Not at all (1)   ○ Quite a bit (4)

○ A little (2)   ○ Very much (5)

○ Somewhat (3)   ○ Don't know / refuse (998)

Menstruation

wom_lstyear_period – Had periods in last year

fer2. Have you had a menstrual period during the last year?

○ Yes (1)   ○ Don't know / refuse (998)

○ No (2)

wom_lsttime_recent - Know time of last period

fer2c. Do you remember when you had your last menstruation?

○ Yes (1)   ○ Don't know / refuse (998)

○ No (2)

wom_lsttime_date - Date of the last period

fer2d. When was the first day you had your last period?

wom_cycle - Days in the cycle

fer3b. {In the last year you had your periods, how many days did you usually have in between your periods?, How many days do you usually have in between your periods?}

{Example: if you used to have your period same day each month, your cycle is 30 days., Example: if you use to have your period same day each month, your cycle is 30 days.}

○ 22 days or shorter (1)

○ 23 - 26 days (2)

○ 27 - 30 days (3)

○ 31 - 34 days (4)

○ 35 - 38 days (5)

○ 39 days or longer (6)

○ Menstruations are irregular (7)

○ Don't know / refuse (998)

Doctor visit

fac_doctorvisit – Doctor visit for symptom

TA4. Have you visited a doctor or other health professional in the last 30 days for any of your symptoms?

(i.e. for {symptoms marked in fac1, fac2 and fac3 and TA2b})

○ Yes (please specify the healthcare facility) (1) _____   ○ Don't know / refuse (998)

○ No (2)

If TA4 is "Yes", show TA4a

fac4

TA4a. For which symptoms, did you visit doctors or other healthcare professionals in the last 30 days? (Mark all that apply)

❑ Hot flashes / hot flushes (fla)

❑ Cold sweats (swe)

❑ Night sweats (nig)

❑ Vaginal discharge (dis)

❑ Vaginal itching / irritation (itc)

❑ Vaginal bleeding or spotting (ble)

❑ Vaginal dryness (dry)

❑ Pain or discomfort with intercourse (int)

❑ Lost interest in sex (sex)

❑ Gained weight (wei)

❑ Lightheaded (dizzy) (diz)

❑ Vomiting (vom)

❑ Diarrhea (dia)

❑ Headaches (hea)

❑ Feel bloated (blo)

❑ Breast sensitivity/tenderness (bre)

❑ Mood swings (moo)

❑ Irritable (irr)

❑ Pain in my joints (pai)

❑ Fragile mucous membranes (mem)

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❑ Rapid heart rate or palpitations (pal)

❑ Muscle cramps (cra)

❑ Eyesight changes (eye)

❑ Hair loss (hai)

❑ Skin rashes (ras)

❑ I have abdominal obesity (obe)

❑ I have dry eyes (dey)

❑ I feel quick (qui)

❑ Other symptom (please specify)(oth) _____

○ None of these (996)

○ Don't know / refuse (998)

Tamoxifen use

med_tamoxifen – Tamoxifen started

When did you start treatment with the Tamoxifen medication?

○ The same day I answered the first questionnaire ({baseline questionnaire date}) (1)

○ Before I answered the first questionnaire (2)

○ After I answered the first questionnaire (3)

○ Don't know / refuse (998)

If med_tamoxifen is 2 or 3, show med_tamoxifen_date

med_tamoxifen_date - Tamoxifen start date

Specify the date when you started the treatment with the Tamoxifen medication

mor_1 - Forget to take medicine

MO1. Do you sometimes forget to take your medicine (Tamoxifen)?

❍ Yes (1)   ❍ Don't know / refuse (998)

❍ No (2)

mor_2 - Forget to take medicine for the past 2 weeks

MO2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medicine(Tamoxifen)?

❍ Yes (1)   ❍ Don't know / refuse (998)

❍ No (2)

mor_3 - Reduce the dose

MO3. Have you ever cut back or stopped taking your medicine (Tamoxifen) without telling your doctor because you felt worse when you took it?

❍ Yes (1)   ❍ Don't know / refuse (998)

❍ No (2)

mor_4 - Forget medicine while traveling

MO4. When you travel or leave home, do you sometimes forget to bring along your medicine(Tamoxifen)?

❍ Yes (1)   ❍ Don't know / refuse (998)

❍ No (2)

mor_5 - Took medicine yesterday

MO5. Did you take all your medicine (Tamoxifen) yesterday?

○ Yes (1)   ○ Don't know / refuse (998)

○ No (2)

mor_6 - Memory help to take medicine

MO6. Do you have a special system to help you remember to take your medicine (Tamoxifen)?

○ Yes (1)   ○ Don't know / refuse (998)

○ No (2)

mor_7 - Difficulty in following medication

MO7. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?

○ Yes (1)   ○ Don't know / refuse (998)

○ No (2)

mor_8 - Difficulty in following medication, frequency

MO8. How often do you have difficulty remembering to take all your medicines (Tamoxifen)?

○ Never / rarely (1)   ○ Usually (4)

○ Once in a while (2)   ○ All the time (5)

○ Sometimes (3)   ○ Don't know / refuse (998)

Other medication

med_nontamoxifen - Other medicine, last 30 days

ME1. Have you taken any other prescribed medicine than Tamoxifen in the last 30 days?

◯ Yes (1)   ◯ Don't know / refuse (998)

◯ No (2)

med_changed - Other medicine, last 30 days

ME2. Have you changed medication, i.e. started or stopped with any new prescribed medicine in the last 30 days?

◯ Yes (1)   ◯ Don't know / refuse (998)

◯ No (2)