OPTIMISE Codebook

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Glossary

CALPAS	Therapeutic alliance measure
CDSS	Calgary Depression Rating Scale for Schizophrenia
CGI	Clinical Global Impression of Severity / Improvement
DAI	Drug Attitude Inventory
EQ-5D	Euroqol Quality of life scale
KPI	Knowledge about Psychosis Inventory
MINI	Mini-International Neuropsychiatric Interview
PANSS	Positive and Negative Symptom Scale
PSP	Personal and Social Performance scale
SCS	Sellwood Compliance Scale
SWN	Subjective Well-being under Neuroleptics
SOFAS	Social and Occupational Functioning Scale
UKU	Udvalg for Kliniske undersogelser Side Effect Rating Scale

Additional notes:

1) an overview of the time points related to each visit can be found in the protocol

2) 'Open text field' indicates that data entered is in text format

3) if applicable, specific questions were skipped for individual patients (e.g. if patient has stopped smoking, the only questions on smoking are related to past smoking whereas the questions related to current smoking are skipped)

General patient information

Variable	Available values	Assessed at time point
Visit date	Date	Each visit
Birth date	Date	V1
Date informed consent signed	Date	V1
Inclusion / exclusion criteria met	Yes / No per inclusion and exclusion criteria	V1

Psychiatric diagnoses and current treatment

Variable	Available values	Assessed at time point
DSM-IV classification	Schizophrenia / Schizoaffective disorder / Schizophreniform disorder	V1
Duration of current psychotic episode	0 to 24 months	V1
Current psychiatric treatment setting	Inpatient / Outpatient / Day Care / Other [open text field]	V1
Current psychosocial intervention aimed at improving course of schizophrenia	Yes / No	V1
Estimated prognosis for patient	Best / good / above average / average / below average / bad / worst	V1
MINI assessment date	Date	V1
MINI: major depressive disorder current (2 weeks)	Yes / No	V1
MINI: major depressive disorder recurrent	Yes / No	V1
MINI: major depressive disorder age of onset	Continuous variable	V1
MINI: major depressive disorder # of episodes	Continuous variable	V1
MINI: mood disorder due to general medical condition – current	Yes / No	V1
MINI: mood disorder due to general medical condition – past	Yes / No	V1
MINI: substance induced mood disorder – current	Yes / No	V1
MINI: substance induced mood disorder – past	Yes / No	V1
MINI: major depressive episode with melancholic features – current (2 weeks)	Yes / No	V1
MINI: major depressive episode with melancholic features – recurrent	Yes / No	V1

MINI: dysthymia – current (past 2 years)	Yes / No	V1
MINI: dysthymia – past	Yes / No	V1
MINI: dysthymia – age of onset	Yes / No	V1
MINI: Suicidality – current (past month)	Yes / No	V1
MINI: Suicidality risk	Absent / low / medium / high	V1
MINI: manic episode – current	Yes / no	V1
MINI: manic episode – past	Yes / no	V1
MINI: manic episode – age of onset	Continuous variable	V1
MINI: manic episode – number of episodes	Continuous variable	V1
MINI: hypomanic episode – current	Yes / no	V1
MINI: hypomanic episode – past	Yes / no	V1
MINI: bipolar disorder II – current	Yes / no	V1
MINI: bipolar disorder II – past	Yes / no	V1
MINI: (hypo)manic episode due to a general medical condition – current	Yes / no	V1
MINI: (hypo)manic episode due to a general medical condition – past	Yes / no	V1
MINI: substance induced (hypo)manic episode – current	Yes / no	V1
MINI: substance induced (hypo)manic episode – past	Yes / no	V1
MINI: panic disorder – current (past month)	Yes / no	V1
MINI: panic disorder – life time	Yes / no	V1
MINI: panic disorder – age of onset	Continuous variable	V1
MINI: anxiety disorder with panic attacks due to a general medical condition – current	Yes / no	V1
MINI: substance induced anxiety disorder with panic attacks – current	Yes / no	V1
MINI: agoraphobia – current	Yes / no	V1
MINI: agoraphobia – life time	Yes / no	V1
MINI: agoraphobia – age of onset	Continuous variable	V1
MINI: social phobia – current	Yes / no	V1
MINI: specific phobia – current	Yes / no	V1
MINI: obsessive compulsive disorder – current (past month)	Yes / no	V1
MINI: obsessive compulsive disorder – age of onset	Continuous variable	V1

MINI: OCD due to a general medical condition – current (past month)	Yes / no	V1
MINI: substance induced OCD – current (past month)	Yes / no	V1
MINI: post-traumatic stress disorder – current (past month)	Yes / no	V1
MINI: post-traumatic stress disorder – age of onset	Continuous variable	V1
MINI: post-traumatic stress disorder – number of episodes	Continuous variable	V1
MINI: alcohol dependence – past 12 months	Yes / no	V1
MINI: alcohol dependence – lifetime	Yes / no	V1
MINI: alcohol abuse – past 12 months	Yes / no	V1
MINI: alcohol abuse – lifetime	Yes / no	V1
MINI: substance dependence – past 12 months	Yes / no	V1
MINI: substance dependence – lifetime	Yes / no	V1
MINI: substance abuse – past 12 months	Yes / no	V1
MINI: substance abuse – lifetime	Yes / no	V1
MINI: psychotic disorders – current	Yes / no	V1
MINI: psychotic disorders – lifetime	Yes / no	V1
MINI: mood disorder with psychotic features – current	Yes / no	V1
MINI: schizophrenia – current	Yes / no	V1
MINI: schizophrenia – lifetime	Yes / no	V1
MINI: schizoaffective disorder – current	Yes / no	V1
MINI: schizoaffective disorder – lifetime	Yes / no	V1
MINI: schizophreniform disorder – current	Yes / no	V1
MINI: schizophreniform disorder – lifetime	Yes / no	V1
MINI: brief psychotic disorder – current	Yes / no	V1
MINI: brief psychotic disorder – lifetime	Yes / no	V1
MINI: delusional disorder – current	Yes / no	V1
MINI: delusional disorder – lifetime	Yes / no	V1
MINI: psychotic disorder due to general medical condition – current	Yes / no	V1
MINI: psychotic disorder due to general medical condition – lifetime	Yes / no	V1
MINI: substance induced psychotic disorder – current	Yes / no	V1

MINI: substance induced psychotic disorder – lifetime	Yes / no	V1
MINI: psychotic disorder NOS – current	Yes / no	V1
MINI: psychotic disorder NOS – lifetime	Yes / no	V1
MINI: mood disorder with psychotic features – lifetime	Yes / no	V1
MINI: mood disorder NOS – lifetime	Yes / no	V1
MINI: major depressive disorder with psychotic features – current	Yes / no	V1
MINI: major depressive disorder with psychotic features – past	Yes / no	V1
MINI: bipolar I disorder with psychotic features – current	Yes / no	V1
MINI: bipolar I disorder with psychotic features – past	Yes / no	V1
Was the patient hospitalized since last visit?	Yes / no	V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
In case of hospitalization: date of admission	Date	V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
In case of hospitalization: reason for admission	1 = psychosis related / 2 = depression / 3 = suicide attempt / 4 = side effects / 5 = mania / 6 = Other [open text field]	V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
In case of hospitalization: date of release	Yes / no	V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22

Demographics

Variable	Available values	Assessed at time point
Race	White / Black / Asian / Other [open text field]	V1
Country of birth	All countries	V1
Country of residence	All countries	V1
Country of birth father	All countries	V1
Country of birth mother	All countries	V1
Country of birth paternal grandfather	All countries	V1
Country of birth paternal grandmother	All countries	V1
Country of birth maternal grandfather	All countries	V1
Country of birth maternal grandmother	All countries	V1
Married at present	Yes / No	V1

Ever divorced	Yes / No	V1
Has patient an occupation currently	Yes / No	V1
Type of current occupation patient	High executive, major professional / administrative personnel, minor professional, owner small business / sales, technician, farmer / skilled manual employee / unskilled manual employee / student / homemaker / unpaid work, volunteer work	V1
Does patient have a previous occupation	Yes / No	V1
Type of previous occupation patient	High executive, major professional / administrative personnel, minor professional, owner small business / sales, technician, farmer / skilled manual employee / unskilled manual employee / student / homemaker / unpaid work, volunteer work	V1
Highest level of occupation father	High executive, major professional / administrative personnel, minor professional, owner small business / sales, technician, farmer / skilled manual employee / unskilled manual employee / student / homemaker / unpaid work, volunteer work	V1
Highest level of occupation mother	High executive, major professional / administrative personnel, minor professional, owner small business / sales, technician, farmer / skilled manual employee / unskilled manual employee / student / homemaker / unpaid work, volunteer work	V1
Number of years in school from 6 years onwards	Continuous variable	V1
Highest degree patient	University (finished) / university (unfinished) / professional training (finished) / professional training (unfinished) / high school (finished) / high school (unfinished) / less than high school	V1
Educational problems patient	Never in special education / held back 1 year, no special education / requiring special education but progressed at rate of 1 grade per year and/or held back less than 2 years / held back 2 or more years / did not complete school / no problems / unknown	V1
Highest degree father	University (finished) / university (unfinished) / professional training (finished) / professional training	V1

	(unfinished) / high school (finished) / high school (unfinished) / less than high school	
Highest degree mother	University (finished) / university (unfinished) / professional training (finished) / professional training (unfinished) / high school (finished) / high school (unfinished) / less than high school	V1
Living alone	Yes / No	V1
Living with	Father / mother / partner / brothers and/or sisters {continuous variable included} / friends or some other group living arrangement {continuous variable included} / children < 6 years {continuous variable included} / children 6-12 years {continuous variable included} / children 13-18 years {continuous variable included} / other [open text field]	V1
Type of dwelling	House / apartment / room / house with formal supervision / dormitory / temporary / other [open text field]	V1
Main source of income	Employment / parents / social security disability insurance / unemployment benefit / other [open text field]	V1
Income, amount per month	Amount specified in Euros or other applicable currency	V1
Living environment	City > 500.000 / city 100.000-500.000 / city 10.000-100.000 / village or rural	V1

Physical examinations

Variable	Available values	Assessed at time point
ECG performed	Yes / No (actual ECGs are not available)	V1
Date ECG performed	Date	V1
Was ECG normal or abnormal	Normal / abnormal [if selected: open text field]	V1
Height	[open text field] in cm	V1
Weight	[open text field] in kg	V1, V5, V8, V16, V20, V21, V22
Waist	[open text field] in cm	V1, V5, V8, V16, V20, V21, V22
Hip circumference	[open text field] in cm	V1, V5, V8, V16, V20, V21, V22

Blood pressure systolic	[open text field] in mm Hg	V1, V5, V8, V16, V20, V21, V22
Blood pressure diastolic	[open text field] in mm Hg	V1, V5, V8, V16, V20, V21, V22
Pulse	[open text field] in beats per minute	V1, V5, V8, V16, V20, V21, V22
Last menstruation was how many days ago	Continuous	V2, V5, V8, V20

Questionnaires

Variable	Available values	Assessed at time point
PANSS 30 individual items	1 = absent / 2 = minimal / 3 = mild / 4 = moderate / 5 = moderate – severe / 6 = severe / 7 = extreme	V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20, V21, V22
Is patient in remission (based on PANSS items)	Yes / no	V5, V8, V12, V16, V20, V21, V22
PSP: domain of functioning 'socially useful activities, including work and study'	1 = absent / 2 = mild / 3 = manifest / 4 = marked / 5 = severe / 6 = very severe	V2, V3, V5, V6, V8, V10, V12, V16, V20
PSP: domain of functioning 'personal and social relationships'	1 = absent / 2 = mild / 3 = manifest / 4 = marked / 5 = severe / 6 = very severe	V2, V3, V5, V6, V8, V10, V12, V16, V20
PSP: domain of functioning 'self-care'	1 = absent / 2 = mild / 3 = manifest / 4 = marked / 5 = severe / 6 = very severe	V2, V3, V5, V6, V8, V10, V12, V16, V20
PSP: domain of functioning 'disturbing and aggressive behaviors'	1 = absent / 2 = mild / 3 = manifest / 4 = marked / 5 = severe / 6 = very severe	V2, V3, V5, V6, V8, V10, V12, V16, V20
PSP final score	Continuous variable	V2, V3, V5, V6, V8, V10, V12, V16, V20
CGI Severity	1 = normal, not ill at all / 2 = borderline mentally ill / 3 = mildly ill / 4= moderately ill / 5 = markedly ill / 6 = severely ill / 7 = among the most extremely ill patients	V2, V3, V5, V6, V8, V10, V12, V16, V20
CGI Improvement	1 = very much improved / 2 = much improved / 3 = minimally improved / 4 = no change / 5 = minimally worse / 6 = much worse / 7 = very much worse	V3, V5, V6, V8, V10, V12, V16, V20
CDSS – depressed mood	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
CDSS – hopelessness	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
CDSS – self depreciation	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
CDSS – guilty ideas of reference	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
CDSS – pathological guilt	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
CDSS – morning depression	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
CDSS – early wakening	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
CDSS – suicide	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
CDSS – observed depression	1 = absent / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20

UKU – personal notes	[open text field]	V2, V5, V8, V12, V16, V20
UKU – in which sections are side effects reported	1 = all / 2 = psychic / 3 = neurologic / 4 = autonomic / 5 = other / 6 = none	V2, V5, V8, V12, V16, V20
UKU – concentration difficulties, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – concentration difficulties, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – astheniat/lassitude/increased fatigability, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – astheniat/lassitude/increased fatigability, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – sleepiness/sedation, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – sleepiness/sedation, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – failing memory, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – failing memory, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – depression, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – depression, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – tension/inner unrest, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – tension/inner unrest, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – increased duration of sleep, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – increased duration of sleep, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – reduced duration of sleep, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – reduced duration of sleep, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – increased dream activity, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – increased dream activity, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – emotional indifference, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – emotional indifference, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – dystonia, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20

UKU – dystonia, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – rigidity, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – rigidity, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – hypokinesia/akinesia, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – hypokinesia/akinesia, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – hyperkinesia logic, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – hyperkinesia logic, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – tremor, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – tremor, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – akathesia, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – akathesia, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – epileptic seizures, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – epileptic seizures, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – paraesthesias, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – paraesthesias, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – accommodation disturbances, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – accommodation disturbances, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – increased salivation, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – increased salivation, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – reduced salivation, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – reduced salivation, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – nausea/vomiting, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – nausea/vomiting, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20

UKU – diarrhoea, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – diarrhoea, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – constipation, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – constipation, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – accommodation disturbances, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – accommodation disturbances, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – micturition disturbances, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – micturition disturbances, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – polyuria/polydipsia, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – polyuria/polydipsia, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – orthostatic dizziness, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – orthostatic dizziness, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – palpitations/tachycardia, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – palpitations/tachycardia, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – increased tendency to sweating, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – increased tendency to sweating, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – rash, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – rash, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – rash: morbilliform, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – rash: morbilliform, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – rash: petechial, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – rash: petechial, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20

UKU – rash: urticarial, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – rash: urticarial, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – rash: psoriatic, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – rash: psoriatic, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – rash: cannot be classified, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – rash: cannot be classified, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – pruritus, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – pruritus, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – photosensitivity, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – photosensitivity, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – increased pigmentation, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – increased pigmentation, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – weight gain, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – weight gain, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – weight loss, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – weight loss, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – menorrhagia, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – menorrhagia, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – amenorrhea, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – amenorrhea, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – galactorrhea, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – galactorrhea, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – gynaecomastia, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – gynaecomastia, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20

UKU – increased sexual desire, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – increased sexual desire, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – decreased sexual desire, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – decreased sexual desire, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – erectile dysfunction, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – erectile dysfunction, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – ejaculatory dysfunction, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – ejaculatory dysfunction, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – orgastic dysfunction, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – orgastic dysfunction, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – dry vagina, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – dry vagina, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – headache, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – headache, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – headache: tension headache, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – headache: tension headache, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – headache: migraine, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – headache: migraine, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – headache: other forms, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – headache: other forms, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – physical dependence, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – physical dependence, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – psychic dependence, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20

UKU – psychic dependence, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – tardive dyskinesia, degree	1 = not or doubtfully present / 2 = mild / 3 = moderate / 4 = severe	V2, V5, V8, V12, V16, V20
UKU – tardive dyskinesia, causal relationship	1 = impossible / 2 = possible / 3 = probable	V2, V5, V8, V12, V16, V20
UKU – global assessment of interference by side effects with daily performance: patient opinion	1 = no side effects / 2 = mild side effects that do not interfere with the patients performance / 3 = side effects that interfere moderately with the patients performance / 4 = side effects that interfere markedly with the patients performance.	V2, V5, V8, V12, V16, V20
UKU – global assessment of interference by side effects with daily performance: physician opinion	1 = no side effects / 2 = mild side effects that do not interfere with the patients performance / 3 = side effects that interfere moderately with the patients performance / 4 = side effects that interfere markedly with the patients performance.	V2, V5, V8, V12, V16, V20
UKU – consequence of side effects for treatment	1 = no action / 2 = more frequent assessment of the patient, but no change in dose and/or occasional treatment of side effects / 3 = reduction of dose and/or continuous drug, treatment of side effects / 4 = discontinuation of drug	V2, V5, V8, V12, V16, V20
SWN: 1. I feel powerless and not in control of myself	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 2. I feel very comfortable with my body	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 3. I find it easy to think	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 4. I have no hope for the future	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 5. My body feels familiar, like it belongs to me	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 6. I am very shy about approaching people and making social contact	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 7. I am imaginative and full of ideas	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 8. My environment seems friendly and familiar to me	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20

SWN: 9. I feel drained and exhausted	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 10. My thoughts and emotions are numb. Nothing matters to me	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 11. My thinking is difficult and slow	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 12. My feelings and behaviour are inappropriate to situations. I get upset about small things, important things hardly affect me at all	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 13. I find it easy to interact with people around me	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 14. I perceive my environment as being changed, strange and threatening.	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 15. I find it easy to draw a line between myself and others	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 16. My body is a burden to me	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 17. My thoughts are flighty and undirected. I find it difficult to think clearly	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 18. I take interest in what is happening around me, and it is important to me	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 19. My feelings and behavior are appropriate to situations	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20
SWN: 20. I am full of confidence. Everything will be allright	1 = not at all / 2 = hardly at all / 3 = a little / 4 = somewhat / 5 = much / 6 = very much	V2, V5, V8, V12, V16, V20

Concomitant medication

Variable	Available values	Assessed at time point
All (co)medication used in past 4 weeks	Yes / no	V1
All (co)medication used since last visit	Yes / no	V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Generic name	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22

Frequency of dose	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Dose (mg/day)	Continuous variable	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Reason for use	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Start date	Date	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Date last dose taken	Date	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Time last dose taken	Time	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Stopped	Yes / no	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Stop date	Date	V1, V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22

Recreational drug use, alcohol use, caffeine use, smoking

Variable	Available values	Assessed at time point
Recreational drug used ever	Yes / no	V1
Recreational drug used since last visit	Yes / no	V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Frequency of dose	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Dose	Continuous variable	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Route	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Reason for use	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Start date	Date	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Date last dose taken	Date	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Time last dose taken	Time	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Ongoing	Yes / no	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Stop date	Date	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Frequency last 4 weeks	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Drug: Dose last 4 weeks	[open text field]	V1, V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20

Caffeine: how many cups of drinks with caffeine do you regularly have per day	Continuous	V2
Caffeine: when did you have your last drink with caffeine	1 = today / 2 = yesterday / 3 = before yesterday	V2, V5, V8, V20
Caffeine: time of last drink with caffeine (only if today or yesterday)	Time	V2, V5, V8, V20
Caffeine: description of last drink with caffeine	[open text field]	V2, V5, V8, V20
Alcohol: did you drink alcohol during the past 12 months	1 = yes / 2 = yes but less than 1 alcoholic drink per month / 3 = no	V2
Alcohol: did you drink alcohol since last visit	Yes / no	V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Alcohol: when did you last drink alcohol	1 = Year [open text field] / 2 = never	V2
Alcohol: why did you stop drinking alcohol	[open text field]	V2
Alcohol: when did you last drink more than 1 alcohol drink per month	1 = Year [open text field] / 2 = never	V2
Alcohol: why did you nearly stop drinking alcohol	[open text field]	V2
Alcohol: during the past 30 days, on how many days did you have at least one alcoholic drink	Continuous	V2
Alcohol: since last visit, on how many days did you have at least one alcoholic drink	Continuous	V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Alcohol: how many alcoholic drinks did you have regularly per day	Continuous	V2
Alcohol: when did you have your last alcoholic drink	1 = today / 2 = yesterday / 3 = before yesterday	V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Alcohol: time of last alcoholic drink	Time	V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Alcohol: description of alcoholic drink	[open text field]	V2, V3, V4, V5, V6, V7, V8, V10, V12, V16, V20
Alcohol: did you drink alcohol the last 7 days	Yes / no	V2
Alcohol: what alcohol did you drink the last 7 days	1 = light beer {continuous variable included for number of glasses} / 2 = beer {continuous variable included} / 3 = wine or sparkling wine {continuous variable included} / 4 = spirits {continuous variable included} / 5 = cocktail {continuous variable included}	V2
Alcohol: what alcohol did you drink since last visit	1 = light beer {continuous variable included for number of glasses} / 2 = beer {continuous variable included} / 3 = wine or sparkling wine {continuous variable included} / 4 = spirits {continuous variable included} / 5 = cocktail {continuous variable included}	V3, V4, V5, V6, V7, V8, V10, V12, V16, V20

Alcohol: what alcohol did you drink yesterday	1 = light beer {continuous variable included for number of glasses} / 2 = beer {continuous variable included} / 3 = wine or sparkling wine {continuous variable included} / 4 = spirits {continuous variable included} / 5 = cocktail {continuous variable included} / 6 = I did not drink yesterday	V2, V5, V8, V20
Alcohol: did you ever think about drinking less alcohol	Yes / no	V2
Alcohol: has it ever annoyed you when people criticized your drinking habits	Yes / no	V2
Alcohol: have you ever felt guilty because of your drinking	Yes / no	V2
Alcohol: have you ever had a drink first thing in the morning to calm your nerves of to get over a hangover	Yes / no	V2
Smoking: do you smoke at present or have you ever smoked	1 = I have never smoked / 2 = I smoke now / 3 = I don't smoke anymore / 4 = I do not smoke cigarettes but cigars or similar or pipes	V2
Smoking: how old were you the first time you smoked a whole cigarette	Continuous variable	V2
Smoking: how old were you when you started smoking cigarettes nearly daily	Continuous variable	V2
Smoking: how old were you when you stopped smoking cigarettes	Continuous variable	V2
Smoking: how many years do you or did you smoke	Continuous variable	V2
Smoking: how many cigarettes do you or did you smoke per day	Continuous variable	V2
Smoking: when did you smoke your last cigarette	1 = today / 2 = yesterday / 3 = before yesterday	V2, V5, V8, V20
Smoking: time of last cigarette (or cigar/pipe)	Time	V2, V5, V8, V20
Smoking: how many cigarettes did you smoke today	Continuous variable	V2, V5, V8, V20

Laboratory assessments

Variable	Available values	Assessed at time point
Date blood sample taken	Date	V2, V5, V8, V20
Time blood sample taken	Time	V2, V5, V8, V20

When did you have your last meal	1 = today / 2 = yesterday / 3 = longer ago than yesterday or unknown	V2, V5, V8, V20
Time of last meal	Time	V2, V5, V8, V20
Type of meal	1 = light breakfast / 2 = full breakfast / 3 = light meal / 2 = full meal	V2, V5, V8, V20
Description of last meal	[open text field]	V2, V5, V8, V20
Concentration of study medication in the blood	applicable lab units	V5, V8, V12, V16, V20

Drug accountability study medication

Variable	Available values	Assessed at time point
Did the patient return any pills / capsules	1 = yes {including continuous variable} / 2 = no	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
Why were not all pills returned	1 = patient forgot to bring pills / 2 = other {open text field}	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
Number of pills / capsules given to patient	Continuous variable	V2, V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
Start date (per dose)	Date	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Dose per day	Continuous variable	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Stop date (per dose)	Date	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20, V21, V22
Is study medication used outside the defined dose ranges	Yes / no	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
Did the patient use a dose higher than the study dose range	Yes {indicate cumulative number of days since start of study drug = continuous variable} / no	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
If the number of days is 15 or more, indicate on which date the 15 day interval was reached	Date	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
What was the reason for a dose above the study dose rage	1 = because of side effects / 2 = insufficient clinical response / 3 = lack of compliance / 4 = other	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
Did the patient use a dose lower than the study dose range	Yes {indicate cumulative number of days since start of study drug = continuous variable} / no	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
If the number of days is 15 or more, indicate on which date the 15 day interval was reached	Date	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20

What was the reason for a dose below the study dose range	1 = because of side effects / 2 = insufficient clinical response / 3 = lack of compliance / 4 = other	V3, V4, V5, V6, V7, V8, V9, V10, V11, V12, V13, V14, V15, V16, V17, V18, V19, V20
Randomization for double blind phase	1 = yes, patient is not in remission and has been randomized / 2 = no, patient is in remission and will not enter double blind phase / 3 = no, patient will not continue in the study	V5

(Serious) Adverse Events

Variable	Available values	Assessed at time point
Adverse event term	Open text field	When applicable
Start date of event	Date	When applicable
Intensity of event	1 = mild / 2 = moderate / 3 = severe	When applicable
Most extreme intensity	1 = mild / 2 = moderate / 3 = severe	When applicable
May event have been caused by study drug	Yes / no	When applicable
Has patient fully recovered	1 = yes / 2 = is currently recovering / 3 = recovered with symptoms / 4 = no / 5 = patient died / 6 = unknown	When applicable
Stop date of event	Date	When applicable
Is one or more SAE criteria applicable	1 = death / 2 = life threatening / 3 = requires (prolongation of) hospitalization / 4 = results in significant disability/incapacity / 5 = congenital anomaly/birth defect / 6 = important medical event / 7 = pregnancy / 8 = event is not serious	When applicable
Description of event	Open text field	When applicable
Is event (incl. severity) expected based on summary of product characteristics	Yes / no	When applicable
Medication that is potentially cause of event	1 = amisulpride / 2 = olanzapine / 3 = clozapine / 4 = other antipsychotic / 5 = patient does not use antipsychotics	When applicable

MRI / MRS data

Variable	Available values	Assessed at time point
Date of scan	Date	V2, V5, V8
Scan data processed by IXICO	Standard MRI/MRS format from	V2, V5, V8

Drop outs

Variable	Available values	Assessed at time point
Date of last visit	Date	No specific time point, is to be completed is patient drops out
Reason withdrawal	1 = adverse event(s) / 2 = non-compliance with protocol / 3 = subject did not wish to continue study / 4 = subject died / 5 = discretion investigator / 6 = other, specify {open text field available}	No specific time point, is to be completed is patient drops out

Work package 3: Motivational Interviewing session

Variable	Available values	Assessed at time point
Date of baseline visit	Date	WP3 baseline
Date of Motivational Interview session	1 = open text field for date / 2 = session not done	V1, V2, V3, V4, V5, V6
Duration of Motivational Interview session	Minutes	V1, V2, V3, V4, V5, V6

Work package 3: Questionnaires

Variable	Available values	Assessed at time point
PANSS 30 individual items	1 = absent / 2 = minimal / 3 = mild / 4 = moderate / 5 = moderate – severe / 6 = severe / 7 = extreme	V2, V6, V7, V7.1, V8
SOFAS total score	Continuous	Baseline visit
EQ-5D mobility	1 = I have no problems in walking about / 2 = I have some problems in walking about / 3 = I am confined to bed	Baseline visit, V6, V7, V8

EQ-5D self-care	1 = I have no problems with self-care / 2 = I have some problems washing or dressing myself / 3 = I am unable to wash or dress myself	Baseline visit, V6, V7, V8
EQ-5D usual activities	1 = I have no problems with performing my usual activities / 2 = I have some problems with performing my usual activities / 3 = I am unable to perform my usual activities	Baseline visit, V6, V7, V8
EQ-5D pain/discomfort	1 = I have no pain or discomfort / 2 = I have moderate pain or discomfort / 3 = I have extreme pain or discomfort	Baseline visit, V6, V7, V8
EQ-5D anxiety/depression	1 = I am not anxious or depressed / 2 = I am moderately anxious or depressed / 3 = I am extremely anxious or depressed	Baseline visit, V6, V7, V8
EQ-5D best imaginable health state	Continuous	Baseline visit, V6, V7, V8
KPI: What were your problems/difficulties when you were unwell	Open text field	Baseline visit, V6, V7, V8
KPI: are these symptoms best thought of as an illness	Open text field	Baseline visit, V6, V7, V8
KPI: how long were you unwell before getting help	Open text field	Baseline visit, V6, V7, V8
KPI: are (listed symptoms) past of yourself or part of the illness	Open text field	Baseline visit, V6, V7, V8
KPI: do you think you can control any of them	Open text field	Baseline visit, V6, V7, V8
KPI: which of the following are common symptoms in psychosis in general: - Hearing/seeing things that are not there - False beliefs that others don't share - Unclear thinking - Little drive to do things - Not able to enjoy things - Being violent to others	Per item: Yes / no	Baseline visit, V6, V7, V8
KPI: which of the following could be problems related to psychosis: - Feeling depressed - Sleep problems - Argument with family member - Misusing illicit drugs - Physical health problems	Per item: Yes / no	Baseline visit, V6, V7, V8

- Difficulty keeping up with school/work		
KPI: what is the severity of your illness	1 = mild / 2 = severe	Baseline visit, V6, V7, V8
KPI: what do you think is the cause of the illness	Open text field	Baseline visit, V6, V7, V8
KPI: which of the following might also be causing your illness: - It is inherited - Difficulties in childhood - Physical illness affecting the way the brain works - Personality - Illicit drug use - Stressful events	Per item: 1 = yes / 2 = no / 3 = possible / 4 = don't know	Baseline visit, V6, V7, V8
KPI: any other reasons that could cause your illness	1 = no / 2 = yes: {open text field}	Baseline visit, V6, V7, V8
KPI: are you taking any medication for your illness	1 = yes / 2 = no / 3 = don't know	Baseline visit, V6, V7, V8
KPI: what is the name of the medication	Open text field	Baseline visit, V6, V7, V8
KPI: how often do you think you should take the medication	1 = when I think is needed / 2 = as prescribed / 3 = when other people think is needed	Baseline visit, V6, V7, V8
KPI: how often do you actually take the medication	1 = when I think is needed / 2 = as prescribed / 3 = when other people think is needed	Baseline visit, V6, V7, V8
KPI: how long do you think you should take this medication	Open text field	Baseline visit, V6, V7, V8
KPI: if you felt completely better and decided to stop taking the medication, what would happen: - I would be better off without them - it would make no difference to me - I might start to get worse again after a while	Per item: 1 = yes / 2 = no / 3 = don't know	Baseline visit, V6, V7, V8
KPI: which of the following are main purposes of taking medication - to cure the illness - to help with sleeping - to reduce/control the symptoms - to help to think more clearly - to calm me	Per item: 1 = yes / 2 = no / 3 = possible / 4 = don't know	Baseline visit, V6, V7, V8
KPI: what are the possible side effects of the medication	Open text field	Baseline visit, V6, V7, V8
KPI: what are the side effects that you have experienced	Open text field	Baseline visit, V6, V7, V8

KPI: have you received other treatment or services	1 = Yes {open text field} / 2 = no	Baseline visit, V6, V7, V8
KPI: what are the helps most useful to you	Open text field	Baseline visit, V6, V7, V8
KPI: what was not so useful	Open text field	Baseline visit, V6, V7, V8
KPI: do you have a care-coordinator/key worker	1 = Yes {what is their role: open text field} / 2 = no	Baseline visit, V6, V7, V8
KPI: has your relative/carer had their needs assessed	1 = yes / 2 = no	Baseline visit, V6, V7, V8
KPI: do they have a key worker	1 = yes {what help have they received: open text field} / 2 = no	Baseline visit, V6, V7, V8
KPI: do you think you may have problems again	1 = yes / 2 = no / 3 = don't know	Baseline visit, V6, V7, V8
KPI: which of the following are likely to make your illness worse or bring the problems back - having nothing to do - stressful life events - stopping medication - being under pressure at home - taking illicit drugs - anything else you can think about {open text field}	Per item: 1 = yes / 2 = no / 3 = possible / 4 = don't know	Baseline visit, V6, V7, V8
KPI: is there anything you can do to help improve the condition or prevent the relapse	Open text field	Baseline visit, V6, V7, V8
KPI: is there anything you should not do	Open text field	Baseline visit, V6, V7, V8
KPI: has anyone ever suggested you should not take medication or another intervention	1 = yes / 2 = no	Baseline visit, V6, V7, V8
KPI: do you think any of the following might help - encouragement to take medication - looking after e.g. someone doing washing/cooking - a relative/carer spending as much time as possible with you, making sure you're fine - encouragement to gradually get back to doing things yourself	Per item: 1 = yes / 2 = no / 3 = don't know	Baseline visit, V6, V7, V8
KPI: do you know any organisations that can provide help to you apart from the service that you are already receiving	Open text field	Baseline visit, V6, V7, V8
KPI: where did you get the info about the psychotic illness - from TV and newspaper - internet search	Per item: 1 = yes / 2 = no	Baseline visit, V6, V7, V8

- staff from the service - books {open text field} - from relatives and friends - personal experience		
KPI section 1: symptomatology	0 = incorrect understanding / 1 = lack of knowledge / 2 = good understanding but not complete / 3 = very good and sufficient understanding	Baseline visit, V6, V7, V8
KPI section 2: cause	0 = incorrect understanding / 1 = lack of knowledge / 2 = good understanding but not complete / 3 = very good and sufficient understanding	Baseline visit, V6, V7, V8
KPI section 3: medication	0 = incorrect understanding / 1 = lack of knowledge / 2 = good understanding but not complete / 3 = very good and sufficient understanding	Baseline visit, V6, V7, V8
KPI section 4: other treatments and services	0 = incorrect understanding / 1 = lack of knowledge / 2 = good understanding but not complete / 3 = very good and sufficient understanding	Baseline visit, V6, V7, V8
KPI section 5: prognosis	0 = incorrect understanding / 1 = lack of knowledge / 2 = good understanding but not complete / 3 = very good and sufficient understanding	Baseline visit, V6, V7, V8
KPI section 6: management	0 = incorrect understanding / 1 = lack of knowledge / 2 = good understanding but not complete / 3 = very good and sufficient understanding	Baseline visit, V6, V7, V8
DAI 1: I don't need to take medication once I feel better	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 2: For me, the good things about medication outweigh the bad	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 3: I feel weird, like a "zombie" on medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 4: Even when I'm not in hospital I need medication regularly	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 5: If I take medication it's only because of pressure from other people	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 6: I am more aware of what I'm doing, of what is going on around me, when I am on medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 7: Taking medications will do me no harm	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 8: I take medications of my own free choice	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 9: Medications make me feel more relaxed	1 = true / 2 = false	Baseline visit, V6, V7, V8

DAI 10: I am no different on or off medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 11: The unpleasant effects of medication are always present	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 12: Medication makes me feel tired and sluggish	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 13: I take medication only when I am sick	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 14: Medication is a slow acting poison	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 15: I get along better with people when I am on medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 16: I can't concentrate on anything when I am taking medications	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 17: I know better than the doctor when to go off medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 18: I feel more normal on medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 19: I would rather be sick than taking medications	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 20: It is unnatural for my mind and body to be controlled by medications	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 21: My thoughts are clearer on medications	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 22: I should stay on medication even when I feel alright	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 23: Taking medications will prevent me from having a breakdown	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 24: It is up to the doctor when I go off medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 25: Things that I could do easily are much more difficult when I am on medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 26: I am happier, feel better, when taking medications	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 27: I am given medication to control behaviour that other people (not myself) don't like	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 28: I can't relax on medication	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 29: I am in better control of myself when taking medications	1 = true / 2 = false	Baseline visit, V6, V7, V8
DAI 30: By staying on medications I can prevent getting sick	1 = true / 2 = false	Baseline visit, V6, V7, V8
Sellwood Compliance Scale	1 = the patient never or very rarely misses doses of medication / 2 = the patient sometimes misses doses / 3 = the patient often misses doses / 4 = the patient	Baseline visit, V6, V7, V8

	rarely if ever takes the medication / 5 = the patient does not take any medication	
Kemp scale: which statement best describes your patients engagement in taking medication	1 = complete refusal / 2 = partial refusal; refuses depot or accepts only minimum dose / 3 = reluctant acceptance; only because compulsory or questions need every 2 days / 4 = occasional reluctance; questions need weekly / 5 = passive acceptance / 6 = moderate participation; no prompting, some knowledge and interest / 7 = active participation; ready acceptance, takes some responsibility / 8 = patient does not take any medication	Baseline visit, V6, V7, V8
CALPAS		

Work package 3: Medication

Variable	Available values	Assessed at time point
All (co)medication used since last visit	Yes / no	V6, V7, V8
Generic name	[open text field]	V6, V7, V8
Frequency of dose	[open text field]	V6, V7, V8
Dose (mg/day)	Continuous variable	V6, V7, V8
Reason for use	[open text field]	V6, V7, V8
Start date	Date	V6, V7, V8
Date last dose taken	Date	V6, V7, V8
Time last dose taken	Time	V6, V7, V8
Stopped	Yes / no	V6, V7, V8
Stop date	Date	V6, V7, V8

Work Package 3: (Serious) Adverse Events

Variable	Available values	Assessed at time point
Adverse event term	Open text field	When applicable
Start date of event	Date	When applicable
Intensity of event	1 = mild / 2 = moderate / 3 = severe	When applicable
Most extreme intensity	1 = mild / 2 = moderate / 3 = severe	When applicable

May event have been caused by study drug	Yes / no	When applicable
Has patient fully recovered	1 = yes / 2 = is currently recovering / 3 = recovered with symptoms / 4 = no / 5 = patient died / 6 = unknown	When applicable
Stop date of event	Date	When applicable
Is one or more SAE criteria applicable	1 = death / 2 = life threatening / 3 = requires (prolongation of) hospitalization / 4 = results in significant disability/incapacity / 5 = congenital anomaly/birth defect / 6 = important medical event / 7 = pregnancy / 8 = event is not serious	When applicable
Description of event	Open text field	When applicable
Is event (incl. severity) expected based on summary of product characteristics	Yes / no	When applicable
Medication that is potentially cause of event	1 = amisulpride / 2 = olanzapine / 3 = clozapine / 4 = other antipsychotic / 5 = patient does not use antipsychotics	When applicable

Work Package 3: physical examination

Variable	Available values	Assessed at time point
Weight	[open text field] in kg	V6, V7, V8
Waist	[open text field] in cm	V6, V7, V8

Work Package 3: Recreational drug use

Variable	Available values	Assessed at time point
Recreational drug used since last visit	Yes / no	V6
Drug	[open text field]	V6
Drug: Frequency of dose	[open text field]	V6
Drug: Dose	Continuous variable	V6
Drug: Route	[open text field]	V6
Drug: Reason for use	[open text field]	V6
Drug: Start date	Date	V6
Drug: Date last dose taken	Date	V6

Drug: Time last dose taken	Time	V6
Drug: Ongoing	Yes / no	V6
Drug: Stop date	Date	V6
Drug: Frequency last 4 weeks	[open text field]	V6
Drug: Dose last 4 weeks	[open text field]	V6

Work package 3: Hospitalisation and relapse

Variable	Available values	Assessed at time point
Did (re)hospitalisation occur since last visit	Yes {date} / no	V8
Did relapse occur since last visit	Yes {date} / no	V8