Outcome domain	Outcome	Concepts	Verbatim outcome from literature	Additional verbatim outcome from interviews
What decisions people make and/or the quality of those decisions	Recruitment (n=74)		Recruitment	
			Recruitment	
			Recruitment	
			Recruitment	
			Recruitment rates	
			Recruitment rates	
			Recruitment rate	
			Recruitment rate	
			Recruitment rate (over time)	
			Rate at which participants were recruited	
			Proportion of target population recruited	
			proportion of eligible individuals or centres recruited	
			Accrual (%)	
			Accrual	
			Actual accrual	
			Actually enrolled	
			Enrolment to the trial	
			Likelihood to enrol	
			Enrolment in trial	
			Enrolment	
			Consent rate	
			Consent rates	
			Proportion of patients consenting	
			Willingness to participate	
			Willingness to participate	
			Willingness to participate	
			Willingness to participate	
			Willingness to participate	
			Willingness to participate	
			Willingness to consent	
			Willingness to join a clinical trial	
			Willingness to enter trial	
			Willingness to participate in clinical trials	
			Participation	
			Participation choice	
			Rates of participation	
			Rate of participation	
			Rate of participation	
			Accepting participation	
			Intended to participate	
			Motivation to participate	
			Motivations to participate	
			Motives for agreeing to participate	
			Motivation	
			Reasons and concerns about participation	
			Reasons for (non-)enrolment	
			Reasons (for giving or not giving consent)	
			Reasons for accepting or declining treatment within a clinical trial	
			reasons for accepting or refusing participation	
			Reasons for participation	
			Reasons for entering the trial	
			Decisions	
			Decision to participate	
			Decision to participate	
			Decision to participate	
			decision whether or not to participate	
			Decision to participate	
			Clinical Trial Decision	
			Decision to participate	
			Proportion undecided	
			Proportion of patients for whom the possibility of participation as discussed	
			Proportion invited to participate in the trial	
			Proportion [of eligible veterans] who agree to participate	
			Agree or refuse to enter	
			Interest in participation	
			Acceptability of recruitment strategy	
			Rates of uptake (or refusal)	
			Randomisation (accept or refuse)	
			Acceptance of allocation	
			Informed participation	
			Trial offer	
			Taking part	
			Behaviour	
			Choice	
	Attrition (n=7)		Attrition	
			Retention	
			Dropped out	
			Rate of withdrawal	
			Adherence to study protocol	
			Level of adherence to[parent] study protocol	
			Adherence to chosen option	
	Therapeutic misconception (n=11)		Therapeutic misconception	
			Therapeutic misconception	
			Therapeutic misconception	
			Therapeutic misconception	

		Therapeutic misconception
		Therapeutic misconception
		Therapeutic misconception
		Therapeutic misconception
		Comprehension of research procedures and therapeutic misconception
		Individual treatment
		Personal care vs. generalizable knowledge
	Decision conflict (n=10)	Decisional conflict
		Decisional conflict
		Decisional conflict
		Decisional conflict
		Decisional conflict
		Decisional conflict
		Decisional conflict
		Decisional conflict
		Decisional conflict
		Decisional conflict
	Decision regret n=9)	Decisional regret
		Decisional regret
		Decisional regret
		Decisional regret
		Decisional regret
		Decisional regret
		Decision regret
		Regret
		Anticipated regret of negative outcomes
	Quality of decision (n=7)	Quality of consent process
		High quality decision making
		Decision making process measures
		Attributes of the decision making process
		Decision making
		Difficulties with decision making
		Valid [decision]
	Deliberation (n=2)	Make a deliberate decision
		Deliberation (weighing up)
	Values congruence n=15)	Values
		Values associated with outcomes
		Values of the research participant
		Value congruence with chosen option
		Values-based decision
		Understand that values affect the decision
		Discuss values with ether practitioner
		Informed participation that is somehow assessed as being congruent with individuals values and other criteria such as health outcomes
		Be clear about the option features that matter most
		Patients' decision making being supported b evidence of knowledge and consistent values (or satisfaction with the decision)
		The way the patient used the information [i.e. consistent with values]
		Ability to identify features of options that matter most
		Participation in a given study is consistent with their interests (research impact)
		Research impact
		Convenience or inconvenience that participating in the study would mean for you
	Anxiety (n=19)	Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Anxiety
		Patient state anxiety
		Consent anxiety
		depression
		emotional distress
		emotions
	Satisfaction (n=35)	Satisfaction
		Satisfaction
		Satisfaction
		Satisfaction
		Satisfaction
		Satisfaction
		Satisfaction
		Satisfaction
		Satisfaction
		Satisfaction
		Patient satisfaction
		Patient satisfaction and perception
		Satisfaction with decision making
		Satisfaction with decision making
		satisfaction with decision making process
		Satisfaction with the decision (to participate or not)
		Satisfaction and anxiety with decision making

		Satisfaction with decision to participate or decline	
		Decisional satisfaction	
		Satisfaction with quality and quantity of information	
		Satisfaction with ease and reading of consent statement	
		Satisfaction with the information provided	
		Satisfaction with the media used	
		satisfaction with media used to convey the information	
		Satisfaction with the discussion	
		Satisfaction with the consent process	
		Satisfaction with the consent consultation	
		Satisfaction and anxiety with the consent process	
		satisfaction with the study	
		satisfaction with the information provide about the parent study	
		Satisfaction and usefulness of intervention	
		Satisfaction (with intervention)	
		Satisfaction with doctor-patient interaction	
		Satisfaction with communication with health professional	
		Satisfaction with the doctors consultation styles and information on trial concepts	
	Confidence (n=5)	Confidence	
		Confidence in patient's decision and whether an informed choice was made	
		Confidence in the ability to participate	
		Confidence in doctors	
		Confidence in the messenger [recruiter]	
	Experience (n=5)	Experience	
		Experience	
		Experience of the clinical trial	
		Experiences and feelings over being included	
		Subjective experience of the process	
Experiences of decision-making in this context	Burden (n=3)		Burden of the consent process
			Burden of informed consent
			Emotional burden
	Time to decide (n=17)	Time	
		Time	
		Time factor	
		Time spent reading the information	
		Time taken to administer	
		Time taken to administer the consent process	
		Time to make the decision	
		Length of time	
		Length of time taken	
		Length of time of the informed consent process	
		Length of consultation	
		Length of consultations	
		Consultation length	
		Consultation length	
		Duration	
		Weren't rushed	
		Delay in decision making or request for more information/further consultations	
	Feeling valued (n=1)		Making a valued contribution
	Respect for decision making (n=2)	Respect	
		Rights were respected	
	Comfortable (n=1)	Less comfortable	
	Coercion (n=4)	Coercion	
		Feeling of coercion	
		Threats	
		Manipulation or deception	
	Helpful (n=1)		Whether the patient felt like it was helpful
	Authenticity (n=1)		Authenticity of someone's consent
	Communication (n=7)	Communication of decision	
		Communication with trial recruiters	
		Patient-clinician communication	
		Patient-practitioner communication	
		Patient-recruiter communication	
		The number of issues about trials discussed	
		The overall complexity of the trial discussion	
	Empowerment (n=2)		Empowers the person in making their decision
			Empowered choice
	Likelihood to engage with future research (n=1)	Consider participating in future trials	
	Protection of rights (n=8)	Protection of human rights	
		Rights of participants	
		How well they felt their human rights were protected	
		Patient decision making rights	
		Right to decide	
		Beneficence	
		Non-maleficence	
		Justice	
	Autonomy (n=11)	Autonomy	
		Autonomy	
		Autonomy	
		Autonomy	
		Autonomy	
		Autonomy of the participant	
		Personal autonomy	
		Competency	
		Competency	
		Decision-making capacity	

	Personhood	Personhood
Voluntariness (n=25)		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntariness
		Voluntary
		Pressures
		Pressure
		Pressured to participate
		Under pressure to join the trial
		Sense of control - locus of control or perception of who made the decision
		Self-governance
		Make own decision
		Involvement in decision
		Become involved in preferred ways
		Participation in decision making
		Preference fro involvement in decision making
		Knew they could refuse or withdraw
		Physicians influence on participation decisions
		Influences in the decision making process
Ask questions (n=4)		Asking questions
		Opportunities to ask questions
		Encouragement in asking questions
		Number of questions asked by the patient
Altruism (n=3)		Altruism
		Altruism
		Burden or benefit [conditional altruism]
Equipoise (n=4)		Equipoise
		Treatment preference
		Treatment preference
		Patient preferences
Knowledge (n=186)		Knowledge
**italics denotes items depiciting knowledge about*		Knowledge
		Knowledge
		Knowledge
		Knowledge
		Knowledge
		Knowledge
		Knowledge
		Knowledge
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		Knowledge
		Knowledge
		Knowledge
		Knowledge
		Knowledge
		Knowledge
		Knowledge/retention/recall
		Knowledge and understanding
		Knowledge and understanding of the parent study.
		Knowledge of the trial
		Knowledge of the trial
		Knowledge about randomised trials
		Knowledge about clinical trials
		Knowledgeable about clinical trials, generally
		General knowledge about clinical trials
		Knowledge of treatment and side effects
		Knowledge of research aspects
		Patient Knowledge of Information Relevant to Informed Consent to Clinical Trials
		Objective knowledge
		Awareness of medical and clinical trial issues:
		Awareness
		Diagnosis
		trial title
		ethics
		equipoise
		informed consent
		voluntary participation
		voluntary nature of participation
		right to refuse to enter
		right to withdraw
		right to withdraw
		freedom to withdraw

	can stop at any time
	informed who to call
	allowed to discuss with others
	treated as an adult
	informed rights as a person
	informed could talk to anyone
	confidentiality
	Aim
	scientific background
	background
	purpose of the study
	purpose of trial
	trial objective
	concept of clinical trial (in general)
	specific purpose
	research study goals
	research value of treatment
	concepts related to the research design and conduct of the parent study (for example the concept of randomisation and how data will be collected)
	purpose
	eligibility requirements
	design
	study design
	randomisation
	randomisation
	random assignment
	meaning of random assignment
	concept of randomisation
	Proposed treatment
	treatment procedures
	treatment objective
	effectiveness of intervention
	knowledge of trial medication
	familiarity with the procedures and medication
	mechanism of action of study drug
	concepts related to the condition of intervention involve din the parent study (for example, potential benefits or harms of the intervention)
	available alternative treatments
	alternative treatments
	alternative treatments
	know the options and their features
	placebo
	treatment risk
	risks/side effects
	side effects
	side effects
	side effects
	side effects
	benefits and risks
	knowledge of probabilities of outcomes
	perceived personal benefits
	perceived negative aspects
	duration of the study
	Study endpoints
	clinic visits schedule
	extra tests
	procedures
	risk of outcome measure assessment
	formalities
	finance
	informed how expenses handled
	Altruism
Disclosure	Disclosure
	Disclosure
	Information disclosure
	Full information disclosure
	Preference for information
	Preferences for information
	Information preference
	Preferred verbal (Word) or numerical descriptors or both [for potential benefits and risks]
	Adequacy
	Adequacy of information
	Adequacy of information
	Adequacy of the information to enable:
	Usefulness of trial information
	How useful was the information
	Importance of information
	Information transmitted
	Sufficiency of information
	Amount of information
	Amount of information
	Length of information
	Level of detail
	Subjective evaluation of the given information
	Desire for further information
	How much of the information they read
	Type of information
	Information you were given about the trial by the surgeon in clinic

			Letter and leaflet explaining about the trial which you received by post
			Accuracy f the consent form
			Statements pertinent to making a decision
		Recall	Recall
		**italics denotes*	Recall
		items depiciting	Recall
		recall of	Recall
			Recall
			Recall
			Recall
			Recall
			Recall
			Recall
			Recall of trial information (as discussed with doctor)
			Recollection
			Recollection
			Remember [recall]
			Remember
			Retention of information
			Retention of information
			Retention of trial related information
			Retention of consent information
			Retention of required consent information
			Retention o knowledge
			Retention f knowledge and understanding
			Retained knowledge
			Retention of actual informed consent understanding
			Communicating trial concepts and procedures
			Making sure of what I heard
			specific study
			purpose of the study
			recall of RCT process
			procedures and assessments
			remuneration
			human rights
			participants rights: rights to confidentiality and who has the right to access source data, that participation is voluntary with the right to withdraw, compensation should injury occur, and what happens to blood samples.
			memory for key aspect s of the decision
			participating in the study
			receiving an informed consent document
			recall of information about IC
			recall of content
			names of study medication
		Informed consent	Appropriateness of consent procedure
			Informed Consent
			Subjective informed consent
			Informed consent
			Quality of informed consent
			Quality of informed consent
	Understanding (n=467)		Understanding
	**italics denotes items depiciting understanding about*		Understanding
			Understanding
			Understanding
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Understand/Understanding
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Understanding (or knowledge)
Understanding/knowledge
Knowledge and understanding
Participants Understanding
Perception f understanding
Perceived Understanding
perceived (subjective) understanding
Perceived/subjective understanding
Subjective understanding
Subjective understanding
Subjective understanding
Objective understandings
Objective understandings
Overall understanding
Overall understanding
Actual (objective) understanding
Actual understanding
Actual and perceived understanding
Understanding of clinical trials
Understanding of (hypothetical) trial
Understanding of clinical trial
Understanding of trial concepts
Understanding of the trial
Understanding of key concepts in clinical trials
Understanding of trial design
Understanding of the aim
Understanding (trial purpose)
Understanding of the purpose of informed consent
Patient Perception of Being Informed (PPBI)- assess understanding of:
Sign a form
Meaning
the intersubjective understanding which exists between the sender and the receiver
the understanding of the graphic symbols
the cognitive understanding of the subject matter
the understanding of the message itself
Participants awareness of enrolment in a clinical trial
policies
future studies
Diagnosis
Prognosis
injury
The main reason AIDS clinical trials are done is so to improve the treatment of future HIV-positive or AIDS patients
Because I am participating in a clinical trial, it is possible that the study sponsors, government agencies, or others who are directly involved in my care could review my medical tissue analysis
human rights protections (i.e. confidentiality)
meaning of trial terms
When I signed the consent form for my current cancer therapy, I knew that I was agreeing to participate in a clinical trial.
All the treatments and procedures in my clinical trial are standard for my type of cancer.
In my clinical trial, one of the researchers' major purposes is to compare the effects (good and bad) of two or more different ways of treating patients with my type of cancer, in
In my clinical trial, one of the researchers' major purposes is to find the highest dose of a new drug or treatment that can be given without causing severe side effects.
In my clinical trial, one of the researchers' major purposes is to find out what effects (good and bad) a new treatment has on me and my cancer.
The treatment being researched in my clinical trial has been proven to be the best treatment for my type of cancer.
In my clinical trial, each group of patients receives a higher dose of the treatment than the group before, until some patients have serious side effects.
There may <u>not</u> be direct medical benefit to me from my participation in this clinical trial.
Because I am participating in a clinical trial, it is possible that the study sponsor, various government agencies, or others who are not directly involved in my care could review
What the researchers are trying to find out in the clinical trial
Which of these treatments and procedures are experimental
Overall, how well did you understand your clinical trial when you signed the consent form?
What is a clinical trial as opposed to standard care?
what are the types of clinical trials (phase I, ii, iii)
why do we do so many tests on clinical trials, like scans, and questionnaires and so forth?
why is it necessary to do clinical trials? Why cant we just use things that should work?
how are patients protected in clinical trials?
how, basically, do statistics work?
who do we do blood testing and tissue testing?

How people make decisions	*what is pharmacokinetics?* *who makes money if I join a clinical trials?* *uncertainty regarding treatment outcomes* *given the name of the illness* *explained everything required* *explained time required* *Understood terms* *Information confusing* *informed may be helped* *the study involves research* *participate in research (research contribution)* *effectiveness/efficacy* *participating in research* *that investigators, unlike clinicians, will be relying on the participants efforts to gather information that might help others* *asking the patient directly if the information had been understood* *relation ship they will have with the investigator (research relationship)* *the process and meaning of consent* *consent forms* *the process and meaning of consent* *consent form* *process and meaning of consent* *The consent form I signed tells me what will happen when I participate in my clinical trial* *When I signed the consent form for my currency HIV/AIDS treatment, I knew I that was agreeing to participate in a clinical trial.* *Consent information* *The consent form* *why do patients have to sign a consent form?* *Purpose of study* *the nature of the trial* *trial procedures* *the nature of the trial* *Purpose of the study* *trial procedures* *study procedures* *research goal* *Nature and purpose of the trial* *purpose and procedures* *study purpose* *in my clinical trial, one of the researchers' major purposes is to compare the effects (good and bad) of two or more different ways of treating patients with HIV/AIDS, in order to* *understanding of the aims of the study* *purpose* *make sense of trial* *the diagnostic procedures and tests at baseline* *purpose* *study purpose* *procedures* *procedures* *The treatments and procedures you will undergo* *specific study procedures* *trial procedures* *trial procedures* *trial procedures* *trial procedures* *ideal method of treatment* *Treatment involves research* *experimental aspects* *The treatment being researched in my clinical trial has been proven to be the best treatment* *individualisation* *research value of treatment* *The fact that your treatment involves research* *randomisation* *what randomisation means* *randomisation* *random selection of the treatment arm* *randomisation* *randomisation* *randomisation* *randomisation* *randomisation* *randomisation* *randomisation* *randomisation* *concept of randomisation* *Treatment randomisation* *randomisation* *why do we use randomisation?* *After I agreed to participate in my clinical trial, my treatment was chosen randomly (by chance) from two or more possibilities.* *Treatment allocation i.e. receive drug or placebo* *allocation to treatment* *After I agreed to participate in my clinical trial, my treatments chosen randomly (by chance) from two or more possibilities* *treatment allocation* *Placebos* *the use of two different treatments* *treatment assignment* *blinding* *In my clinical trial, both my provider and I know which treatment I am receiving* *Placebo controlled*

in my clinical trial, I have a chance of getting a placebo in combination with treatment. A placebo is a pill that does not contain and medicine or drug
placebo
why do we use placebo
Voluntariness
voluntary participation
of voluntary choice to participate
voluntariness
voluntariness
the fact that participation in the clinical trial is voluntary
participation is voluntary
voluntariness
voluntary nature of participation
Voluntarism
If I had not wanted to participate in the clinical trial, I could have declined to sign the consent form
voluntariness
participation is voluntary
did not feel forced to enrol
If I had not wanted to participate in this clinical trial, I could have declined to sign the consent form.
The fact that participation in the clinical trial is voluntary
Right to withdraw
right to withdraw
right to withdraw
withdrawal
awareness of the possibility of withdrawing from participation at any time
I will have to remain in the clinical trial even if I decide someday that I want to withdraw
withdrawal
conditions of withdrawal of consent
I will have to remain in the clinical trial even if I decide someday that I want to withdraw.
Side effects
I was given a list of possible side effects relating to the drugs studies in my clinical trial
major associated risks
side-effects
possible risks
risks
risks and benefits
risks and benefits
benefits and risks
risks and benefits
risks and benefits
risks and benefits
risks and benefits
risks and benefits
risk through participation
benefit for future patients
dis/advantages of participating
Possible risks and discomforts of participating in the trial
any direct benefits to you of participating gin the clinical trial
whether your participation in this clinical trial may benefit future patients
the clarity of the explanation of risks and benefits of study participation
risks of participation
benefits of participation
Compared with standard treatment, my clinical trial does not carry any additional risks or discomforts
If the e treatment to which I have been assigned in my clinical trial gives me side effects, the provide can change it to another treatment
risk
risk
benefit
benefit
benefit
consequences
risks of the study drugs on contraception and exclusion of pregnant women
risks
potential benefits
Risks and benefits
relevant risks explained
informed possible will suffer
benefits were listed
risks
potential benefits
likelihood of certain events occurring
Compared with standard treatments for my type of cancer, my clinical trial does not carry any additional risks or discomforts.
The possible risks and discomforts of participating in the clinical trial
The possible benefits <u>to you</u> of participating in the clinical trial
Study duration
Amount of time you will be in the clinical trial
I have been informed how long my participation in this clinical trial will last
I have been informed how long my participation in this clinical trial is likely to last.
How long you will be in the clinical trial
equipoise
equipoise
care outside the trial
Confidentiality of personal info
privacy and confidentiality
that your data from the clinical trial is kept confidential
measures used to protect confidentiality
confidentiality
confidentiality

	confidentiality
	confidentiality of records
	The effect of the clinical trial on the confidentiality of your medical records
	study intervention
	knowledge of trial medication
	nature and purpose of intervention
	Expenses reimbursed
	reimbursement
	who will pay for treatment if you re injured or become ill because of participation in their clinical trial
	who will pay for treatment if you re injured or become ill because of participation in their clinical trial
	non-payment for participating in the study
	If I am injured or become ill as a result of participation in this clinical trial, costs of any medical care related to the injury will be billed to me and /or my insurance company
	research related injury compensation
	remuneration
	The consent form I signed describes who will pay for treatment if I am injured or become ill as a result of participation in this clinical trial.
	informed may help others
	How your participation in this clinical trial may benefit future patients
	The main reason cancer clinical trials are done is to improve the treatment of future cancer patients.
	By participating in the clinical trial, I am helping the researchers learn information that may benefit future HIV/AIDS patients
	By participating in this clinical trial, I am helping the researchers learn information that may benefit future cancer patients.
	treatment alternatives
	alternatives
	Alternatives for treatment off trial
	treatment alternatives
	the alternatives to participation in the clinical trial
	potential alternatives
	available alternative treatments
	alternatives
	alternatives
	My providers did not offer me any alternatives besides treatment in this clinical trial
	treatment alternatives
	My doctors did not offer me any alternatives besides treatment in this clinical trial.
	The alternatives to participation in the clinical trial
	alternatives
	alternatives
	Eligibility i.e. pregnancy
	Why are we so selective about who goes son a clinical trial?
	GP being informed
	authorisation
	the sponsor
	FDA status of study intervention
	relevant legislation
	contact details
	whom you should contact if you have questions or concerns about the clinical trial
	the consent form I signed lists the name of the person (ore persons) whom I should contact if I have any questions about the clinical trial
	study contact information
	recourse in the event of being harmed (i.e. whom to contact with additional questions or concerns)
	The consent form I signed lists the name of the person (or persons) whom I should contact if I have any questions or concerns about the clinical trial.
	safety
	in my clinical trial, one of the researchers' major purposes is to test the safety of a new drug or combination of drugs
	in my clinical trial, one of the researchers' major purposes is to find out what effects (good or bad) a new treatment has on me
	safety and efficacy of the tested medicines
	safety and efficacy of the tested medicines
	safety and efficacy of tested medicine
	In my clinical trial, one of the researchers' major purposes is to test the safety of a new drug or treatment.
Comprehension **italics denotes items depiciting comprehension about*	Comprehension
	Comprehension
	Comprehension
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	Comprehension
	Comprehension
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	Comprehension
	Comprehension
	Comprehension
	Comprehension
	Comprehension
	Comprehension
	Comprehension
	Comprehension
	Comprehensibility
	Comprehension and recall of trial information
	Ease of comprehension
	Confusion
	Draw inferences from the information
	Thinking
	Appreciation
	Reasoning
	Balance pros and cons
	evidence of comprehension of the information provided and the patients situation beyond factual recall

	study-background (why is the study
	being conducted, by whom, which are the involved centres,
	why are you being asked to participate, how will be the study
	conducted)
	Elements of treatment and diagnosis
	trial purpose and nature
	Purpose of research
	study purpose
	purpose of the study
	receive best possible treatment
	what is a clinical trial?
	is the treatment given as a trial?
	what is the purpose of the trial?
	eligibility i.e. pregnancy
	contraindications i.e. pill
	Purpose of consent form
	Elements of informed consent
	study procedures
	study procedure
	treatment protocol
	rights (to withdraw from the study, refuse to
	participate, to compensation in case of injury, confidentiality)
	Elements of patient rights
	voluntariness
	Autonomy/decision making
	choice
	were you explained that you will still receive treatment if you decline the trial?
	were you explained that your participation is voluntary?
	right of refusal
	right of withdrawal
	withdrawal
	withdrawing from the study
	Freedom to withdraw
	were you explained you can withdraw?
	confidentiality
	Confidentiality
	confidentiality
	Privacy
	compensation
	financial
	design (how many groups, what determines
	which patient will go to which group, who will know which
	treatment you are getting, how the drugs are to be taken,
	follow-up visits)
	randomisation
	randomisation
	randomisation and placebo trial design
	Randomisation (accept or refuse)
	how is the treatment assigned?
	why is the assign method used?
	blinding
	meaning of double-blind
	placebo
	Interventions
	Action of drug A
	Acton of drug B
	side effects
	side effects
	side effects/risks
	risks
	risks
	risks/side effects
	risks and benefits
	benefits and risks
	benefits
	benefit to others
	personal benefit
	Repeated study procedures
	Duration of trial
	miscellaneous (approval for the conduct of the study,
	sponsors, centres involved in the study, whom to contact in
	case of queries/emergency, treatment subsequent to study
	period)
	reasons to be taken off study
	what re alternatives to treatment?
Perceptions	Perceptions of clinical trials
**italics denotes*	Perceived risk of clinical trial participation
items depiciting	Perceptions of the consent process
perceptions about	Participants perceptions of the process of seeking informed consent
	Perceptions regarding their understanding of the study
	Perceptions of the [intervention]
	Perceived side effects
	Perception of risk
	Accurate risk perceptions
	Accurate risk perceptions
	Percieve/perception

				value of the intervention	
				physicians language	
				structure of consultation	
				complexity of conversation	
				saturation	
				dialogue atmosphere	
				trial related uncertainty	
			Beliefs	Belief about risk of participating in research	
				Clinical trial beliefs	
				Positive beliefs	
				Emotions and thoughts	
				Hopes	
	Trust (n=7)			Trust	
				Trust	
				Trust	
				Trust	
				Trust	
				Trust	
				Trust	
	Relational affects (n=8)			Personal doctor-patient relationship	
				Personal relations	
				Relation to physician	
				Research relationship	
				Relationships with trial recruiters	
				Inter-relational communication	
				Presence of friends or family members	
				Interactions	
	Attitude (n=17)	*italics		Attitudes	
	denotes items depiciting attitudes about			Attitudes to trials	
				Attitudes towards the trial	
				Attitudes towards RCTs	
				Attitudes about participation	
				Attitudes towards participating	
				Attitude toward participating in the trial [positive or negative]	
				Attitudes about clinical trial entry	
				Attitudes to trial barriers	
				Attitude towards informed consent process	
				Attitudes towards consent procedure	
				form preferred	
				discouraged research participation	
				participation in fictive RCTs	
				enrolment of children in clinical research	
				role of physicians	
				clinical research in general	
	Expectations (n=8)			Expectations	
				Expectations	
				Expectations of the trial	
				Expectations for the trial	
				Expectations towards the trial	
				Expectations regarding personal adherence	
				What I expected to occur	
				Previous research involvement	
	Choice awareness (n=7)			Decision needs to be made	
				Recognition that a decision needs to be made	
				Expression of choice	
				Make an informed choice	
				Meaningful choice	
				Attributes of the choice	
				Evaluation of informed choice	
	Choice to engage with research team (n=1)				Choice about whether they're going to engage with the research team
Personal characteristics that influence the decision	Health literacy (n=1)			Health literacy	
	Reading recognition (n=2)			Reading recognition	
				Easy to read	
	Agency (n=1)				Agency
Assessment level - *Subsequently excluded outcomes	Clinician outcomes (n=6)			Clinician outcomes	
				clinician researcher satisfaction with the informed consent process	
				ease of use of intervention to improve gaining of informed consent	
				clinical researcher ease of use of informed consent process	
				research unit staff and environment	
				research investigators team	
	Healthcare system outcomes (n=10)			Healthcare system outcomes	
				System outcomes	
				Legal protection for doctors and hospitals	
				complaints and litigation	
				litigation rates	
				economic/resource use	
				cost-effectiveness	
				cost-effectiveness	
				costs	
				cost of intervention	
TOTAL				**1006**	**10**