Multiprofessional Advance Care Planning and shared decision making for end of life care

MAPS Trial

Sponsor-Investigator (Principal Investigator): *Tanja Krones, MD, PhD*

Head physician Clinical ethics

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Table of Contents

1 GENERAL INFORMATION 3

2 STUDY SYNOPSIS 5

STUDY FLOW CHART 7

3 LIST OF ABBREVIATIONS 9

4 INTRODUCTION 10

4.1 BACKGROUND 10
4.2 RATIONALE FOR CURRENT STUDY 12

5 STUDY OBJECTIVES AND OUTCOMES 14

6 STUDY DESIGN 15

6.1 STUDY OUTCOME MEASURES 18

7 SUBJECT SELECTION AND WITHDRAWAL 19

7.1 SUBJECT RECRUITMENT AND SCREENING 19
7.2 INCLUSION CRITERIA 20
7.3 EXCLUSION CRITERIA 20
7.4 WITHDRAWAL CRITERIA 21

8 EFFICACY AND SAFETY VARIABLES 21

8.1 EFFICACY VARIABLES 21
8.2 SAFETY VARIABLES 24

9 COURSE OF STUDY AND FOLLOW-UP 25

9.1 SCREENING VISIT 25
9.2 VISIT 1 25
9.3 INTERVENTION VISITS 2-4 26
9.4 DISCHARGE VISIT (VISIT 3, 4 OR 5) 26
9.5 FOLLOW UP INTERVIEW AT 3 MONTHS 27
9.6 FOLLOW UP INTERVIEW AT 6 MONTHS 27
9.7 FOLLOW UP INTERVIEW AT 3 MONTHS AFTER DEATH 27

10 SAFETY 28

11 STATISTICS AND DATA ANALYSIS 28

11.1 POWER CALCULATION 28
11.2 ANALYSIS 29

12 REGULATORY ISSUES 29

12.1 ETHICS APPROVAL AND ETHICAL CONDUCT OF THE STUDY 29
12.2 SUBJECT INFORMATION AND CONSENT 30
12.3 CONFIDENTIALITY 30
12.4 INSURANCE 31
12.5 FUNDING 31
12.6 AUDITS AND INSPECTIONS 31

13 STUDY MANAGEMENT 31

13.1 DATA MANAGEMENT 31

14 PUBLICATION POLICY 31

15 SIGNATURES 32

16 REFERENCES 33

1 GENERAL INFORMATION

Sponsor-Investigator (Principal Investigator):

Name:Tanja Krones,
Head Clinical Ethics
Address: Derm C 18, Gloriastrasse 31, 8091 Zürich
Phone:41 2553470
Email:tanja.krones@usz.ch

Conceptional team:

Name: Nikola Biller-Andorno, Director, Institute for Biomedical Ethics, University of Zurich
Address: Pestalozzistrasse 24 8032 Zürich
Phone:044 6344081

Name: Christine Mitchell, Director
Office of Ethics Associate Director,
Clinical Ethics Children's Hospital Boston
350 Longwood Avenue
Longwood Galleria – GL116
Boston, MA 02115
617-355-6920 (office)

Name: Rebecca Spirig
Head of the Center of Clinical Nursing Science, University Hospital Zürich and Professor at Institute of Nursing Science, University of Basel, Basel, Switzerland
Address: Rämistrasse 100
Phone: 044 255 2194

Name: Kathrin Zaugg, Stefan Obrist: Leitende Ärztin and Oberarzt Radiation Oncology and Palliative Care competence Center
Address NUK E 17
Phone: 044 255 4204
Email: kathrin.zaugg@usz.ch, stefan.obrist@usz.ch

Settimio Monteverde, nursing ethics
monteverde@gmx.com

Different Departments agreed to the participation in the trial (Physician/Nurses/Social Service) (see also below)

Edouard Battegay/ Beatrice Biotti/ Martin Bruesch/ Karsten Bodden/Lars French/Margarete

	Garlichs/Theodore Otto/ Christoph Renner/Esther Linka/Tina Plötz/Thomas Rosemann/ Stefan Segerer/Michael Weller/Alexander Knuth
	Sozialdienst and Seelsorge University Hospital Zurich
	Study Team (, Physician Palliative Care (Dr. Barbara Loupatatzis), Social Worker (Theodore Otto), Study Nurse (CTC, Nursing Science Isabelle Karzig
Study sites:	*Departments of Internal Medicine/Multimorbidity Network (E. Battegay/head of nursing), Neurology (M. Weller/head of nursing), Oncology (A. Knuth/head of nursing) Dermatology (L French/head pf nursing), Nephrology (S Segerer/head of nursing) Radiooncology (, S Obrist/head of nursing), Primary Care (T. Rosemann); Emergency Care (M. Brüesch) NN.*
Other institutions involved in the trial :	*Beizeiten Begleiten Team (Jürgen in der Schmitten, Düsseldorf, Main International Cooperating Partner, Planning of educational intervention), Swiss red cross (main national cooperating partner, Osman Besic, certification of the educational intervention) , Harvard University (co coordinator Christine Mitchell, Angelo Volandes, finalizing the video decision aids, support in educational intervention and final study prodecures) Ottawa Health Research Institute (Dawn Stacey, Ottawa, finalizing the decision aids), Institut Neumünster (Evelyn Huber) ; Lighthouse (Stefan Obrist) planning the implementation of ACP in the ambulatory sector, Respecting Choices (Linda Briggs, Bud Hammes, USA consultants), Respecting Patient Choices (Karen Detering Melbourne University Hospital, consultant) Jane Seymour (consultant), Joe Weiner (consultant)all of these institutions finalizing the educational intervention*

2 STUDY SYNOPSIS

Sponsor-Investigator	*Tanja Krones MD PhD,*
Study Title:	*Multiprofessional advance care planning and shared decision making*
Short Title/Study ID:	*MAPS Trial*
Amended Protocol Version and Date:	*22th of April 2013, Version 4.0*
Methodology:	*Single ~~(attending physician)~~blinded randomized controlled trial of a complex intervention (multiprofessional training) on Advance care planning and shared decision making*
Study Duration:	*Patients: informed consent to last study-specific procedure 6 months; relatives/surrogate decision maker 9 months*
Study Center:	*University Hospital Zurich, NN*
Investigator(s):	*Study Team: T. Krones, , B. Loupatatzis, T. Otto, I.Karzig, Heads of referrals and local conception: S. Obrist, G. Eisele, D. Poster, S. Bader, T. Rordorf, K. Schad, L. Zimmerli*
Objective(s)/ Outcome(s):	*Efficacy measure: end of life wish on resuscitation known (if alive) or fulfilled (if not alive) at the end of life (primary endpoint) after 6 months: other end of life wishes known or fulfilled known/not known/ met/not met, Patient bereavement questionnaire Question 6 Detering et al 2010; Question D4 TIME Instrument; crosscheck with AD, medical charts and asking main physician in charge (attending physician, Specialists as indicated by patient) whenever possible (Detering et al 2010, Teno et al 2004).;* *secondary endpoints for patients are , satisfaction of patients with care and information at discharge (Detering et al 2010), Decisional conflict DCS (O' Connor et al 1995) at discharge and after 6 months (if alive), Depression (HADS) number of ADs and of power of attorneys after 6 months,* *Secondary variables for main relative/ surrogate decision maker are: HADS (Hospital Anxiety and Depression Scale)(all patients relatives/surrogates): Impact of Event Scale (IES), German version (IES) in patients who died, the TIME questionnaire (German version) will be applied in relatives/surrogate decision makers as secondary endpoint for patients after death (Teno et al 2004, In der Schmitten et al 2011 a,b,c)*
Number of Subjects:	*180 Patients and their main/nominated relative/surrogate decision maker*

Diagnosis and Main Inclusion Criteria:	• *Patients in which the treating physician on the ward would not be surprised if the patient died during the next year; surprise question of Weissman et al 2011; Patients are prioritized for being approached for the study if more primary criteria are fulfilled* • *Male and female patents above 18 years of age and with full decisional capacity* • *Signed Informed Consent after being informed* • *Patients able to appoint a SM and attending physician to be contacted after discharge*
Main Exclusion Criteria:	*Patients not capable of speaking German* *Inhouse patients being discharged within the next 2 days or ambulatory patients not regularly coming to the wards (at least every two months)* *Patients in obvious denial of their illness and prognosis*
Study Schedule:	*Month Year of First-Subject-In: (planned): Juni 2013* *Month Year of Last-Subject-Out (planned): May 2015 (last relatives interviewed if patient died)*
Statistical Methodology:	*We calculate cross tabs (Fishers exact test 2 x 2 cells) and logistic regression models separately for categorical data for the main outcome variable(s). A separate analysis will be undertaken on patients who died during the study period comparing intervention and control group via cross tabs and logistic regression models adjusting for relevant variables* *Besides the intention to treat analysis including all randomized patients, a per protocol analysis will be undertaken.* *Scale scores of secondary variables will be calculated according to published criteria and means compared between intervention and control group via T Tests or Man Whitney U tests if T Test is not appropriate. Multiple linear regression models are also calculated to adjust for relevant variables*
Statement:	*This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki as well as all national legal and regulatory requirements*.

STUDY FLOW CHART

STUDY SCHEDULE General

	Year 1 2012		Year 2 2013				Year 3 2014				Year 4 2015			
Quarter/ months	3/ July	4/ 6	1/ 9	2/ 12	3/ 15	4/ 18	1/ 21	2/ 24	3/ 27	4/ 30	1/ 33	2/ 36/	3	(4)
Expert Interviews	**x**	**x**	**x**	**x**										
Final Design of Decision Aids (Paper and Video Based)	**x**	**x**	**x**	**x**										
Testing Assessment tools	**x**	**x**												
Final Design of educational and patient Intervention	**x**	**x**	**X**	**x**										
Piloting of Intervention		**x**	**x**	**x**										
Advance care planning Staff training			**x**	**x**										
Intervention					**x**	**x**	**x**	**x**	**x**					
Data retrieval					**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	
Follow up					**(x)**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	
Analysis										**x**	**x**	**x**	**x**	
Publication						**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**(x)**

Study Schedule intervention

Study Periods	***Screening***	***Intervention***				***Follow-up***
Visit		***1***	***2***	***3-5***	***3-5***	***Telephone/ Qal Interviews***
Day	***-1/-3 (physician on ward with study team)***	***0***	***1-2***	***2/ +8***	***Before dis-charge***	***3 and 6 months after intervention/3 month after patient died***
Subject Information and Informed Consent		*x*				
In- /Exclusion Criteria	*x*	*x*				
Demographics		*x*				
Baseline Assessment		*x*				
Randomization		*x*				
Advance care Planning/ routine discharge care planning		*X Deciding on day of Inter-vention only I: supply Dec. Aids*	*X Interventi on ACP or Discharg e Planning*	*X*		*x*
Primary Variables						*X (subjects/relati ves/attending physician)*
Secondary variables					*X*	*X (subjects/relati ves/attending physicians) X (relatives bereaved questionnaires)*
Safety					*X*	*X*

3 LIST OF ABBREVIATIONS

AE	Adverse Event
CRF	Case Report Form
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
ACP	Advance Care Planning
AD	Advance directive
POLST	Physician orders for life sustaining treatment
IC	Informed consent
SDM	Shared decision making
SM	Surrogate decision maker
EbM	Evidence-based medicine
CPR	Cardiopulmonary resuscitation
CPD	Continuous professional development program
DA	Decision aids
HADS	Hospital Anxiety and Depression Scale
IES	Impact of Event Scale
TIME	Toolkit of Instruments to measure end of life care
DCS	Decisional conflict scale

4 INTRODUCTION

4.1 BACKGROUND

Over the past decades two movements have had an especially high impact on the view on end of life issues and the treatment of palliative patients: First, the development of Palliative Medicine, determining and promoting treatment goals beyond solely focusing on healing a terminally ill patient in the last months of life. Second, the development of "Biomedical" Ethics beyond the professional medical ethics of physicians, contributing to the awareness of respecting patients' autonomy (or prerogative to make their own health care decisions) and "dying with dignity" as central values of health care. In the UK and the US, starting in the 1970ties, both movements were promoted and several efforts were made to implement best palliative care, to discuss patients' wishes and enhance quality of care, decision-making and a "good death". One of the central results of these scientific, philosophical and societal developments was the ethical, legal and political conceptualization of advance directives (ADs) to be used, if patients became incapable of making their own decisions at the end of their lives, as it is often the case. By the end of the 80ties it was believed that much would be improved if ADs, already having been ethically and legally recognized as important tools to document values and wishes of patients were more widely known and filled out. Several approaches and formats were tested around the world, the largest benchmarking study being the SUPPORT Study (The SUPPORT Principle Investigators 1995). This large Study To Understand Prognoses and Preferences about Outcomes and Risks of Treatment however failed to increase not only the number of ADs filled out (which in itself is secondary as a meaningful clinical endpoint) but also failed to reach its main goals: to improve quality of discussions and of care as perceived by health care teams, patients and their families and, most important with regard to the principle of autonomy at the end of life: the fulfilment of documented wishes of patients in medical treatment decisions at the end of life. The rate of the ADs in the US in regions without specific advance care planning/shared decision making programs on end of life care typically does not exceed 15-25%, similar to the average rate reported in Australia (Detering et al 2010), Benelux (one third have plans made, 8% in writing, Meeusen et al 2011) and Germany (in der Schmitten 2011 a, b ,c). The current rate in Switzerland is probably slightly lower according to the GFK custom research study sponsored by the BAG (Vodoz 2009); in their study, 66% of the general population over 65 years and 69% over 75 years knew what an advance directive is. Out of these, 20% (over the age of 65) and 29% (75 +), corresponding to about 12% /21% of the whole population at this age were reported to possess an advance directive.

Another approach was discussed and promoted –sometimes within the realm of ADs, sometimes as an alternative due to the lack of impact of ADs on medical care at the end of life: The appointment of surrogate decision makers (SM) by patients who then decide on behalf of the patient when the patient becomes incapable of deciding him- or herself. Growing evidence on SM decision making however revealed that often SM do not know the actual will or disagree with the patient about his or her wishes about end-of-life care will (Shalowitz et al 2006, Rid et al 2010, Ditto et al. 2001).

Recently, a Swiss enterprise launched the distribution of a commercially available “NO CPR Stamp) to be printed and renewed by oneself on the chest. A vigorous debate resulted among emergency physicians, emergency medical assistants and within the public regarding questions about legal obligations to adhere to the so-expressed wish and the ethical values and implications of this “short AD”. On the one hand it was discussed that this measure reflects the quite understandable fear of patients that their wish not to be resuscitated will not be followed even if put down in an AD in an emergency case. On the other hand, it is also considered as quite understandable that especially emergency medical assistants and emergency physicians feel uncomfortable with trusting this very small piece of information resulting from this stamp. Internally it is agreed upon that if a person is found with the stamp on his chest, the emergency team starts CPR and tries to find an AD in the purse. Yet, the ADs might not be there and most are not very suitable for an emergency situation: The have very different formats are often long and have to be interpreted with regard to agreement or disagreement with single measures such as to resuscitate or not.

Lessons learned during the last 15 years from the SUPPORT Study, the reviews on surrogate decisions and of monitoring patients wishes about end of life care were manifold, among these the identification of necessities and main barriers to achieve the goals of ADs understood as an informed consent or informed refusal of future life-sustaining treatments and measures

1) Lack of communication skills of physicians and health care teams to discuss end of life choices with patients

2) Lack of interdisciplinary approaches to end of life care communication and documentation

3) Lack of Information on illness trajectories and evidence based information on outcomes of life-sustaining treatments at the end of life (e.g. resuscitation, feeding tubes) among health care professionals

3) Lack of understandable and patient tailored information formats to achieve the standard of an informed consent (IC) with regard to future decisions

4) Lack of well structured information and shared documentation in general as well as in case of emergencies

leading to insights into

1) the necessity to implement a structured communication process to support a shared understanding among relevant persons (patients/loved ones/Physicians/Health care teams in charge of the patient)

2) The necessity to develop EbM based patient tailored information regarding treatment at the end of life

3) the necessity to develop a better documentation of options and wishes discussed including emergency plans (Physician Orders for Life sustaining Treatment Forms POLST)

4) The necessity to design interdisciplinary educational programmes to overcome , existing cognitive and emotional barriers to an open interdisciplinary communication process of discussing end of life choices with patients and their families

Evidence during recent years demonstrated that an open and well documented communication process about advance care planning (ACP) initiated by health care professionals was considered as most helpful for most patients in general and with regard to questions about how to deal with future deterioration of health in particular. Almost all patients want to speak about these issues while many physicians are still reluctant to do so (Leydon et al 2000; Hagerty et al. 2004, Baile et al 2002; Gordon et al 2003 Ptacek et al 2001; The et al 2001; Cherlin et al 2005 ; Helft 2005 Lamont et al 2000; Hancock et al 2007, Redmond 1998 Clayton et al 2007, Fallowfield et al 2002, Stiefel et al 2010). Recent evidence further suggests that introducing ACP early leads not only to a better quality of life in the last months of life, but may even prolong life (Temel et al 2010) while concomitantly reducing costs (Zangh et al 2009) due to less intensive medical care as is chosen by most patients in an ACP process if well informed about alternatives and supported by staff.

Finally evidence suggests that an interdisciplinary training focussing on complex issues such as putting ADs into medical practice is very important to promote a structured planning and treatment approach not only with regard to end of life decisions (Journal of Interprofessional Care (2011), Hammick et al (2007), Gaudine et al (2011), Monteverde (unpublished)

4.2 RATIONALE FOR CURRENT STUDY

The aim of our study is to develop, implement and test a complex intervention (continuous multiprofessional development - CPD programme) for improving patients' preparation for and participation in end of life decisions. In cooperation with local, national and international partners, we will focus on strategies to enhance advance care planning (ACP) and shared decision making (SDM) on end of life issues, and documentation and transferability of end of life decisions across health care settings in a coordinated approach involving patients, their families and care givers (in and out of hospital). Research subjects will be palliative, cancer and non cancer patients and their families with full decision making capacity in an acute care hospital setting.

This study builds upon two current international "best practice" programs, ACP and SDM/Decision aids (DA), which we plan to combine and adapt to the Swiss/ Hospital Setting for use by a multiprofessional team approach.

Programs on designing educational interventions and structured documentation for facilitating ACP (Beizeiten Begleiten/RESPEKT, Respecting Choices, Respecting Patient Choices, ACare Program) were developed by our international cooperating

partners (beizeiten begleiten (main cooperating partner), in der Schmitten et al 2011a, in der Schmitten et al 2001 b Briggs et al, Hammes et al, Detering et al, Weiner et al).

Further scientific advances in improving decision making in general include the development of “decision support tools/decision aids” (DA) (see Ottawa Health Reseach Institute: (http://decisionaid.ohri.ca/, Volandes et al (2010)) combining structured communication processes with developing tailored information for patients and families going far beyond normal informed consent forms. According to a recently updated Cochrane Review (O`Connor et al 2009), paper- or videobased decision aids (among these one of the Sponsor and our Canadian and US American cooperating partners (Dawn Stacey, see Murray et al, Volandes et al) have been shown to enhance patients’ and also physicians’ understanding of treatment options, to reduce decisional conflicts and distress, and to promote a SDM process also regarding end of life issues.

Research Questions:

a) Does the implementation of the developed advance care planning program in combination with the use of paper and video based decision aids in hospital and after discharge by patients and their relatives lead to

- Main end of life wishes known (if alive) or fulfilled (if not alive) after 6 months by main health care professionals as perceived by patients or relatives, cross checked by documentation of wishes in retrievable medical charts and asking the primarily responsible physician (attending physician, Specialist) whenever possible (primary endpoint: wish to be resuscitated or not)
- less decisional conflict after discharge and after 6 months regarding end of life decisions
- more satisfaction with treatment and communication and support after discharge and after 6 months
- less traumatic impact of event (in case patient died) and depression of main relative/surrogate decision maker after 3 months of death (if died until 6 months after discharge) and HADS 6 months after discharge of main relative/surrogate decision maker

b) Does the implementation of the continuous professional development and support program for ”advance care planning“ by health care professionals lead to

- better knowledge and better skills to support patients and their relatives in difficult decision making situations and encourage talking about issues concerning care at the end of life and about life and death
- Knowledge of patient’s end of life wishes by main physician (attending physician, specialist) in charge?
- less ethical conflicts and moral distress to deal with end of life issues as perceived by health care professionals after training ?

5 STUDY OBJECTIVES AND OUTCOMES

The main primary objective is to improve communication processes and knowledge of end of life wishes of palliative patients by relatives and health care professionals, leading to goals of care consistent with values of patients at the end of life, measured by the primary outcomes of wishes of patients known/fulfilled (see 8.1.of study protocol). We want to reach this aim via facilitating the process on end of life communication and documentation via a multi faceted complex educational intervention of teaching ACP according to international standards in a multiprofessional team approach (2 x 2 hours of training all together (physicians of the department , 4 hours with physicians on their own, 16 hours of ACP and SDM training with future facilitators (nursing staff of wards, social workers and chaplains) following at least one supervised ACP planning with a patient to get the certification of being a professional ACP planner (certification will be planned and given by the Swiss red cross also in the future if the ACP programme may disseminate across settings and country as intended). The core Study team is planning the educational intervention together with our cooperating partners based on the best practice programmes described above (Beizeiten begleiten based on Respecting Choices and Respecting Patient Choices, ACare) and conducting the educational intervention.

The evaluation of professional skills training also serving as secondary study variables is developed until end of 2012 by a PhD project also belonging to the Biomedical ethics and law track being part of the study team on the basis of best practice programs on ACP (ACare, Beizeiten Begleiten (Main Cooperating Partner), based on Respecting Choices and Respecting Patient choices) and multiprofessional CPD programs.

We hope to retrieve all data on the primary outcome measure of wishes known by main health professionals asking capable patients included in the study after six months (or, if patient becomes incapacitated, main surrogate decision maker) if they think the health care professional is informed about their wishes. We will approach all appointed attending physicians by patients or relatives after discharge by information letter and telephone shortly after discharge. In case of consent of their patient to participate in the study we will have a short telephone interview with the attending physician 6 months after discharge or, if death occurs during this time, after death, asking about their knowledge on end of life wishes of their patient if, to their knowledge these wishes were fulfilled and furthermore try to retrieve the medical record of the patient according to the study design of Detering et al. If data on subjective patients perceptions and on health care professionals or chart are available, the real congruence will serve as primary outcome. Only in cases when verification via interview or chart is not possible the perceived knowledge or fulfilment will be recorded as wishes met/not met.

Secondary outcomes are other important impacts of the intervention on patients and their main surrogate (SM) including decisional conflict on important end of life decisions at discharge and after 6 months in capable patients, Satisfaction with care and information at discharge (Patient discharge questionnaire Detering et al) and

depressive symptoms of patients, depressive symptoms of main relative/SM at six months , Impact of Event Scale and TIME inventory in bereaved SM after three months of death.

Skills, satisfaction with skills, confidence in talking about end of life issues and the impact of the educational intervention on all health care professionals involved will, as described above, be measured in the context of the PhD project within the study.

6 STUDY DESIGN

The study is a single () blinded complex intervention (according to the Campbell classification phase (0) I-III) to measure the impact of ACP and SDM taught to multiprofessional teams responsible for palliative patients whose life expectancy is assessed to be weeks to several months (patients in which the surprise question of Weissman et al elicits a positive answer in physicians responsible for them). The intervention is monitored by a follow up of a maximum of nine months after the intervention, collecting epidemiological and psycho-social data on the patient and their main relative/SM situation.

To blind participants of complex interventions and to avoid contamination of study arms by the intervention is a difficult task. The “gold standard” for complex CPD interventions of a cluster randomized trial was considered as not being feasible in a hospital setting. We decided therefore in accord with the study of Detering et al, to randomize on the patient level, which might lessen the power of the study to demonstrate the intervention effect due to contamination of the educational intervention effect on the control arm. We calculated the sample size on the basis of a lower impact of the intervention compared to the Respecting patient choices and Respecting patient choices programmes so that the power of the study to demonstrate the effect should be sufficient (see below).
In our study, physicians on the ward responsible for patients, ACP facilitators and social workers talking to patients are not blinded to the study arm. The coder of the interviews and the responsible attending physician will be blinded to study arm. We will try to avoid contamination/deblinding of patients by describing the intervention as measuring the impact of talking in two different manners in a structured way about the future course of disease and information processes and to monitor the care of severely ill patients in and outside the hospital.

Attending physicians will also get the same information letter in both study arms, informing about our study evaluating the impact of two different structured planning approaches about the future in palliative patients and are asked to answer some questions about their assessment of the patient in six months. They will also receive an informed consent form for participation in the study that will be developed together with the Institut für Hausarztmedizin. Attending physicians of both arms will get a reimbursement of 30 CHF for this telephone interview.

The educational intervention is planned by the core study team (Krones/Biller/Zaugg/Spirig/co workers of MAPS) in cooperation with our local, national

and international partners adapting existing interprofessional CPD ACP programs, documentation systems and sheets and DAs to the Swiss context (main cooperating partner: Beizeiten Begleiten, in der Schmitten et al). Expert interviews with cooperating national and international institutions including a workshop will also serve as an input.

The educational program is designed in three main parts:

In the first training phase, knowledge about ACP and SDM, the legal and evidence basis of ADs, ACP, SDM/DA and interprofessional approaches on patient and professional outcomes addressing end of life issues are discussed.

In the second phase, cognitive and emotional barriers to an interdisciplinary approach to ACP and SDM are addressed and best practice examples regarding ACP and SDM demonstrated via ACP video demonstrations of breaking bad news, talking about resuscitation and goals of care; Paper based decision aids are demonstrated. Physicians are invited to talk with at least one patient in whom they consider ACP to be relevant.

Future ACP facilitators talking with patients about ACP will have an intense practical training on how to address the issues, do role plays and then have one talk with a patient on ACP choices supervised and evaluated by the moderators.
In both groups, experiences on ACP are evaluated and discussed. The session will be approved by FMH for credits for continuous medical education.

The evaluation of the intervention will also serve as a secondary outcome criteria on the level of participants as part of a PhD project.

In the third part, the complex study intervention is planned in the interdisciplinary group,roles are discussed, defined and process on the ward regarding study flow optimized.

The study material for the complex intervention during the hospital stay consists of

1) CRFs of inclusion, exclusion and baseline criteria and discharge questionnaires, including IC of Patients, main relative/SM (if appointed), consent into review of medical records after death and address of attending physician in charge of the patient
2) Documentation of the usual discharge plan
3) DAs on paper and video
4) Documentation material (ACP AD, POLST, appointed Surrogate decision maker)

We will design several decision aids on the base of the following documents: Intubation, Resuscitaton, Feeding tubes, last place of care

- General Goals of care ACP Video General goals of Care) (offered to all intervention patients and relatives)

- Feeding tube and Dementia (PEG und Demenz; Hanson LC et al 2011AOK decision aid and translated ACP video Feeding tubes) Volandes et al) (offered if decision is impon artificial nutrition is important)

- Resuscitation (Carenet Resuscitation for multimorbid patients, ACP Video on Resuscitation in advanced diseases) (offered all intervention patients and relatives)

- Last place of care (Expert Interviews of cooperating Institutions, including expertise of Jane Seymour UK, Murray et al decision aid on Last place of care at home or facility) (all intervention patients and relatives)

- Intubation (OHRI CA Decision Aid Making Choices Intubation versus supportive Care (OHRI)

- Dialysis (Healthwise Decision Aid Should I stop kidney Dialysis?)

Most decision aids are of the decision aid inventory of the Ottawa Health Research Institute (http://decisionaid.ohri.ca/)

In cooperation with the departments/ wards participating in our study (internal medicine, neurology, , oncology, radio-oncology, nephrology, dermatology (NN, wards and other centres are interested and might become part of the study until study start), we plan the study and will consecutively implement the educational programme during half a year and start recruitment in order to concentrate on wards to optimize recruitment procedures.
Wards will be approached at least once a week during the intervention time by the study team and patients being on the ward will be screened by the study team while assessing new patients with physicians asking the screening questions of Weissman et al,

All patients in which the “surprise question” (I would not be surprised if the patient died within the next year) and being capable of decision making are eligible for the study.

We will include 180 male and female patients (18 years or older) capable of decision making (90 intervention 90 controls) and a close relative (SM) if appointed by patients.

Decisional capacity will be assessed by the responsible physician in charge as is routinely assessed. In cases in which the physician is unsure about the decisional capacity, a psychiatric consult will be ordered to assess decisional capacity .We hope to

incorporate aspects of the SNF study by Biller-Andorno et al to assess the decisional capacity.

In case of too many patients being eligible at the same time, those patients in which more screening questions of the Weissman questionnaire are positive will be prioritized.

The intervention group will have up to three ACP planning meetings including the discharge process in the intervention group. The control arm will have one to three meetings on planning the discharge process with their social worker in charge.
We will do the best to avoid patients being in the same room in the hospital both participating in the study (if two patients are in the same room, the patients meeting more inclusion criteria on the Weissman et al scale will be first approached by the study team, being in the same room serving as an exclusion criteria if not solvable otherwise).

Patients and, , main relative/SM will be approached before discharge by the study team, and have a follow up via a telephone interview (three months after discharge to ask for special events, where patients are, what care is given and care planned) and after six months to assess primary and secondary outcome criteria (wishes known by health care professionals, decisional conflict, Depression). If the patient dies within these three months, relatives/SM are approached approximately three months after death to assess the situation for patient and relative via the Impact of event scale and the TIME interview.

The recruitment of patients starts in June 2013. The recruitment will last 15 months until August 2014. The follow up finishes after a maximum of 9 months in May 2015 (if a patient recruited in August 2014 has died within six months and relatives have to be interviewed three months after the event.)

6.1 STUDY OUTCOME MEASURES

The primary and secondary outcome measures are described in detail under point 9.1. Therefore we do only summarize our primary and secondary outcome measures:

The Primary outcome measure/s: are

Wish of the Patient regarding CPR known by primary care physician (attending physician/Specialist) after six months or wish to be resuscitated known and respected (as performed or documented in the medical record if patient died) and other end of life wishes known/respected by attending physician/caregivers regarding: Last place of care, (home, nursing home, hospice, hospital, intensive care unit), Placing of feeding tube, Antibiotics for pneumonia, Intravenous fluids, Dialysis (continuation until futility, conscious withdrawal) Intubation, Deep or light sedation at the end of life.

Main Secondary outcome measures are wishes on end of life decisions at discharge, after three and after six month (also baseline question), decisional conflict on end of life issues at discharge and after 6 months, satisfaction with information and care during the hospital stay, depression at discharge and after six months (also relative/friends/SM) Having an AD at discharge, after three and after six months (also baseline question),

Having an appointed SM at discharge, after three and after six months (also baseline question) and Decisions regarding end of life issues made after six months.

Cross check of end of life wishes made or documented in medical charts at six months if applicable, and possible to retrieve.

7 Subject Selection and Withdrawal

7.1 SUBJECT RECRUITMENT AND SCREENING

As already described above, patients are eligible if they are regular in house patients or frequent regular ambulatory patients of the participating wards/centers at the university hospital Zurich (internal medicine, neurology, nephrology, oncology, radio oncology, , dermatology) in whom the surprise question of Weissman et al results in a positive answer ("I would not be surprised if the patient died within 12 months"), are 18 years or older and capable of decision making. Other centers in the University Hospital and in two other acute care hospitals in the canton are discussing participation and might be included till start of the study.

Members of the study team will visit all wards/ambulatories at least once a week during the recruitment period and ask the responsible physicians if one or more patients fulfil the main inclusion criteria, the positive answer to the surprise question, also evaluating the other primary criteria (see below) and if ACP can be made due to logistics (no imminent discharge/change of primary responsible hospital).

If many patients are eligible at the same time or in the same room, patients are prioritized to be further screened or asked for IC if more primary criteria of the Weissman scale are fulfilled.

Patients of 18 years or older are included if they can give IC themselves, are capable decision makers and can appoint a responsible physician (attending physician/specialist) and/ a contact person of friend/relative for the study.

Patients who are assumed to be discharged within 2 days and patients in which the physician has the impression that they are in clear denial of their disease or prognosis are not asked for participation in the trial.

If possible, an appointed relative/friend/SM is already contacted during hospital stay, may be part of the intervention if possible and if agreed to by the patient. He or she is then already asked for IC to be contacted after discharge. If this person is not available at that time, IC will be sought after discharge for the telephone interview. The attending physician/specialist appointed by the patient is informed about study participation of his or her patient via information letter and telephone as soon as possible(to be formulated by our cooperating partner Institut für Hausarztmedizin) and asked to participate in the study. This responsible physician being contacted after discharge who consents into taking part in the study gets a reimbursement of 30 CHF for the information retrieval after six months or after death of the patient.

Due to our power calculation (see below), we need 89 patients in each study arm, that is 178 patients to be included. The attending physician and close relative are both included. We aim to recruit 180 patients.

After first assessment and selection of patients in the cooperating hospital departments, in about 20 to 40% of patients the physician is not surprised if the patient dies within the next year, about 5 % might actually die within half a year. About 2500 patients are being treated on our cooperating wards according to hospital statistics during the intervention period of 15 months. Since other centres in the canton are also interested we hope to be able to broaden the basis of our recruitment.

7.2 INCLUSION CRITERIA

Patients fulfilling all of the following inclusion criteria may be enrolled in the study

- *Patient in which the surprise question is positive*
- *Male and Female patients above 18 years of age and with full decisional capacity*
- *Signed Informed Consent after being informed*
- *Patients able to appoint a SM and attending physician to be contacted after discharge*

7.3 EXCLUSION CRITERIA

The presence of any one of the following exclusion criteria will lead to exclusion of the subject:

- *Patients not capable of speaking German*
- *Inhouse patients being discharged within the next 2 days or ambulatory patients not regularly coming to the wards (at least every two months)*
- *Patients assessed by their physician to be in obvious denial of their situation (illness/prognosis)*

For our study, the participation in other trials such as drug trials does not interfere in principle; Patients are asked if they participate in another trial. The principal investigator of that trial will be asked if there is an interference and the individual burden of patients participating in other that our trial individually assessed.

7.4 WITHDRAWAL CRITERIA

Any patient or appointed relative/surrogate may be withdrawn from the study if, as assessed by the responsible investigator during intervention or during follow up, he or she becomes distressed by the planning process or by answering the questionnaires. The documentation of the reason for withdrawal is part of the CRF.

Criteria for withdrawal are strictly following the Declaration of Helsinki and GCP, being always possible for any participant (patient/relative/SM) if consent is withdrawn. Participants are informed in IC that withdrawal may occur at any time for any reason, that no measure is then taken and no new data retrieved but that data retrieved so far are stored and used anonymously in the trial for data analysis. In case of withdrawal patients or participating SM are asked if they want to give reasons for withdrawal and if yes, these reasons are documented if consent is given for this documentation,

8 Efficacy and Safety Variables

8.1 EFFICACY VARIABLES

All efficacy variables are collected by the study team via paper based face to face (discharge) or telephone interviews (3 months, 6 months) and via review of medical records whenever possible regarding wishes documented and fulfilled.

As already described above, the primary efficacy variable is the wish of the patient to be resuscitated known by the physician responsible for him or her (wants to be resuscitated, does not want to be resuscitated, is undecided or leaves this decision to SM or attending physician) and is measured via telephone interviews 6 months after discharge, the paper based questionnaire sent to physicians in advance to prepare for questions.

These questions are adapted from the Patient Questionnaire at Baseline and the Patient deceased questionnaire of Detering et al and Question D 2 to D 4 of the TIME inventory (ACP questions regarding knowledge of doctor/staff):

Do you/does your relative have any wishes regarding end of life care (e.g. regarding where you / he or she want/s to die; if you/ he or she wants to be resuscitated when your/her/his heart stops beating?)

Yes/no/ Don't know/undecided

If yes what is your/your relatives' preference with regard to:

1) Cardiopulmonary resuscitation

a)
I/he/ she/ wants to be resuscitated
I/ he/she does not want to be resuscitated
I/he/she leaves this question explicitely to my SM/me/the doctor

I/he/she is undecided

b)
Does the doctor primarily caring for you/your relative/friend know about your/his/her wish regarding cardiopulmonary resuscitation?
Yes/no/don't know

2) Other end of life wishes known by attending physician/caregivers regarding are asked in the same manner:

Last place of care: (home, nursing home, hospice, hospital, intensive care unit, unsure /don't know)

Placing of feeding tube (yes/no/left to doctor/SM to decide/undecided)

Antibiotics for pneumonia (yes/no/left to doctor/SM to decide/undecided)

Intravenous fluids (yes/no/left to doctor/SM to decide/undecided)

Dialysis (continuation until futility, conscious withdrawal, left to doctor/SM to decide/undecided)

Intubation (yes/no/left to doctor/SM to decide/undecided)

Sedation for symptom management at the end of life (deep/light/ left to doctor/SM to decide/undecided)

In patients alive, crosscheck with knowledge of primary care physician is undertaken via the attending physician/physician questionnaire

Does your patient have any wishes regarding end of life care (e.g. regarding where he or she want/s to die; if he or she wants to be resuscitated?)

Yes/no/ Don't know

If yes, what is your patient s preference with regard to

1) Cardiopulmonary resuscitation

He/ she/ wants to be resuscitated
He/ she does not want to be resuscitated
He/ she leaves this question explicitly to his/her SM or to me/to the doctor in charge
He/ she is undecided

If these answers of attending physician are obtained, the efficacy variable is measured via right or wrong answer of physician, in other patients alive, the efficacy variable is the perceived knowledge of doctor by patient or relative on wish to be resuscitated (yes versus no/don't know)

In patients being dead after three and six months, the same questions are asked with regard to the past and answers of SM (at Follow Up Interview 3 months after death) and doctors crosschecked with medical records if wishes were a) documented and b) fulfilled at the time of death according to the study of Detering et al.

Secondary outcome measures:

Patient

- Decisional conflict on end of life issues at discharge and after 6 months (decisional conflict scale, DCS, O Connor et al 1995)
- Satisfaction with information and care during the hospital stay (Patient discharge questionnaire Detering et al, 7 questions regarding satisfaction with stay, information and care)
- Depression at discharge and after six months (Hospital Anxiety and Depression Scale HADS German version)
- Having an AD at discharge, after three and after six month (also baseline question) (Question D 6 of the TIME inventory) adapted to the context
- Having an appointed SM at discharge, after three and after six months (also baseline question) (Question D 5 of the TIME inventory) adapted to the context
- Any hospital stay during three / six months
- Open question on important medical decisions being made at three months
- Decisions regarding end of life issues already having been made/ taken place during/until six months after discharge:

    - Having been resuscitated
    - Decision on last place of care made (home, nursing home, hospice, hospital, intensive care unit)
    - Placing of feeding tube (decided for/against)
    - Antibiotics for pneumonia (given/not given)
    - Intravenous fluids (yes/no/)
    - Dialysis (continuation /withdrawal)
    - Intubation (yes/no)/ Sedation for symptom management (deep/light)

Appointed Relative/Friend/SM to participate in the study:

-Patient alive

- Depression after six months (HADS, German Version)
- Knowledge on patients end of life wishes after six months as described above
- Decisional conflict regarding decision making for patient for SM after six months (DCS , O Connor et al)
- Decisions regarding end of life issues already having been made/ taken place during/until six months after discharge (as described above)

-If patient is alive but to sick or incapable after three or six months

- Knowledge on patients end of life wishes after six months as described above

- Depression of SM after six months (HADS, German Version)
- Decisional conflict regarding decision making for patient for SM after six months (DCS , O Connor et al)
- Patient having an AD after three and after six month (Question D 6 of the TIME inventory) adapted to the context
- Patient having an appointed SM after three and after six months (Question D 5 of the TIME inventory) adapted to the context
- Any hospital stay during three / six months
- Open question on important medical decisions being made at three months
- Decisions regarding end of life issues already having been made/ taken place during/until six months after discharge (as described above)

-If patient has died, about three months after death

- Knowledge on patients end of life wishes after six months as described above
- Depression (HADS, German version)
- Impact of Event (IES (Horowitz et al 1979, German version (Maercker Schützwohl 1998)
- TIME Inventory interview, Hospital version (Teno et al, German version In der Schmitten et al)
- Decisions regarding end of life issues already having been made/ taken place during/until six months after discharge (as described above)

Appointed Physician in charge (attending physician/specialist)

- Knowledge on end of life wishes of patient after six months as described above
- Decisions regarding end of life issues made after six months as described above
- Cross check of end of life wishes made or documented in medical charts at six months if applicable and possible o retrieve

8.2 SAFETY VARIABLES

An open question regarding the impact of talking about the patients future plans will be integrated into the questionnaire at discharge, and about participation in the study three and six months after the intervention. This question will be documented in the CRF. If the interviewee indicates that the impact of the study is very distressing, this is considered as a safety concern and withdrawal is discussed even if not indicated by the patient/SM him or herself.

9 Course of Study and Follow-Up

9.1 SCREENING VISIT

The screening procedure consists of screening with the physician in charge of the patient if

-he or she is eligible in principle (surprise question of Weissman et al positive, no, no denial), and how many screening questions of primary criteria by Weissman et al are answered by yes:

- frequent admissions (more than one admission for same condition within the last months)
- admission prompted by difficult to control symptoms (e g moderate to severe symptom intensity for more than 24 hours)
- complex care requirements (functional dependency, complex home support for ventilator/antibiotics/feedings)
- decline in function, feeding intolerance or unintended decline in weight

if he or she has full decisional capacity by the physician (if very unsure and agreed to by the patient, a short psychiatric consilium is undertaken)

if the patient is assessed to speak enough German to be able to understand the study materials

and checked if another patient in the same room is also a probable participant or already is a participant in the study. If yes, the patient with more positive answers to screening question is chosen to be approached by the study team.

This is followed by a screening visit of the patient, asking for a principle interests in the study, if the criteria of having a relative and attending physician to be approached is met by patients.

If the answer is positive the information (IC material) on the study is given and the study explained to patient andto the main relative/friend/SM. IC of SM can be obtained later

Those patient who are approached for the study and don't want to participate are asked to fill in a short questionnaire (adapted from "enrollment questionnaire" Detering et al) regarding their current situation. The questionnaire entails an informed consent and data will be analyzed anonymously according to the informed consent given on the short questionnaire.

9.2 VISIT 1

After the IC is obtained, randomisation takes place the same day in the Clinical trial center and the first visit (intervention: ACP facilitator, control: social worker for discharge planning) is organized.

The baseline questionnaire (derived from enrollment Questionnaire of Detering et al) is distributed, containing questions about sociodemographic variables (gender, age, address, telephone number or contact details), contact details of attending physician/main physician in charge after discharge, (main) illnesses, having an AD or SM, having decided on medical treatment if he or she is very sick (open question) having decided on CPR (If required, would you want CPR? Yes, yes depending on outcome, no, don't know

Attending physician will be approached by the study team and Informed consent will sent by post.

The physician in charge is asked for the main diagnosis of the patient approached (pulmonal, cancer, heart, neurology, nephrology, other disease)

In the intervention group, suitable decision aids are given to the Patient together with instructions to use these DA.

9.3 INTERVENTION VISITS 2-4

Intervention: ACP or discharge planning

In the Intervention group up to three ACP meetings are organized with the patient and if possible and agreed to by the patient together with a main close relative/friend/SM.

Paper based DA are first reviewed and further illuminated by Video DA also during the visit with the patient. The Patient is asked if he used DA already on his own. If agreed to, an Advance care plan is made and documented, including, if agreed to, by a POLST form and appointment of a surrogate decision maker. If such a plan is made, the physician in charge is informed and has a short talk at last visit about the plan made. A POLST form has to be signed by the physician, the ACP can be signed if the patient wants to. The Patient will be asked if he has an AD/changes an AD/makes a new AD.

It will be documented if he already has an officially and legally appointed surrogate decision maker.

The patient is encouraged to talk about the plan made with the attending physician In the control arm up to three visits regarding discharge problems are organized as usual, we will document if these visits are conducted with an appointed relative/friend/SM and if the consultations are very distressing (Adverse Event)(belonging to routine care procedures at the University hospital by the social service).

9.4 DISCHARGE VISIT (VISIT 3, 4 OR 5)

Patients are finally having a discharge visit in both groups, in which the discharge questionnaire (Patient discharge questionnaire, Detering et al, also including HADS and

Decisional Conflict Scale) is given. Patient and relative/friend/SM are reminded that the next telephone call by the study team will take place in three months, questions can be sent already prior to the telephone interview.

In exceptional cases, if discharge is very prompt, discharge questionnaire can be filled in by telephone interview.

9.5 FOLLOW UP INTERVIEW AT 3 MONTHS

After three months of discharge, the study team tries to contact the patient directly, by phone. If not possible, the assigned relative and/or physician is contacted to find out if and where the patient can be interviewed by phone. Questions address the illness course during the last three months, any decisive medical measures taken (open question to avoid contamination of control arm), if the patient has an AD or a SM and if there was any medical procedure that was performed or not performed inconsistently with his or her wishes (Question D4) as an AE monitoring. If the patient is too sick, the previously appointed relative or attending physician is asked these questions as described above.
The reminder is given that the study team calls again in three months.
If the patient is dead, the attending physician is contacted to answer questions on knowledge on will and treatment on end of life, decisions regarding end of life issues made/taken place after discharge, and we will cross check of end of life wishes made or documented in medical charts if applicable and possible to retrieve. An appointed relative/friend/SM is asked for an interview in three months, (HADS-D, german version, Impact of Event, IES-R, Maercker Schützwohl, TIME Inventory Interview adapted Version Teno et al, In der Schmitten et al, Decisions regarding end of life issues already having been made/taken place after discharge, knowledge on end of life wishes of patient as described above)

9.6 FOLLOW UP INTERVIEW AT 6 MONTHS

After six months of discharge, the study team tries to contact the patient directly, by phone. If not possible, the assigned relative/friend/SM and/or physician is contacted to find out if and where the patient can be interviewed by phone. The primary variables efficacy and secondary variables are assessed by patient, relatives and attending physician as described above.

If the patient is dead, the attending physician is contacted to answer questions on knowledge on will and treatment on end of life, the appointed relative is asked for an interview in three months as described above in 9.5

9.7 FOLLOW UP INTERVIEW AT 3 MONTHS AFTER DEATH

The appointed relative/friend/SM is contacted about three months after death of the patient and the TIME interview , including the HADS and IES is performed,asking about

the decisions regarding end of life issues made/taken place after discharge if possible face to face, if not possible by phone.

The Study ends with the interview at 6 moths if patient is still alive or at 9 months with the Bereavement interview with appointed relatives/friends/SM.

10 SAFETY

In our study only different formats of talking about future plans of the patients are tested, therefore we do not expect and document AEs and SAEs in the normal sense. Death of the patient might occur during the study due to the underlying illness and thus is no SAE to be reported to the IRB. The main safety issue that might be considered as an Adverse Event (AE) is distress of patients or relatives/friends/SM because of the content of the consultation. We will address this problem, as described above, by an open question regarding the impact of talking about the patients future plans that will be integrated into the questionnaire at discharge, three and six months after the intervention. If the interviewee indicates that the impact of the study is very distressing, this is considered as a safety concern and withdrawal is discussed even if not indicated by the patient/SM him or herself.

The second safety /monitoring issue is treating patients against their will or not treating patients according to their will, interfering with the study intervention. We address this question by asking both groups Question D 4 of the TIME inventory at three months, six months and in patients who died as part of the TIME inventory about three months after death.

These variables will all be recorded in the CRF.

11 STATISTICS AND DATA ANALYSIS

11.1 POWER CALCULATION

Our power calculation rests on the study of Detering et al and on the primary outcome measures of advance care plans made, wishes assessed to be known by caregives as assessed by patients/relatives and wishes fulfilled of those patients died within 6 months. After first assessment and selection of patients in the cooperating hospital departments, in about 20 to 40% of patients the physician is not surprised if the patient dies within the next year, about 5 % might actually die within half a year. We have estimated a lower baseline (10%) and smaller effect (30% increase of 20%) of wishes documented and assessed to be known by caregivers, but will ask patients and their relatives both survived and not survived about wishes documented and known by caregivers. To achieve a 90% power and a certainty of 95% we need 89 patients in each study arm, that is 178 patients to be included. The attending physician and close relative are also included if agreed by the patient during a period of a maximum of 15 months. We plan to include 180 patients.

After first assessment and selection of patients in the cooperating hospital departments, in about 20 to 40% of patients the physician is not surprised if the patient dies within the next year, about 5 % might actually die within half a year About 2500 patients are being treated on our cooperating wards according to hospital statistics during the intervention period of 15 months. Since other centres in the canton are also interested we hope to be able to broaden the basis of our recruitment.

Data and all appropriate documentation will be stored for 10 years after the completion of the study, including the follow-up period.

11.2 ANALYSIS

We calculate cross tabs (Fishers exact test 2 x 2 cells) and logistic regression models for each group (A /B) separately for categorical data for the main outcome variable(s) of main wishes to compare intervention and control group with SPSS /STATA software.

Logistic regression models adjusting for study group, gender, age, illness (cancer/non cancer), last place of living/care, baseline characteristics before intervention will be performed for the primary outcome variables

A separate analysis will be undertaken on patients who died during the study period comparing intervention and control group via cross tabs and logistic regression models regarding the primary outcome variables of wishes fulfilled. Besides the intention to treat analysis including all randomized patients, a per protocol analysis will be undertaken comparing patients with a full advance care planning (AD, POLST form signed, Surrogate decision maker appointed after ACP) after intervention with the control group regarding primary and secondary outcome criteria.

Scale scores of secondary variables (HADS; DCS; IES, TIME Inventory, Satisfaction with Care at discharge) will be calculated according to published criteria and means compared between intervention and control group in each study group via T Tests or Man Whitney U tests if T Test is no appropriate. Multiple linear regression models are also calculated to adjust for study group, gender, age, illness (cancer/non cancer), last place of living/care and baseline characteristics

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

12 REGULATORY ISSUES

12.1 ETHICS APPROVAL AND ETHICAL CONDUCT OF THE STUDY

Before this study will be conducted, the protocol, the proposed subject information and consent form as well as other study-specific documents will be submitted to a properly

constituted Independent Ethics Committee (IEC) in agreement with local legal requirements, for formal approval. The decision of the IEC concerning the conduct of the study will be made in writing to the Sponsor-Investigator before commencement of this study.

The study will be carried out in accordance with principles enunciated in the current version of the Declaration of Helsinki.

12.2 SUBJECT INFORMATION AND CONSENT

The investigator will explain to each subject the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits and any discomfort it may entail. Each subject is be informed that the participation in the study is voluntary and that he/she may withdraw from the study at any time and that withdrawal of consent will not affect his/her subsequent medical treatment.

The subject is informed that, , his/her medical records may be examined by authorized individuals other than their treating physician by the study team in order to monitor if wishes are followed.

All subjects for this study will be provided a subject information sheet and a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study.

The subject information sheet and the consent form will be submitted with the protocol for review and approval for the study by the IEC. The formal consent of a subject, using the approved consent form, must be obtained before that subject is submitted to any study procedure.

The subject should read and consider the statement before signing and dating the informed consent form, and will be given a copy of the signed document. The consent form is also signed and dated by the investigator and it will be retained as part of the study records.

12.3 CONFIDENTIALITY

The investigators will treat all information related to the study and the compiled data as strictly confidential. Any passing-on of information to persons that are not directly involved in the study must be approved by the owner of the information.

Data generation, transmission, archiving and analysis of personal data within this study, strictly follows the current Swiss legal requirements for data protection. Prerequisite is the voluntary approval of the subject given by signing the informed consent prior start of participation of the clinical trial.

Individual subject medical information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited. Subject confidentiality will be further ensured by utilising subject identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the subject's personal physician or to other appropriate medical personnel responsible for the subject's welfare

12.4 INSURANCE

Insurance is covered by “Haftpflichtversicherung für den Kanton Zürich betreffend das UniversitätsSpital Zürich“ (Policy no.: *1023), signature date 14th of october 2011.*

Any damage developed during the course of the study is covered by this insurance.

12.5 FUNDING

The Study will be fully funded by the SNF, NFP 67 End of Life.

12.6 AUDITS AND INSPECTIONS

The study may be subject to inspection and audit by regulatory bodies to ensure adherence to GCP, national law, and regulatory requirements. The quality assurance auditor/inspector will have access to all medical records, the investigator's study related files and correspondence, and the informed consent documentation that is relevant to this clinical study.

The investigator will allow the persons being responsible for the audit or the inspection to have access to the source data/documents and to answer any questions arising. All involved parties will keep the patient data strictly confidential.

13 STUDY MANAGEMENT

The day-to-day management of the study will be coordinated through the Study group and the CTC.

13.1 DATA MANAGEMENT

The Data will all be stored on a personalized computer at the CTC on a research platform where only the internal study team has access. All data will be entered in an anonymized form. A separate list on codes for merging follow up with baseline data to addresses will be stored separately in a close cupboard , is only available for study personel and will be destroyed after the trial is finished. SecuTrial will be used for data management and storage.

14 PUBLICATION POLICY

After the statistical analysis of this trial the investigator will make every endeavour to publish the data in a medical journal.

15 SIGNATURES

Sponsor-Investigator (Principal Investigator):

This clinical trial protocol was subject to critical review and has been approved by the Sponsor-Investigator. The information herein is consistent with

- the current risk/benefit evaluation of the investigational procedure(s)
- the moral, ethical and scientific principles governing clinical research as set out in the current version of the Declaration of Helsinki, Good Clinical Practice and respective SAMW guidelines.

Name of Sponsor-Investigator

PD Dr. med. Tanja Krones

Zurich, 22th of April 2013 Signature

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