Breaking potentially bad news of cancer workup to well-informed patients by telephone versus in-person

A randomised controlled trial on psychosocial consequences

Bodtger, Uffe; Marsaa, Kristoffer; Siersma, Volkert; Bang, Christine Winther; Høegholm, Asbjørn; Brodersen, John

Published in:
European Journal of Cancer Care

DOI:
10.1111/ecc.13435

Publication date:
2021

Document version:
Accepted manuscript

Citation for pulished version (APA):
Bodtger, U., Marsaa, K., Siersma, V., Bang, C. W., Høegholm, A., & Brodersen, J. (2021). Breaking potentially bad news of cancer workup to well-informed patients by telephone versus in-person: A randomised controlled trial on psychosocial consequences. *European Journal of Cancer Care*, *30*(5), [e13435]. https://doi.org/10.1111/ecc.13435

Title

Breaking potentially bad news of cancer workup to well-informed patients by telephone *versus* in-person: a randomised controlled trial on psychosocial consequences

Running title: Breaking bad news over the phone in well-informed patients

Authors

[1,2,3] Uffe Bodtger, professor (e-mail: ubt@regionsjaelland.dk)

[1,4] Kristoffer Marsaa, consultant (e-mail: dokmarsaa@gmail.com)

[5] Volkert Siersma, statistician (e-mail: siersma@sund.ku.dk)

[5] Christine Winther Bang, statistician (e-mail: cwb@econ.ku.dk)

[1] Asbjørn Høegholm, head of respiratory medicine (e-mail: ahoe@regionsjaelland.dk)

[5] John Brodersen, professor (e-mail: jobr@sund.ku.dk)

Affiliations

[1)] Department of Respiratory Medicine, Zealand University Hospital Naestved, 61 Ringstedgade; DK-4700 Naestved, Denmark

[2)] Institute for Regional Health Research, University of Southern Denmark, 55 Campusvej; DK-5230 Odense M, Denmark

[3)] Department of Respiratory Medicine, Zealand University Hospital Roskilde, 10 Sygehusvej, DK-4000 Roskilde, Denmark

[4)] Palliative Unit, Copenhagen University Hospital Herlev, 1 Borgmester Ib Juuls Vej, DK-2730 Herlev, Denmark

[5)] The Research Unit for General Practice and Section of General Practice, Department of Public Health, University of Copenhagen, 5 Øster Farimagsgade; DK-1014 Copenhagen K, Denmark

Corresponding author

Uffe Bodtger, PhD, MD, Professor in Respiratory Medicine

Department of Respiratory Medicine; Naestved Hospital

61 Ringstedgade; DK-4700 Næstved; Denmark

E-mail: ubt@regionsjaelland.dk

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/ECC.13435

Tel: +45 5651 4592

Acknowledgements

We thank all participants for their interest and time, Specialist nurse Stine Lenart for her devotion and care for the patients, and Professor Mike Thomas (University of Southampton) for invaluable comments and suggestions.

Data availability

Data pertaining to this study are included in the manuscript and Supplemental Tables. Additional datasets used and/or analysed during the current study are available from the corresponding author upon request.

Competing Interest Statement

All authors have completed the Unified Competing Interest form and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Role of the funding source

This study was supported by a unrestricted grant from The Region Zealand Research Foundation, Denmark (REGSJ-2014/102).

Author contribution

The study director UB and principal investigator KM take responsibility for the integrity and the accuracy of the analyses. UB, KM, VS, AH and JB generated the hypothesis for and designed the study. UB, KM and JB wrote the first protocol, obtained funding for the study, and initiated the study. UB and KM coordinated the trial and were responsible for monitoring and data collection. UB, KM and AH constituted the clinical study staff, and recruited and followed up patients. VS, CWB and JB were non-clinical assessors. VS and CWB did the statistical analyses. All authors interpreted the data. UB and KM drafted the manuscript, and all authors critically revised the manuscript. All authors read and approved the final manuscript.

Authorities' approval

Ethical approval was provided by the Research Ethics Committee of Region Zealand, Denmark (no. 12/000660), and the study was performed in accordance with the Declaration of Helsinki.

Data collection was approved by the Danish Data Protection Agency (REG-032-2013).

PROF. UFFE BODTGER (Orcid ID : 0000-0002-1231-9209)

Article type : Original Article

Title

Breaking potentially bad news of cancer workup to well-informed patients by telephone versus in-person: a randomised controlled trial on psychosocial consequences

Abstract

Background

The use of telephone in delivering cancer care increases, but not in cancer workup. Current protocols for breaking bad news assume a single in-person meeting. Cancer workup involves multiple opportunities for patient information. We investigated the psychosocial consequences in gradually informed patients of receiving lung cancer workup results by telephone versus in-person.

Methods

A randomised, controlled, open-label, assessor-blinded, single-centre trial including patients referred for invasive workup for suspected malignancy (clinical trials no. NCT04315207). Patients were informed on probable cancer at referral, after imaging, and on the day of invasive work-up (Baseline visit). Primary endpoint: change (Δ) from Baseline to Follow-up (4 weeks after receiving workup results) in scores of a validated, sensitive, condition-specific questionnaire (COS-LC) assessing consequences on anxiety, behaviour, dejection and sleep.

Results

Of 492 eligible patients, we randomised 255 patients (mean age: 68 years; female: 38%; malignancy diagnosed: 68%) to the Telephone (n=129) or In-person (n=126) group. Groups were

comparable at baseline and follow-up, and no between-groups difference in ΔCOS-LC was observed in the intention-to-treat population, or in subgroups diagnosed with or without malignancy.

Conclusion

Breaking final result of cancer workup by telephone is not associated with adverse psychosocial consequences compared to in-person conversation in well-informed patients.

Keywords

Lung cancer, Communication, Adults.

Introduction

Lung cancer is the world leading cause of cancer death [1]. Disclosure of bad news is challenging for patients, relatives and healthcare providers [2-4], yet breaking bad news professionally is a clinical cornerstone for clinicians involved in workup of suspected malignancy. An increasing number patients receive a cancer diagnosis by telephone [5, 6], but available models for delivering a cancer diagnosis were developed for in-person conversation [7-10]. Furthermore, these models focus on a single visit [4], while cancer workup is a process involving multiple clinical interactions with numerous opportunities to gradually prepare the patients and their family for a potential life-limiting diagnosis [2, 3, 11, 12]. Generally, there is a lack of rigorous intervention studies measuring psychosocial outcomes for patients in the context of cancer workup [13, 14].

Efficacious and empathic communication is understandable and compassion-filled and is pivotal to transfer the knowledge from the healthcare professional to the patients' insight and understanding of life-changing diagnoses [15]. Retrospective observational studies have identified higher patients' satisfaction scores when the cancer diagnosis is conveyed by a physician with high communicative skills, in personal rather than in impersonal settings, in-person rather than by telephone, when the patients experienced the opportunity to ask questions, and when conversations lasted more than 10 minutes and included discussion of treatment options [4, 6, 16]. The inherent bias in these retrospective studies has not been addressed.

To date no randomised clinical trials (RCTs) have been published assessing the impact of breaking bad news of cancer workup by telephone vs usual care (in-person visit).

Therefore, the aim of the present RCT was to investigate whether the psychosocial consequences four weeks after receiving the final diagnosis of workup for suspected cancer in lung(s), pleura or mediastinal lymph nodes was affected by type of disclosure, i.e. in-person vs. telephone.

Methods

Trial design

A single-centre, investigator-initiated, open-label, assessor-and statistician-blind, parallel-group RCT with 1:1 allocation to Telephone group versus In-person group. No changes to methods (including inclusion criteria) were made after trial commencement. Study reporting adhere to CONSORT guidelines [17]. Trial protocol is available at clinicaltrials.gov (NCT04315207) and at our institutional website [18].

Setting and participants

The RCT was conducted in a Danish tertiary centre for diagnostic lung cancer package pathway [12, 19]. Our unit offers single-day invasive workup with bronchoscopy, endosonography and percutaneous biopsies [20, 21].

Patients were eligible if suspicious lesions in lung, pleura or mediastinum at CT or PET-CT with a pulmonologist's judgement of indication for invasive workup and expected survival of >1 month. Key exclusion criteria were age <18 years, need of in-patient care including acute oncological conditions (e.g. spinal cord invasion), or inability to provide verbal and written informed consent.

Enrolment, randomisation, blinding, and baseline data collection

No targeted tool has been developed to measure psychosocial outcomes or consequences of cancer workup including lung cancer. The "Consequences of Screening for in Lung Cancer (COS-LC)" questionnaire [22] was sufficiently sensitive to detect significant psychosocial consequences in a lung cancer screening trial [23].

Patients were informed about the present RCT and if uninterested then offered participation in a similar study without randomisation (Telephone group n= 105/151 patients (70%), manuscript in preparation). After providing written informed consent, participants completed the baseline COS-LC part1. Randomisation was performed using a centralized, computer-based system (Scientific Trial Randomiser®, Cloud Create, Denmark) in blocks of twenty. Trial group assignments were made in a 1:1 ratio without minimizations, and was revealed to patient, clinicians and clinical study staff at end of baseline visit (i.e. the day of invasive workup). The non-clinical assessors were

blinded to group labels until all primary outcome analyses were completed. A written conclusion on observed inter-group differences was made before un-blinding.

Interventions

At every physician contact, patients were informed about the possibility of malignancy. The precise content depended on the available information at each time point concerning likelihood of cancer, suspected stage and differential diagnoses (see Table 1 for details) and explained by the physician in a plain, non-medical language.

Before going home, patients were informed by the responsible physician about [1)]macroscopic findings during workup, [2)]microscopic results expected after 3-5 working days, [3)]randomisation result, [4)]expected content of conversation (diagnosis, stage and approximate treatment plan), [5)]relatives/key persons welcome to attend if patient's wish, and [6)]provided with a written out-patient clinic appointment five working days later (In-person group only).

Workup results were disclosed – whenever possible – by a physician that the patient was familiar with (day of invasive workup, previous conversations) regardless of group allocation. The same team of clinicians disclosed results by telephone and in-person, and all had attended basic courses in patient communication during specialist training but never received any specialised telephone communication training.

Follow-up questionnaire

Four weeks after receiving the final result participants completed COS-LC parts 1 and 2. This questionnaire were posted to the patients' private address with written instructions and a postage pre-paid/-addressed return envelope. Two to four weeks later, non-responders were reminded by a telephone call from the research nurse.

Primary outcome

The predefined primary outcome was the between-groups change in COS-LC part1 from baseline (prior to invasive workup) to 4 weeks after receiving the final diagnosis of workup (follow-up). Psychometric properties of COS-LC are described in detail in [22]. Shortly, COS-LC is a condition-specific questionnaire developed and validated to measure psychosocial consequences of lung cancer screening [22]. COS-LC part1 consists of 4 core scales ("Anxiety" (7 items, score 0-21), "Behaviour" (7 items, score 0-21), "Dejection" (6 items, score 0-18), and "Sleep" (4 items, score 0-

12)), and 5 lung-cancer-screening-specific scales ("Self-blame" (5 items, score 0-15), "Focus on Airway Symptoms" (2 items, score 0-6), "Stigmatisation" (4 items, score 0-12), "Introvert" (4 items, score 0-12), and "Harm of Smoking" (2 items, score 0-6)), each with four response categories ordered on a continuum ("not at all", "a bit", "quite a bit" and "a lot" = score range 0 to 3). The higher the scale-score, the more negative the psychosocial consequences [22].

Secondary outcomes

COS-LC part2 was designed and validated to measure changes in patient-perceived changes at follow-up compared to baseline, and encompasses six scales: "Calm/Relaxed" (2 items), "Social Relations" (3 items), "Existential Values" (6 items), "Impulsivity" (6 items), "Empathy" (3 items), and "Regretful of still Smoking" (4 items) [22]. All items have five response categories scored laterally reversed: "much less" 2, "less" 1, "the same as before" 0, "more" 1, and "much more" 2 [22].

The content validity of the COS-LC was validated in the current target population via 20 qualitative interviews in spring 2012 with patients with suspected lung cancer using the Think Aloud Test [24]. These patients were not included in the trial. Before these interviews, all wordings about screening were reformulated into the setting of diagnostic workup of suspected cancer in the chest. The 20 patients found all instructions and items relevant, easy to understand and complete, and none expressed to miss items or domains in the COS-LC.

Data

At randomisation, age, sex, and date were recorded. Six months after randomisation, clinical data were extracted from electronical medical files concerning baseline data on medication use, comorbidities (Charlson's comorbidity index), forced expiratory volume in the first second (FEV_1 in percentage of predicted), presence of chronic obstructive pulmonary disease (COPD), smoking history, former cancer diagnoses, and number and type(s) of invasive procedure(s) performed. Furthermore, vital status (including date of death), diagnostic outcome, and final diagnosis were retrieved. Workup was considered true negative in absence of a cancer diagnosis at 6 months follow-up. Data on cohabitation, income and education were obtained from Danish national administrative databases.

Statistical analysis

Due to absence of previous studies, we chose a pragmatic approach to calculation of sample size as argued by Norman and colleagues [25]. COS-LC has high sensitivity and has previously proved ability to measure differences in a cohort of minimum 100 screening participants and in minimum 500 individuals in the general population [26]. We expected higher scores and greater differences in patients with suspected cancer so a cohort of 200 patients was expected to be sufficient. There is no overall COS-LC score, and still no identified minimal important difference.

Data were analysed and present on an intention-to-treat basis. Continuous variables were summarized using mean and standard deviation (SD), and compared using Student's T-test. Categorical variables were summarized using frequencies and percentages and compared using Pearson's Chi-squared test.

The effect of randomisation on outcomes was assessed in linear regression models. For Part1 outcomes, we analysed both baseline and follow-up measures in the regression, and this regression contrasts the mean follow-up measure beyond possible differences at baseline between the randomisation arms. For Part2 outcomes, this regression contrasts the mean follow-up measure between two randomisation arms. Potential differential dropout and missingness between randomisation arms is adjusted for by weighting non-missing data by the inverse probability of these data being observed at that time. These probabilities were estimated from data in logistic regression models including demographics, medical and smoking history, randomisation arm and, if available, corresponding outcomes from previous time points [27]. Generalized Estimating Equation methods were used to adequately adjust for repeated observations and for weighting.

Subgroup analyses of COS-LC was made according to a final diagnosis of malignancy or not.

A p value of <0.05 was considered significant. Statistical Analysis Software (SAS) version 9.4 was used to analyse the data.

Results

Recruitment, population characteristics and diagnoses

Enrolment began 9 October 2012, and ended 19 October 2016. Last follow-up data were entered 20 April 2017 and closed 28 February 2019 after validation.

In total, 492 potential participants were approached: 255 underwent randomisation (mean age 68 years (SD 9.7); 97 (38%) females), with 126 patients assigned to the In-person group, and 129 to the Telephone group (Figure 1, Table 2).

During workup, 174 patients (68%) were diagnosed with malignancy, predominantly non-small cell lung cancer (Table 3). Among the 81 patients with non-malignant results, 25 (31%) had a conclusive benign diagnosis of infection or sarcoidosis (overall diagnostic yield 78%), whereas 17 (21%) were referred for further workup due to high risk for malignancy. The remaining 40 (49%) patients were considered as low-risk and thus referred for non-invasive follow-up (low-dose CT, clinical control). One patient in each of the two latter groups were diagnosed with malignant lymphoma within 4 months from inclusion (Table 3). Twenty-five (10%) patients died within 2 months after randomisation.

The two trial groups were generally well-matched (Tables 2&3). Eighty-one (36%) participants did not return the follow-up COS-LC questionnaire (Figure 1): completers and non-completers differed in several variables including shorter survival among non-completers (Table S1). A single patient in the Telephone group requested an in-person conversation after the telephone conversation (treated as Telephone group in analyses).

Primary outcome

We observed no statistically significant intra-group differences in the nine COS-LC scales from baseline to follow-up (Figure 2). No statistically significant differences between groups was observed except concerning “focus on airway symptoms” at follow-up (Table 4).

Secondary outcomes

Self-perceived change at follow-up differed insignificantly between groups (Table 5). In the subgroup with a final diagnosis of malignancy, we observed no significant between-groups differences in psychosocial consequences. However, in the subgroup with non-malignant results, we observed significantly higher scores in Anxiety and Dejection in the Telephone group (COS-LC part1; Table S2) but with insignificant differences in the self-perceived change reported at follow-up (COS-LC part2; Table S3).

Discussion

This RCT were unable to show that receiving the result of workup of suspected malignancy per telephone resulted in worse psychosocial outcomes than when receiving the results in-person in the out-patient department. The result was consistent in the subgroup diagnosed with malignancy.

Our result might not be generalizable to all institutions involved in workup of suspected malignancy, as there are several obvious prerequisites. Firstly, patient and physician should agree on how results are delivered, as not all patients prefer to have results by telephone: nearly 50% of eligible patients declined participation in our RCT due to reluctance to randomisation, yet 105 out of 155 decliners chose to have results by telephone. Secondly, providing the result of workup is an integrated part of information providing throughout the workup process.

The use of telephone in delivering healthcare may be the patient's preference or a consequence of healthcare resources or restrictions as observed during the COVID19 pandemic [28]. Systematic use of telephone in delivering health-care has been acknowledged for more than 30 years in various medical interactions such as genetic counselling, delivery of screening results, smoking cessation programmes, palliative interventions, and disclosing result of breast cancer workup [5, 29-31]. The preference for telephone disclosure among patients refusing to participate in our RCT supports the heterogeneity in patients' preferences, which are probably based on a multitude of aspects, but no research has so far investigated this. We find it likely that access to transportation, distance to hospital, impaired hearing, performance level, cognitive functioning, language skills, mental or physical comorbidity, local or personal tradition, and dependency on relatives/care-givers are likely factors, but this is an area for future research [5, 14, 29].

In 1997, Campbell et al reported a one-page note on a retrospective, questionnaire-based study on satisfaction with disclosure by telephone or in-person of invasive workup of suspected breast cancer after mammography [14]: overall satisfaction was higher with receiving a diagnosis by telephone compared to in-person even among the patients diagnosed with malignancy. The authors state that "careful preparation is necessary and a skilled communicator essential", but do not describe how patients were prepared, how communication was planned and performed, or how or when satisfaction was measured.

In the current RCT we provide a model for continuous information to patients so they know which information to be expected during an invasive workup. This model is not strictly evidence-based but is a result of many years of clinical experiences. It is in perfect conjunction with contemporary findings that disclosure of bad news in cancer care is an ongoing process [2-4]. Training in existing models focusing on breaking bad news at a single encounter is highly relevant in many clinical settings in which bad news arise suddenly [7-10]. Furthermore, our approach seriously includes patients' preferences when breaking bad news: [A)]setting (i.e., privacy, in-person consultation, sufficient consultation time), [B)]manner of communicating (i.e., physicians speaking clearly and

honestly, avoiding medical jargon, showing images and laboratory data), C)what and how much information to be provided (i.e. told illness was cancer, chance of a cure, effectiveness of treatment), and D)emotional support (i.e. use supportive language and allow patients to express their feelings) but spread over several conversations during the course of workup [32]. No other studies have investigated telephone use in lung cancer workup, but McElroy et al reported that an increasing number of patients receive the result of breast cancer workup by telephone, and advocates for the development on new models that incorporate other modes of communication than in-person conversations [5]. In their short note from 1997, Campbell et al advocated for randomised trials in breaking bad news [14], and the relevance of this wish remains undiminished, however there is also a need for insight into health care professionals' experience and emotional stress of disclosing bad news over the telephone compared to an in-person setting.

We used the COS-LC questionnaire with high content validity and adequate psychometric measurement properties originally developed to measure psychosocial consequences of lung cancer screening [22]. COS-LC part1 was sufficiently sensitive to detect differences in especially behaviour and dejection scales in participants in the Danish Lung Cancer Screening Trial (DLCST) [23]. In the DLCST, each mean of the nine COS-LC part1 scales averaged 1 point thus clearly in the lower range, as the scale scores vary from 0-6 to 0-21. In our study, the corresponding means were 6 to 10 (Figure 2), suggesting that COS-LC part1 has sufficient sensitivity to detect that undergoing workup of suspected malignancy is associated with worse psychosocial consequences than attending a lung cancer screening programme [23]. Yet, the rigorous validation process of COS-LC for the setting of lung cancer screening [22] was not repeated for the present setting. Instead, we conducted interviews using the Think Aloud Method that revealed that the content validity of COS-LC in the present context was high [24]. Therefore, we consider that we used an adequate questionnaire to measure the psychosocial consequences of receiving the final result of workup of suspected intrathoracic malignancy and comparing the two different and common settings of In-person or telephone conversation.

RCTs invariably infers some kind of selection bias. In the present RCT, accepting randomisation and completing COS-LC twice might have excluded mentally stronger patients with a clear opinion on how to have their diagnosis disclosed. In addition, physically or mentally vulnerable patients might have declined participation because they did have the capacity to comply with this extra burden, or needed close assistance by family or other caregiver. Furthermore, our focus on

ambulatory care excluded hospitalized patients, who most likely form a specifically fragile group. Hence, our results may not be directly transferable to mentally or physically fragile patients.

The rate of missing follow-up questionnaires where larger than expected. No patients withdrew consent, but apparently questionnaire completion was challenged by more imminent problems, as suggested by the fact that a quarter of the non-completers died within 8 weeks after randomisation. The follow-up questionnaire were to be completed 4 weeks after receiving their final diagnosis, thus at a time point were most patients with malignant disease are accommodating to a life as a patient with cancer including dealing with physical, psychological and social impact of disease and treatment [33-35]. Despite these turbulent circumstances, completers were consistent in their COS-LC responses over time (Figure 2, Table 4).

Patients with non-malignant diagnoses had higher levels of anxiety and dejection in the Telephone group than in the In-person group. This was in contrast to the retrospective study by Campbell et al where satisfaction generally was higher in the Telephone group but direct comparison is difficult as the Campbell study lacks key information on methods (including time spent), and "satisfaction" and "psychosocial consequences" are not the same constructs [14]. We did not measure time spent on each disclosure method, but the involved clinicians unanimously shared the impression that disclosure by telephone requires the least time, as it was easier to focus directly on the obtained results (personal communication). Only 2/81 patients had a false-negative non-malignant result thus misclassification cannot explain our findings. Currently, it is unknown whether this is a spurious finding due to the multiple statistical tests performed, or a true finding. If true, we suggest it dealt with by giving the patient access to a follow-up conversation, either booked or an on as-needed basis.

Other studies have found that benign results of cancer workup are associated with distress and decreased quality of life comparable to that observed in patients diagnosed with malignancy, and it is plausible that the uncertainty of possible a false-negative diagnosis induces increased levels of anxiety [23, 36-39]. Both newly diagnosed benign disease (e.g. sarcoidosis) and malignancy is associated with decreased quality of life and substantial symptoms burden [35, 40], which could explain the apparently contra-intuitive observation that patients with malignant and non-malignant results had so similar COS-LC results at follow-up. Future research should address the patients' perspectives of receiving a benign or malignant diagnosis during cancer workup, including prior experiences (own or relatives'), health literacy, and emotional/existential crisis handling. There is a

need for qualitative research to clarify how continuous information in cancer workup is perceived and used by our patients.

Our study suggests that there are no inherent disadvantage of receiving results of cancer workup by telephone compared to in-person, when patient and physician agree on the mode of communication, and the patients are continuously informed of plans, suspicion and expected content of the planned conversation.

References

1. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin* 2018: 68(6): 394-424.
2. Bousquet G, Orri M, Winterman S, Brugiere C, Verneuil L, Revah-Levy A. Breaking Bad News in Oncology: A Metasynthesis. *J Clin Oncol* 2015: 33(22): 2437-2443.
3. Schaepe KS. Bad news and first impressions: patient and family caregiver accounts of learning the cancer diagnosis. *Soc Sci Med* 2011: 73(6): 912-921.
4. Dean A, Willis S. The use of protocol in breaking bad news: evidence and ethos. *Int J Palliat Nurs* 2016: 22(6): 265-271.
5. McElroy JA, Proulx CM, Johnson L, Heiden-Rootes KM, Albright EL, Smith J, Brown MT. Breaking bad news of a breast cancer diagnosis over the telephone: an emerging trend. *Support Care Cancer* 2019: 27(3): 943-950.
6. Kuroki LM, Zhao Q, Jeffe DB, Powell MA, Hagemann AR, Thaker PH, Massad LS, Mutch DG, Zighelboim I. Disclosing a diagnosis of cancer: considerations specific to gynecologic oncology patients. *Obstet Gynecol* 2013: 122(5): 1033-1039.
7. Baile WF, Buckman R, Lenzi R, Glober G, Beale EA, Kudelka AP. SPIKES-A six-step protocol for delivering bad news: application to the patient with cancer. *Oncologist* 2000: 5(4): 302-311.
8. Kaye P. Breaking bad news : a 10 step approach. EPL. Northampton., 1996.
9. Pereira CR, Calonego MA, Lemonica L, Barros GA. The P-A-C-I-E-N-T-E Protocol: An instrument for breaking bad news adapted to the Brazilian medical reality. *Rev Assoc Med Bras (1992)* 2017: 63(1): 43-49.
10. Narayanan V, Bista B, Koshy C. 'BREAKS' Protocol for Breaking Bad News. *Indian J Palliat Care* 2010: 16(2): 61-65.
11. Gaga M, Powell CA, Schraufnagel DE, Schonfeld N, Rabe K, Hill NS, Sculier JP, Cancer AETFotRotPitMoL. An official American Thoracic Society/European Respiratory Society statement: the role

of the pulmonologist in the diagnosis and management of lung cancer. *Am J Respir Crit Care Med* 2013: 188(4): 503-507.

12. Silvestri GA, Gonzalez AV, Jantz MA, Margolis ML, Gould MK, Tanoue LT, Harris LJ, Detterbeck FC. Methods for staging non-small cell lung cancer: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest* 2013: 143(5 Suppl): e211S-250S.

13. Paul CL, Clinton-McHarg T, Sanson-Fisher RW, Douglas H, Webb G. Are we there yet? The state of the evidence base for guidelines on breaking bad news to cancer patients. *Eur J Cancer* 2009: 45(17): 2960-2966.

14. Campbell L, Watkins RM, Teasdale C. Communicating the result of breast biopsy by telephone or in person. *Br J Surg* 1997: 84(10): 1381.

15. Sinclair S, Beamer K, Hack TF, McClement S, Raffin Bouchal S, Chochinov HM, Hagen NA. Sympathy, empathy, and compassion: A grounded theory study of palliative care patients' understandings, experiences, and preferences. *Palliat Med* 2017: 31(5): 437-447.

16. Figg WD, Smith EK, Price DK, English BC, Thurman PW, Steinberg SM, Emanuel E. Disclosing a diagnosis of cancer: where and how does it occur? *J Clin Oncol* 2010: 28(22): 3630-3635.

17. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010: 340: c332.

18. Bodtger U. [cited; Available from: https://portal.findresearcher.sdu.dk/en/projects/is-it-harmful-to-receive-a-lung-cancer-diagnosis-by-phone-compare

19. Lung Cancer Package Pathways in Denmark (Danish). Copenhagen, Denmark: Danish National Board of Health; 2018 07 September 2018.

20. Madsen KR, Hoegholm A, Bodtger U. Accuracy and consequences of same-day, invasive lung cancer workup - a retrospective study in patients treated with surgical resection. *Eur Clin Respir J* 2016: 3: 32590.

21. Sidhu JS, Salte G, Christiansen IS, Naur TM, Høegholm A, Clementsen PF, Bodtger U. Fluoroscopy-guided percutaneous biopsy in combination with bronchoscopy and endobronchial ultrasound in the diagnosis of suspicious lung lesions – the triple approach. *European Clinical Respiratory Journal* 2020: in press.

22. Brodersen J, Thorsen H, Kreiner S. Consequences of screening in lung cancer: development and dimensionality of a questionnaire. *Value Health* 2010: 13(5): 601-612.

23. Rasmussen JF, Siersma V, Pedersen JH, Brodersen J. Psychosocial consequences in the Danish randomised controlled lung cancer screening trial (DLCST). *Lung Cancer* 2015: 87(1): 65-72.

24. Fonteyn ME, Kuipers B, Grobe SJ. A Description of Think Aloud Method and Protocol Analysis. *Qualitative Health Research* 2016: 3(4): 430-441.
25. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. *Med Care* 2003: 41(5): 582-592.
26. Hestbech MS, Siersma V, Dirksen A, Pedersen JH, Brodersen J. Participation bias in a randomised trial of screening for lung cancer. *Lung Cancer* 2011: 73(3): 325-331.
27. Dufouil C, Brayne C, Clayton D. Analysis of longitudinal studies with death and drop-out: a case study. *Stat Med* 2004: 23(14): 2215-2226.
28. Greenhalgh T, Koh GCH, Car J. Covid-19: a remote assessment in primary care. *BMJ* 2020: 368: m1182.
29. Patrick-Miller L, Egleston BL, Daly M, Stevens E, Fetzer D, Forman A, Bealin L, Rybak C, Peterson C, Corbman M, Bradbury AR. Implementation and outcomes of telephone disclosure of clinical BRCA1/2 test results. *Patient Educ Couns* 2013: 93(3): 413-419.
30. McBride CM, Rimer BK. Using the telephone to improve health behavior and health service delivery. *Patient Educ Couns* 1999: 37(1): 3-18.
31. Jenkins J, Calzone KA, Dimond E, Liewehr DJ, Steinberg SM, Jourkiv O, Klein P, Soballe PW, Prindiville SA, Kirsch IR. Randomized comparison of phone versus in-person BRCA1/2 predisposition genetic test result disclosure counseling. *Genetics in Medicine* 2007: 9(8): 487-495.
32. Fujimori M, Uchitomi Y. Preferences of cancer patients regarding communication of bad news: a systematic literature review. *Jpn J Clin Oncol* 2009: 39(4): 201-216.
33. Stanze H, Schneider N, Nauck F, Marx G. "I can't get it into my head that I have cancer..."-A qualitative interview study on needs of patients with lung cancer. *PLoS One* 2019: 14(5): e0216778.
34. Chabowski M, Polanski J, Jankowska-Polanska B, Lomper K, Janczak D, Rosinczuk J. The acceptance of illness, the intensity of pain and the quality of life in patients with lung cancer. *J Thorac Dis* 2017: 9(9): 2952-2958.
35. Siemens W, Schonsteiner SS, Orellana-Rios CL, Schaekel U, Kessler J, Eschbach C, Viehrig M, Mayer-Steinacker R, Becker G, Gaertner J. Severe symptoms and very low quality-of-life among outpatients newly diagnosed with advanced cancer: data from a multicenter cohort study. *Support Care Cancer* 2020.
36. Pelletier M, Knauper B, Loiselle CG, Perreault R, Mizrahi C, Dube L. Moderators of psychological recovery from benign cancer screening results. *Curr Oncol* 2012: 19(3): e191-200.
37. Qian F, Yang W, Chen Q, Zhang X, Han B. Screening for early stage lung cancer and its correlation with lung nodule detection. *J Thorac Dis* 2018: 10(Suppl 7): S846-S859.

38. Brodersen J, Siersma VD. Long-term psychosocial consequences of false-positive screening mammography. *Ann Fam Med* 2013: 11(2): 106-115.
39. Lemonnier I, Baumann C, Jolly D, Arveux P, Woronoff-Lemsi MC, Velten M, Guillemin F. Solitary pulmonary nodules: consequences for patient quality of life. *Qual Life Res* 2011: 20(1): 101-109.
40. Voortman M, Hendriks CMR, Elfferich MDP, Bonella F, Moller J, De Vries J, Costabel U, Drent M. The Burden of Sarcoidosis Symptoms from a Patient Perspective. *Lung* 2019: 197(2): 155-161.

Tables

Table 1.

Actions and information content at the four steps of patient-doctor interactions during workup for suspected malignancy in the present study.

Information step	Cancer work-up step	Pulmonologist's Action †	What is said to the patient? Examples of typical phrases.
1	Referral for suspected lung cancer	Telephone Call 1: a) Medical history obtained including symptoms needing action? b) Available imaging results c) Clinical suspicion. d) Plan (step 2 and/or 3)	"We need to rule out cancer." "Cancer is a possibility, as is chronic infection".
2	Advanced Imaging (CT, MR, PET-CT)	Telephone Call 2: a) Imaging results b) Clinical suspicion including stage (local/advanced/metastatic) c) Plan including content of step 3	"Cancer is likely/possible/unlikely." "Cancer or chronic infection/inflammation are the most likely causes." Repeating Step 1 phrases
3	Invasive Workup in Bronchoscopy suite	In-person meeting: a) Physical examination + confirmation medical history, b) Sharing CT/PET-CT images with patient +/-	As Step 2 + "If cancer, curative treatment is likely/unlikely." "If the biopsies confirm cancer suspicion, then the most likely

		relatives c) Invasive workup d) Study randomization ‡	treatment is [eg. curative surgery/radiation/combination treatment OR expectedly non-curative oncological treatment with drugs to eradicate as much cancer as possible] §
4	Results	In-person meeting or Telephone Call	Diagnosis, stage, referral for therapeutic intervention, need for further diagnostic interventions.

† All patient contacts ended with the doctor summarizing the conversation, and giving an invitation to ask questions. If questions, then a new summary followed. The conversation ended when the patient had no more questions after the last summary.

‡ In our unit, we routinely use the described approach. Then this point replaced by: d) Shared decision on breaking the results in-person or by telephone.

§ List not exhaustive. These are the most common phrase types but exact phrasing on treatment options depends on patients' wishes, clinical presentation, stage, and cancer subtype.

Table 2. Baseline data in the intention-to-treat cohort.

	In-person group (n=126)	**Telephone group (n=129)**	**p-value**	**Missing data**
Female, n (%)	52 (41.3)	45 (34.9)	0.29	0
Age (years), mean (sd)	68.12 (8.8)	67.03 (10.7)	0.37	0
Living alone, n (%)	34 (27.9)	49 (38.6)	0.073	0
Education, n (%)			0.90	6
None registered	5 (4.0)	5 (4.0)		
Primary school	55 (44.0)	51 (41.1)		
Secondary school	55 (44.0)	60 (48.4)		
Higher education	10 (8.0)	8 (6.5)		
Annual income (quartiles), n (%)			0.75	6
<16,600 €	31 (25.4)	26 (20.5)		

16,600 € - 21,483 €	30 (24.6)	30 (23.6)		
21,483 € - 28,017 €	31 (25.4)	34 (26.8)		
>28,017 €	30 (24.6)	37 (29.1)		
Charlson's Comorbidity Index, n (%)			0.26	0
0	64 (50.8)	55 (42.6)		
1	29 (23.0)	41 (31.8)		
2+	33 (26.2)	33 (25.6)		
Previous cancer, n (%)	23 (18.3)	35 (27.1)	0.09	0
ECOG, n (%)			0.12	17
0	100 (84.0)	109 (91.6)		
1	17 (14.3)	10 (8.4)		
2	2 (1.7)	0 (0.0)		
Number of medications used, mean (sd)	4.76 (4.3)	3.98 (3.8)	0.21	85
FEV_1 (% predicted), mean (sd)	72.0 (21.0)	75.0 (22.0)	0.29	12
Smoking, n (%)			0.53	7
Never	14 (11.5)	19 (15.1)		
Previous smoker	52 (42.6)	46 (36.5)		
Current smoker	56 (45.9)	61 (48.4)		
Tobacco exposure (packyears), mean (sd)	34.23 (20.4)	34.64 (22.9)	0.89	20

1 FEV_1, Forced Expiratory Volume in one second

2

3 **Table 3**. Results of invasive work-up conferred to the patients (intention-to-treat cohort).

	In-person group (n=126)	**Telephone group (n=129)**	**p-value**
Malignant results, n (%)	85 (67.5)	89 (69.0)	0.79
Lung cancer, n (%)			0.20†
Adenocarcinoma*	42 (49.4)	44 (49.4)	
Squamous Cell Carcinoma	18 (21.2)	22 (24.7)	
Carcinoma not otherwise specified (NOS)	1 (1.2)	4 (4.5)	
Small Cell Lung Cancer	13 (15.3)	9 (10.1)	
Other Neuroendocrine tumours	4 (4.7)	3 (3.4)	
Malignant pleural mesothelioma	0 (0)	4 (4.5)	

Metastatic extra-pulmonary cancer	7 (8.2)	3 (3.4)	
Non-malignant results, n (%)	41 (32.5)	40 (31.0)	0.68*
Infection‡	9 (22.0)	8 (19.5)	
Sarcoidosis	4 (9.8)	3 (7.5)	
Non-infectious, non-malignant lesions: referred for CT follow-up.	21 (51.2)§	19 (47.5)	
Unsolved: referred for further work-up	7 (17.1)§	10 (25.0)	

† Including one patient in each group with two simultaneous, primary low-stage lung cancers (adenocarcinoma and squamous cell carcinoma).

‡ Including one patient in each group with tuberculosis.

§ One patient diagnosed with malignancy (lymphoma) during CT follow-up *resp.* further workup.

* *P* for trend (*Chi*^{2}-test)

Table 4. Primary endpoint: mean between-group difference (SD) in COS-LC part1 scores at baseline and follow-up showing how the In-person group differs from the Telephone group. Negative values equal higher psychosocial consequences in the Telephone group.

COS-LC part 1	**Between groups difference**			
	Baseline		**Follow up**†	
	Δ (95%CI)	p-value	Δ (95%CI)	p-value
Core scales				
1. Anxiety.	-0.60 (-2.14 ; 0.95)	0.45	-0.40 (-2.02 ; 1.22)	0.63
2. Behaviour	-0.05 (-1.22 ; 1.12)	0.93	1.16 (-1.4 ; 3.72)	0.37
3. Dejection	-0.43 (-1.75 ; 0.89)	0.52	-0.95 (-3.18 ; 1.28)	0.40
4. Negative impact on sleep	0.40 (-0.68 ; 1.48)	0.47	-0.17 (-1.75 ; 1.4)	0.83
Lung cancer specific scales				
5. Self-blame	0.43 (-1.06 ; 1.93)	0.57	0.64 (-1.29 ; 2.57)	0.51
6. Focus on airway symptoms	0.39 (-0.16 ; 0.94)	0.16	-1.11 (-2.11 ; -0.1)	**0.031**
7. Stigmatisation	-0.11 (-0.81 ; 0.59)	0.75	-0.07 (-1.41 ; 1.27)	0.92
8. Introvert	-0.23 (-1.11 ; 0.65)	0.61	-1.12 (-3.76 ; 1.52)	0.41
9. Harms of smoking	0.25 (-0.46 ; 0.95)	0.49	0.01 (-0.93 ; 0.94)	0.99

†Beyond difference at baseline. COS-LC, Consequences of Screening Lung Cancer questionnaire

Table 5. Secondary endpoint: mean between-group difference (SD) in COS-LC part 2 scores at follow-up showing how the In-person group differs from the Telephone group.
Negative values equal higher perception of psychosocial change in the Telephone group.

COS-LC part 2	**Between groups difference**	
	Δ (95%CI)	p-value
1. Calm/relax	-0.43 (-0.93 ; 0.06)	0.083
2. Social network	0.04 (-0.41 ; 0.49)	0.86
3. Existential values	-0.01 (-1.17 ; 1.15)	0.98
4. Impulsivity	-0.53 (-1.41 ; 0.35)	0.24
5. Empathy	0.00 (-0.52 ; 0.53)	0.99
6. Regretful of still smoking	1.09 (-0.4 ; 2.57)	0.15

COS-LC. Consequences of Screening Lung Cancer questionnaire

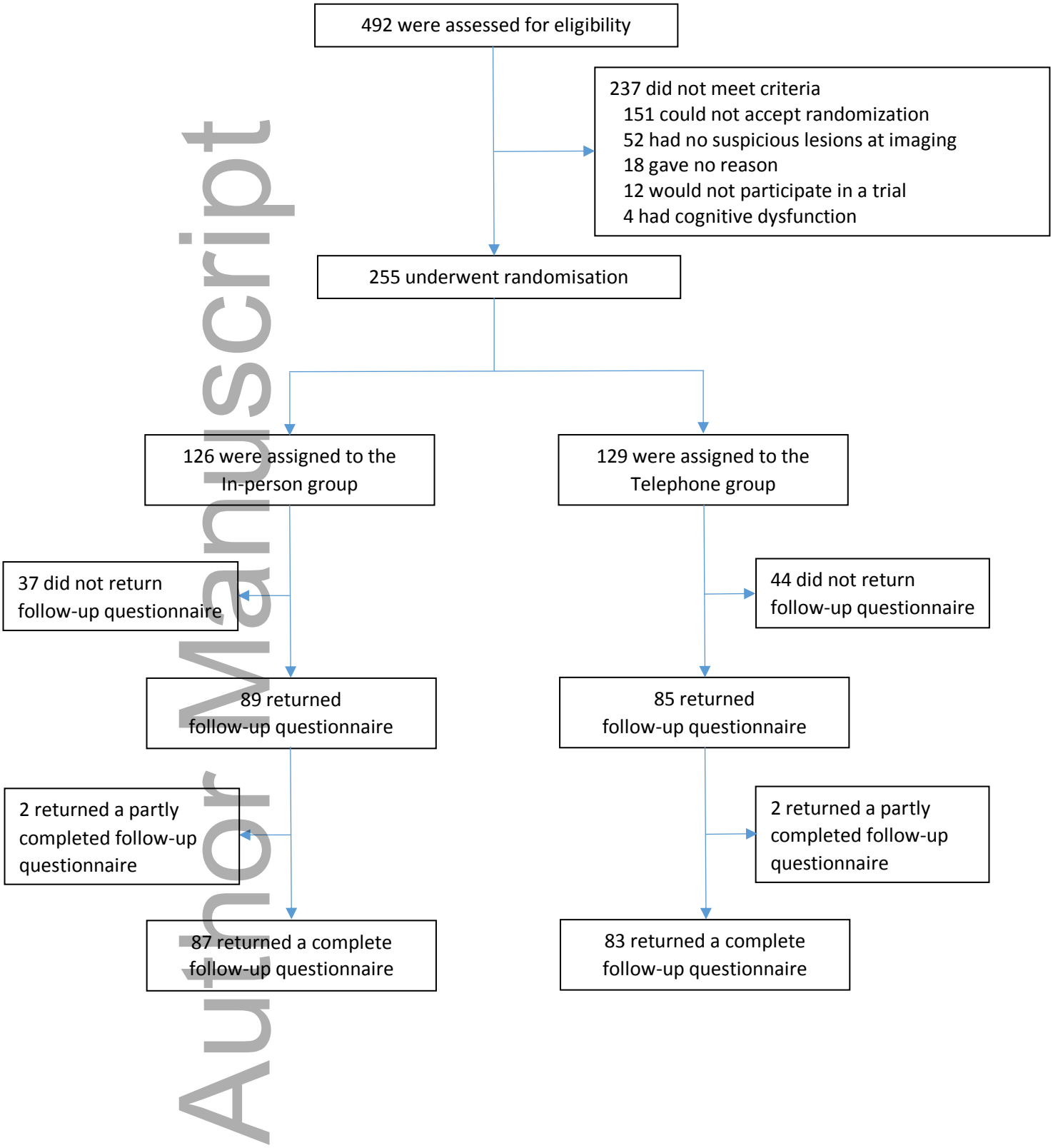
Figure legends

Figure 1. CONSORT diagram on identification, enrolment, randomisation and follow-up of the patients. None withdrew consent.

Figure 2. Mean estimates of the nine psychosocial outcomes in the In-person group (red lines) and the Telephone group (blue lines) at baseline and follow-up (intention-to-treat cohort). See Table 4 for statistical comparison.

(Figure 1)

ecc_13435_f1.pdf



(Figure 2)

ecc_13435_f2.pdf