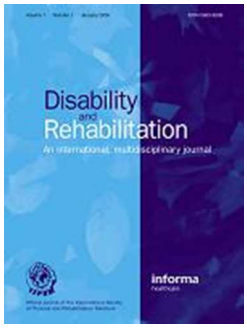

Burden of treatment in the light of the International Classification of Functioning, Disability and Health: A "Best Fit" Framework Synthesis

Journal:	*Disability and Rehabilitation*
Manuscript ID	TIDS-06-2015-113.R1
Manuscript Type:	Review
Keywords:	Review, burden of treatment, ICF, comprehensive ICF core sets, long term conditions

Review

Burden of treatment in the light of the International Classification of Functioning, Disability and Health: A "Best Fit" Framework Synthesis

Abstract

Purpose: This systematic literature review aimed to 1) summarise and explain the concept of Burden of Treatment (BoT) using the International Classification of Functioning, Disability and Health (ICF) terminology, and 2) inform the development of a future Comprehensive ICF Core Set for BoT.

Method: Searches on EMbase, Medline, CINAHL and Psychinfo were conducted. Only qualitative studies were considered for inclusion. The screening and data extraction stages were followed by a "Best-fit" framework synthesis and content analysis, using the established ICF linking rules. Screening, data extraction, quality appraisal and data analysis were performed by two independent researchers.

Results: Seventeen studies were included in this review. The "Best–fit" framework synthesis generated 179 subthemes which identified that BoT impacts negatively on Body Functions and Structures, restricts valued Activities and Participation and influences Contextual Factors through life roles, self-identify and relationships. The identified subthemes were linked to 77 ICF categories.

Conclusions: This study is part of the preparatory phase of a Comprehensive ICF Core Set for BOT and our findings will inform the further needed studies on this phase. The use of ICF terminology to describe BoT provides an accessible route for understanding this complex concept, which is pivotal for rethinking clinical practice.

Key words

Review, burden of treatment, ICF, comprehensive ICF core sets, long term conditions

Introduction

Patients' decisions regarding treatment options, such as which treatment to receive and how much they adhere to treatment recommendations, are related to the anticipated and actual experience of undertaking the treatment [1], particularly, the perceived burden of treatment (BoT)[2]. BoT has been described as the increased demand experienced from performing self-care activities, undertaking treatment regimens and monitoring health outcomes [3]. It also includes the impact of treatment on patient functioning and well-being [4]. Increased BoT is associated with non-adherence, wasted resources, poor health outcomes, reduced quality of life and, ultimately, with increased mortality [3-7]. Health professionals therefore need to be sensitive to recognising, understanding and reducing BoT, in order to balance the potential benefits and burdens of treatments and maximise adherence [7, 8].

The International Classification of Functioning, Disability and Health (ICF), developed by the World Health Organization, provides a framework for the description of health and health-related states within a common terminology [9, 10]. This classification, with its four components (Body Functions and Structures, Activities and Participation, Environmental Factors and Personal Factors) reflects the biopsychossocial model in a unified and coherent view of various dimensions of health (biological, individual and social) [10]. The ICF proposes that patients are not a “passive receiver of medical care” [11]. Rather, their experiences of

illness are more than just the direct impact of disease on Body Functions and Structures (i.e., physiological systems or anatomical structures): they are influenced by the effect of health conditions on their ability to undertake valued activities (such as walking and dressing) and to participate in life situations (such as work, leisure and family). Each patient's illness experience is also influenced by both Environmental Factors (i.e., physical, social and attitudinal environment in which patient live, such as family support or wheelchair provision) and Personal Factors (i.e., attributes of the patient with an internal influence on functioning and disability, such as resilience or skills). The ICF captures these various perspectives of functioning, disability and health, and has been increasingly applied by healthcare professionals worldwide, as the reference framework for describing health according to the biopsychosocial model [11].

The concept of BoT has not been previously aligned with the ICF framework; however, the conceptual connections are apparent. Patients' experiences and perceptions of BoT have been shown to relate to various factors such as fatigue or pain (Body Functions) [6, 12], family circumstances, treatment design, health care systems (Environmental Factors) [4-8, 12-16] and Personal Factors [4-8, 12-16]. Many health professionals are familiar with and applying the ICF in research and clinical practice [11]. The ICF framework can therefore act as a useful tool for elucidating the complex concept of BoT. As a novel concept, BoT is receiving increasing attention in the literature [17, 18] however, robust outcome measures, to cover the complexity of this concept across conditions are still being developed and fundamental understanding of this concept, based on the perspectives of patients and researchers, has been generated by qualitative studies [4, 18]. Linking the findings from these studies with the ICF will inform future developments of an ICF Core Set for BoT.

The development of ICF Core Sets is recommended by the World Health Organisation as they represent a list of categories specifically relevant for a health condition or context, promoting the applicability of the ICF in clinical practice [19, 20]. ICF Core Sets are designed in comprehensive and/or short versions. The former are exhaustive lists of categories used to describe a health condition or context; the latter represent only the most essential of these categories [20]. Recent guidance on the development of ICF Core Sets has been published and recommends a three stage process: a preparatory phase, followed by an international ICF consensus conference and a last phase, which consists of the implementation of the first version of the ICF Core Set [20]. The preparatory phase includes a systematic literature review which aims to gather the perspectives of researchers and identify aspects of functioning that can then be linked to the ICF through the established linking rules [9, 20]. The type and characteristics of the systematic review may vary in this preparatory phase [20]. In this particular case, it is important to consider that the concept of BoT is complex and recent in the literature [3, 18, 21], and has not yet been widely linked to measurement tools [22].

This systematic qualitative literature review aimed to i) summarise and explain the concept of BoT using the ICF terminology, and ii) inform the development of a future Comprehensive ICF Core Set for BoT. The results of this study will facilitate communication within multidisciplinary teams regarding BoT; allow the concept of BoT to be mapped to the ICF and therefore understood and recognised among more health professionals; and ultimately, inform the development of instruments/assessment tools of BoT.

Methods

This qualitative literature review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, developed to promote optimal clarity, transparency and reliability of systematic literature reviews [23]. The following sections adopted the PRISMA terminology, with the necessary adaptations for a qualitative literature.

Eligibility criteria

Qualitative studies that focused on patients' experiences of BoT in any health condition were sought. The decision to only include qualitative studies was based on the need to gain a rich and deep understanding of "what" BoT is, from the perspective of both patients and researchers, and to then link this to "how" it is represented in the ICF. Therefore, studies met the inclusion criteria if they: 1) used both qualitative data collection and analysis methods; 2) contained the expressions "treatment burden" or "burden of treatment" in the title or abstract and 3) considered BoT as the main focus or included BoT in the research questions. Studies that may have contained the expressions "treatment burden" or "burden of treatment" only in the body of the paper, but not in the title or abstract, were excluded. This was used as an indicator of studies that have BoT as their main focus, and would therefore explore this topic in greater depth. Studies describing "burden of disease", "caregiver burden", "financial burdens to society or health services"; not written in English or Portuguese; and, those not including qualitative data were also excluded.

Search and information sources

The search was undertaken electronically in four different databases - EMbase, Medline, CINAHL and Psychinfo - aiming to achieve an extensive search strategy that would cover the available studies focusing on BoT. The key words "treatment burden" OR "burden of treatment" were used in all the listed databases. No restrictions were established regarding treatment intervention, health condition, participant demographics, year of publication or study settings. No filters were used in any of the databases. The search was initially conducted in June 2012 and updated in December 2014.

Screening and study selection

Two blinded researchers screened the titles, abstracts and, when necessary, full texts of all studies to determine inclusion and exclusion and remove duplicates. In order to avoid early incorrect filtering of qualitative studies, no restrictions regarding paradigm were set on the data bases and the identification of qualitative studies was undertaken manually, during the screening of titles and abstracts [24].

Quality appraisal

The Critical Appraisal Skills Programme Checklist for qualitative studies [25] was used to assess the quality of studies. Quality appraisal was initially performed independently, and then discussed and agreed, by two researchers [SH and KH]. An increasing body of evidence proposes that neither study design nor quality assessment scores should be used to exclude qualitative studies [26, 27]. All studies were therefore included and analysed regardless of their design or quality score. Quality scores are provided to enrich the description of the included studies.

Synthesis of results

The extracted data were analysed using two methods: firstly a qualitative "Best-fit" framework synthesis; secondly a content analysis applying the ICF linking rules [9]. Both methods are described below. "Data" were defined as both direct primary quotations presented in the included studies and authors' analytical interpretations presented in either the results/findings or discussion sections. The use of both "quotations" and "analytical interpretations" as data for this literature review aimed to allow the gathering of a richer set of data to better illustrate the concept of BoT. This approach has been used in previous reviews of qualitative studies [28].

"Best-fit" framework synthesis. "Best-fit" framework synthesis uses the conceptual categories of an existing model or theory to facilitate thematic data extraction and analysis. This synthesis method offers the means to test, reinforce and build on an existing published model, conceived for a potentially different but relevant population or context [26, 27, 29]. The ICF was selected as the model of "Best-fit" to explore how BoT may be conceptualised within a biopsychosocial perspective of health [10]. An *a priori* framework using the ICF components (Body Functions and Structures, Activities and Participation, Environmental Factors and Personal Factors) was used to extract data from the included studies. NVivo software (v.10 QSR International Pty Ltd., Melbourne, AU) was used to aid data management.

Framework analysis allows a description of both *a priori* and newly emerged themes. Following extraction, data attributed to the *a priori* framework were further thematically analysed, grouping similar issues to generate a list of emergent themes and subthemes. For

instance, the quotes "*One individual adopted a more generally sedentary lifestyle to prevent symptoms rather than undertake physical activity alongside their peers*" [16] and "*Fatigue alongside breathlessness and cough, was reported as a factor limiting ability to keep up with peers, and also as a cause of low motivation*" [16] were both coded under the theme "Participation linked to Body Functions and Structures" and the subtheme "Symptoms limiting participation with peers".

The themes and subthemes and the links and conflicts between them were thereafter used to explain the concept of BoT from the perspective of the ICF.

Content analysis following the ICF linking rules. Content analysis, applying the ICF linking rules [9], was undertaken to classify the subthemes generated as previously described, against the most appropriate ICF category. According to these rules, meaningful concepts should be extracted from a text prior to assigning the ICF categories [30]. The example below, extracted from the analysis, illustrates this process:

The subtheme (generated by "Best-fit" synthesis) *"Having a routine as a strategy to reduce treatment workload and promote adherence"* was analysed and the following meaningful concepts were identified: i) "*having a routine as a strategy to reduce treatment workload*"; ii) "*having a routine as a strategy to promote adherence*" and iii) "*reduced workload promotes adherence"*.

Two researchers experienced in using the ICF and with a deep understanding of the concept of BoT [ACG and CJ] independently linked the meaningful concepts to the appropriate ICF

categories. The example above was coded as d230 (Carrying out a daily routine); the concepts "treatment workload" and "adherence" were coded as not covered by the ICF and the concept "*having coping strategies*" was coded as Personal Factors. The agreement between the codifications of both researchers was calculated with Cohen's Kappa statistics [31], using IBM SPSS statistics (Version 21, IBM Corp. Released 2012, Armonk, NY). The strength of agreement associated to the Cohen's Kappa statistics can be classified as poor (<0), slight (0.00-0.20), fair (0.21-0.40), moderate (0.41-0.60), substantial (0.61-0.80) or almost perfect (0.81-1.00) [32]. Any disparities were discussed by the same researchers, a third party [SHD] resolved disagreements and a final list was generated.

Results

Study selection

The search generated 1736 studies. Once duplicates (n=590) were removed, 1146 abstracts and titles were screened; 378 full texts were considered for eligibility. Studies not using qualitative methods (n=167), or not exploring patients' perspective of BoT (n=194) were excluded. Seventeen studies met the inclusion criteria and were included in this review. A PRISMA flow chart illustrating the study selection process is presented in figure 1.

Inset figure 1 about here

Study characteristics

The samples of the included studies show a wide range of ages (from 7 to 96 years old), health conditions and countries. Further details about the included studies can be found in table 1.

Insert table 1 about here

The quality scores for regarding aspects such as recruitment, data collection, validity, methodology, relationship between researchers and participants, ethical issues, data analysis and relevance of the findings were considered high in all included studies. However, the "relationship between researchers and participants" and a detailed discussion of "ethical issues" were often less clear.

ICF components applied to the concept of burden of treatment: best-fit framework synthesis

Burden of Treatment and Body Functions and Structures. All studies reported BoT experienced as either physical and/or emotional side effects. Applying the ICF, these side-effects can be considered as treatment induced impairments to Body Functions and Structures additional to those generated by the disease itself. These included pain, fatigue and nausea and altered emotional functions, such as feeling anxious or depressed. For instance, patients using Percutaneous Endoscopic Gastrostomies described a large range of treatment generated physical impairments:

> *"Blockage, leakage, site infection, tube falling out, emesis caused by excessively rapid infusion of feed, sleep difficulties due to noise from machines, bleeding from PEG* [Percutaneous Endoscopic Gastrostomies] *sites when coughing, and malodorous leakage from the stoma. Feeling seek and terrible coughing that leads to vomiting, nausea, regurgitation or heartburn (…) [and] abdominal pain"* [8].

The included studies also described the increased treatment workload (BoT), which was frequently required in order to manage the side-effects (Impairments in Body Functions and Structures) generated by the treatments.

> *"The primary issue during the first injections was adjusting to the cycle of symptoms and 'side effects'" [12].*

Finally, impairments in Body Functions and Structures often reduced patients' physical capacity to engage with the recommended treatment requirements. For instance a patient with diabetes, stated:

> *"I was supposed to look at my feet once a week but I can't see my feet because of my poor vision" [4].*

Treatment induced impairments were also frequently reported as contributing to restrictions in patients' activities and their ability to participate in life roles, and it was the impact of treatments on participation restriction that appeared to be most burdensome for patients.

> *"People wanted me to come and play bridge and to do other things, [but] I think, on the higher dose of the prednisone I feel tremulous and it is more difficult to concentrate"* [4].

How BoT relates to Activities and Participation is described under the following section.

Burden of Treatment and Activities and Participations. The studies also identified that treatment regimens often required patients to engage in a complex set of new and additional treatment activities; for instance, exercising, learning about treatment options and modifying diets. These activities took time and impacted on patients' ability to engage in their valued activities. According to the included studies, participation in valued occupational, social and leisure activities, sports or other hobbies contributed to patients' identity and sense of self. Maintaining these activities was therefore seen as a priority and a way of keeping a "normal life". For instance, one woman worried about the impact of injections for spasmodic dysphonia on her valued activity of hiking:

> *"I'm more concerned that [if I have the treatment] I'm not going to be able to go hiking with my friends"* [12].

Many patients therefore engaged in complex decision making and prioritisation, adapting their life to enable both their treatment and meaningful activities to occur.

> *"A friend called me 'Hey, I have tickets to a baseball game. Do you want to go?' I am like, 'Well, can I plan my treatment around it?'"* [13].

However, the ability to maintain a stable self-identity by participation in valued activities and roles was often seen as a greater priority than engaging in treatment. Participants of the included studies described the process of making rational decisions to modify or even

cease their adherence to treatments, in order to preserve aspects of participation, such as career or social/leisure activities:

> *"When I am out with friends, I don't carry them (enzymes) like my parents tell me to"* [13].

Conversely, when treatment activities were meaningful, compatible with patients' valued activities or caused less disruption to participation were seen as less burdensome:

> *"I used to not be able to do anything when I went to parties and now* [thanks to oral immunotherapy] *I can sit with other kids and actually enjoy ice cream instead of watching . . . I was sort of glad I could be more like normal kids" [36].*

A further link was identified between the concept of BoT, Activities and Participation and Environmental Factors. For instance the financial costs of treatment (which would be classified as Environmental Factors) were described as a factor contributing to a restriction in family leisure activities (Activities and Participation).

> *"Money spent on obtaining treatment had a negative impact on family leisure and social/sporting activities*" [7].

In other cases, where treatment-induced activity restrictions might otherwise have led to non-adherence, involvement and support of relatives (also considered Environmental Factors) increased patients' capacity to engage in treatment and promoted adherence.

> *"I'm getting a repeat [prescription], my daughter (takes) it up to the chemist and X in the chemist (takes) it to the doctor, (gets) everything signed and it will be ready today, so my daughter will bring it down.... I can't get up there…"* [5].

Further information as to how BoT relates to the Environmental Factors is described in the following section.

Burden of Treatment and Environmental Factors. Environmental Factors were reported as sources of BoT by all studies in this review. Aspects such as health policies and health professionals' attitudes were described as causes of BoT through their disruption to patients' self-identity, as demonstrated by this quote, about a patient with tuberculosis:

> *"[She] Felt she had no say over her treatment and could not approach healthcare staff with her concerns, for fear of recrimination"* [15].

Family support, attitudes of health professionals, architectural barriers or treatment related stigma clearly worked as either barriers to or facilitators of treatment which may influence the perception of BoT. Others were considered responsible for triggering a more complex cycle of burden.

> *"Treatment burden encompassed a cyclical aspect. For example, contradictory advice on treatment by health care professionals (health care access burden) could lead to polypharmacy (medication burden), which could then result in both a requirement for*

extra time to organise medications (time burden) and extra strain on financial resources (financial burden)" [7].

However, it is important to highlight that Environmental Factors were not just acting as triggers, barriers or facilitators, but were also negatively affected by the treatment. An example commonly found in the included studies was the negative impact of treatment regimens on patients' relationships and support received from family and friends, which can both be linked to Environmental Factors (support and relationships) and Activities and Participation (particular interpersonal relationships).

"It was down to the point where it was nothing but, you know, "the rules"…It is hard for a parent to be a nurse at the same time. It just changes the whole dynamics of the relationship…" [38].

Burden of Treatment and Personal Factors. Personal characteristics influenced each patient's psychological and emotional capacity to deal with a treatment and their perception of the burden generated:

"*The ability to overcome fear and manage symptoms varies between individuals, with less distress expressed in situations of self-confidence"* [16].

The BoT literature also identified age as an important factor in patients' ability and willingness to tolerate treatment burdens:

"I'm too old now, that dialysis thing is more for younger people… Not for me" [14].

Finally, treatment regimens can also be seen to negatively influence Personal Factors. Adhering to complex and potentially stigmatising treatment regimes, as well as the tendency for people to be viewed as "patients" rather than "individuals" may directly influence patients' self-identity:

"The parameters of normality in patients with PCD (Primary Ciliary Dyskinesia) are developed through experiences, achievements, expectations and comparison with healthy peers" [16].

The impact of treatment on Personal Factors, such as individual priorities, preferences or sense of normality, was described by patients as reasons not to adhere*:*

"My time is more valuable to me than that. It's not worth it for me….I just don't [do the treatment] because it is more fun not to" [5].

Although, non-adherence can result in deterioration of patients' health status (thus having direct consequences on Body Functions and Structures), patients in the included studies were often aware of these potential negative consequences but still decided to prioritise their personal life.

"*Patients' treatment adherence behaviour is to some extent a product of rational decisions by the patient after contemplating perceived benefits and weighing them against perceived risks."(…) "Instances of non-adherence take place even when patients are aware of direct immediate negative consequences*" [6].

The concept of burden of treatment and the ICF categories: content analysis following the ICF linking rules

There was substantial inter-rater agreement for the initial coding (ICF component: k=0.748, 95%CI= 0.71 to 0.792; 1st t level: k=0.811, 95%CI= 0.768 to 0.854; 2nd level: k=0.744, 95%CI= 0.697 to 0.791; 3rd level: k=0.715, 95%CI= 0.620 to 0.805).

The thematic analysis of the studies included in this review (described above) generated 179 subthemes. Using the ICF linking rules [9], these subthemes were coded to 77 ICF categories: 36 of which refer to the Body Functions and Structures, 19 to the Activities and Participation, and 22 to the Environmental Factors (table 2). Only the 1st and 2nd level categories are presented in table 2, when a 3rd level category was agreed, the equivalent 2nd level was selected.

Inset stable 2 about here

Additionally, 44 meaningful concepts emerged from the second stage of the analysis and were not possible to link to a specific ICF category. These included 33 Personal Factors (which have not yet been classified by the ICF) and 11 'not-covered' concepts by the ICF,

identified as “nc”. Tables 3 and 4 list all Personal Factors and concepts identified as “nc”, respectively. A table with a list of subthemes, its meaningful concepts and the corresponding ICF codes is available on Appendix 1.

Insert tables 3 and 4 about here

Discussion

The present systematic review and best–fit analysis is, to our knowledge, the first to explain the concept of BoT using the standardised ICF terminology. The content analysis generated lists of ICF categories (tables 2 to 4) that form the first list of candidate categories of a future ICF Core Set for BoT. These findings represent a robust base of knowledge that can now inform and be complemented with further studies of the preliminary phase of the development of a Comprehensive ICF Core Set [20], namely qualitative studies and expert surveys using our findings as a framework.

BoT has been shown to impact negatively on Body Functions and Structures and restrict valued Activities and Participation, life roles and self-identity. Environmental and Personal Factors were shown to shape the experience of BoT. For instance, strong family support can reduce the perception of burden; similarly lack of appropriate equipment can increase the perceived BoT. Conversely, BoT can also impact on Personal and Environmental Factors such as when treatment obligations have a negative impact on family relationships and family support. This description of BoT using the ICF terminology can be linked to previous studies exploring the concept of BoT, as it has been described a biographical (self-identity; Personal

Factors), relational (Environmental Factors and Activities and Participation) and biological (Body Functions and Structures) disruption [18].

The findings of this literature review also represent an important contribution for future developments of the ICF itself. Our analysis found the current list of ICF categories insufficient to fully describe BoT. Many fundamental BoT concepts such as “adherence”, “capacity” and “workload” [3-5, 18] are “not covered” by the ICF (table 4). This is, nevertheless, an understandable finding, given that the concept of BoT post-dates the development of the ICF framework. Other concepts such as “treatment goals” or “treatment outcomes” were too general to be linked to the ICF and were coded as “not defined”. Additionally, many concepts where linked to Personal Factors which have not yet been specified by the ICF, although BoT theory places a significant emphasis on how treatments affect and are affected by people’s personal identities [3]. This study has begun to delineate and specify some of the important concepts under the component Personal Factors and highlighted the importance of Contextual Factors in general. These have relevance beyond a future ICF Core Set for BoT and can inform future developments of the ICF document itself [9].

Strengths and limitations and future directions

BoT is a new concept which, authors have argued, has the potential to radically change the way that interventions are prescribed and managed in the patient/professional relationship [3, 18, 21]. However, BoT may be unfamiliar to many health professionals. By using the uniform terminology of the ICF, this study enables health professionals to more readily access a potentially complex [21], but highly relevant theory.

This study has its limitations. Including only qualitative studies, which expressly used the terms “Burden of Treatment” or “Treatment Burden” may have resulted in the exclusion of studies which explore the concept but without using the same terminology. A further limitation, common to all qualitative literature reviews, is that some of the information and context provided by the original participants may have been excluded from the original papers and therefore, lost to the secondary analysis. Lastly, the inclusion of all relevant qualitative studies regardless of their quality may have influenced our findings.

This study sought to explore the links between BoT and the ICF across a range of conditions and treatments. This was an appropriate approach for demonstrating the conceptual similarities between the two models. However, this approach of combining conditions could potentially lead to an infinite number of categories, especially in the component Body Functions and Structures. As BoT research progresses into more conditions it may become more appropriate to incorporate the important BoT factors into the condition specific Core Sets.

Future studies to complete the preparatory phase of a future ICF Comprehensive Core Set for BoT are necessary. Qualitative research involving a range of stakeholders (patients, healthcare professionals, policy-makers and caregivers) is needed. Furthermore, the need of developing outcome measures of BoT has also been suggested in previous literature [4, 5]; the ICF could provide a useful framework for this.

Conclusion

BoT impacts negatively on Body Functions and Structures and restricts valued Activities and Participation, life roles and self-identity. Contextual Factors have a dual role both influencing and being influenced by treatment burden. The use of ICF terminology to describe BoT provides an accessible route for understanding this concept which although complex is pivotal for rethinking clinical practice. This may lead to recognition that BoT is an important consideration for treatment plans and patient adherence. Additional studies are also necessary complete the preparatory phase of development of a future Comprehensive ICF Core Set for BoT.

Declaration of interest

The authors report no declarations of interest.

Reference List

[1] Fried TR, Bradley EH. What Matters to Seriously Ill Older Persons Making End-of-Life Treatment Decisions?: A Qualitative Study. Journal of Palliative Medicine 2003; 6: 237-42.

[2] Sawicki GS, Sellers DE, Robinson WM. High treatment burden in adults with cystic fibrosis: challenges to disease self-management. J Cyst Fibros 2009; 8: 91-6.

[3] May CR, Eton DT, Boehmer k, Gallacher k, Hunt K, et al. Rethinking the patient: using Burden of Treatment Theory to understand the changing dynamics of illness. BMC Health Services Research 2014; 14: 1-11.

[4] Eton DT, Ramalho de Oliveira D, Egginton JS, Ridgeway JL, Odell L, et al. Building a measurement framework of burden of treatment in complex patients with chronic conditions: a qualitative study. Patient Relat Outcome Meas 2012; 3: 39-49.

[5] Gallacher K, May CR, Montori, VM, Mair FS. Understanding patients' experiences of treatment burden in chronic heart failure using normalization process theory. Ann Fam Med 2011; 9: 235-43.

[6] Karamanidou C, Weinman J, Horne R. A qualitative study of treatment burden among haemodialysis recipients. J Health Psychol 2014; 19: 556-69.

[7] Sav A, Kendall E, McMillan SS, Kelly F, Whitty JA et al., 'You say treatment, I say hard work': treatment burden among people with chronic illness and their carers in Australia. Health Soc Care Community 2013; 21: 665-74.

[8] Jordan S, Philpin S, Warring J, Cheung WY, Williams J. Percutaneous endoscopic gastrostomies: the burden of treatment from a patient perspective. J Adv Nurs 2006; 56: 270-81.

[9] Cieza A, Geyh S, Chatterji S, Kostanjsek N, Ustun G, et al. ICF linking rules: an update based on lessons learned. J Rehabil Med 2005; 37: 212-8.

[10] World Health Organisation, International Classification of Functioning, 1st ed: Geneva: Disability and Health; 2001.

[11] Stamm TA, Cieza A, Machold K, Smolen J, Stucki G. Exploration of the link between conceptual occupational therapy models and the International Classification of

Functioning, Disability and Health. Australian Occupational Therapy Journal 2006; 53: 9-17.

[12] Baylor CR, Yorkston KM, Eadie TL, Maronian NC. The psychosocial consequences of BOTOX injections for spasmodic dysphonia: a qualitative study of patients' experiences. J Voice 2007; 21: 231-47.

[13] George M, Rand-Giovannetti D, Eakin MN, Borrelli B, Zettler M, et al., Perceptions of barriers and facilitators: self-management decisions by older adolescents and adults with CF. J Cyst Fibros 2010; 9: 425-32.

[14] Johnston S, Noble H. Factors influencing patients with stage 5 chronic kidney disease to opt for conservative management: a practitioner research study. J Clin Nurs 2012; 21: 1215-22.

[15] Lewis CP, Newell JN. Improving tuberculosis care in low income countries - a qualitative study of patients' understanding of "patient support" in Nepal. BMC Public Health 2009; 9: 1-9.

[16] Schofield LM, Horobin HE. Growing up with Primary Ciliary Dyskinesia in Bradford, UK: exploring patients experiences as a physiotherapist. Physiother Theory Pract 2014; 30: 157-64.

[17] Jani B, Blane D, Browne S, Montori V, May C, et al. Identifying treatment burden as an important concept for end of life care in those with advanced heart failure. Curr Opin Support Palliat Care 2013; 7: 1-5.

[18] Demain S, Goncalves AC, Areia C, Oliveira R, Marcos AJ et al. Living with, managing and minimising treatment burden in long term conditions: a systematic review of qualitative research. PLoS One 2015; 10: 1-18.

[19] World Health Organisation, How to use the ICF: A practical manual for using the International Classification of Functioning, Disability and Health (ICF). Exposure draft for comment. Geneva: WHO; 2013.

[20] Selb M, Escorpizo R, Kostanjsek N, Stucki G, Ustun B, et al. A guide on how to develop an International Classification of Functioning, Disability and Health Core Set. European Journal of Physical and Rehabilitation Medicine 2015; 51: 105-117.

[21] Shippee ND, Shah ND, May CR, Mair FS, Montori VM. Cumulative complexity: a functional, patient-centered model of patient complexity can improve research and practice. J Clin Epidemiol 2012; 65: 1041-51.

[22] Eton DT, Elraiyah TA, Yost KJ, Ridgeway JL, Johnson A, et al. A systematic review of patient-reported measures of burden of treatment in three chronic diseases. Patient Relat Outcome Meas 2013; 4: 7-20.

[23] Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, et al., The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. PLoS Med 2009; 6: 1-28.

[24] Dixon-Woods M. How can systematic reviews incorporate qualitative research? A critical perspective. Qualitative Research 2006; 6: 27-44.

[25] CASP [Internet]. Critical appraisal skills programme - Qualitative Checklist. 2013 [cited 2014]; Available from: http://www.casp-uk.net/#!casp-tools-checklists/c18f8.

[26] Dixon-Woods, M. Using framework-based synthesis for conducting reviews of qualitative studies. BMC Med 2011; 9: 1-2.

[27] Carroll C, Booth A, Cooper K. A worked example of "best fit" framework synthesis: a systematic review of views concerning the taking of some potential chemopreventive agents. BMC Med Res Methodol 2011; 11: 1-9.

[28] Gallacher K, Morrison D, Jani B, McDonald S, May C, et al. Uncovering treatment burden as a key concept for stroke care: a systematic review of qualitative research. PLoS Med 2013; 10: 1-17.

[29] Gallacher K, Jani B, Morrison D, McDonald S, Blane D, et al. Qualitative systematic reviews of treatment burden in stroke, heart failure and diabetes - Methodological challenges and solutions. BMC Medical Research Methodology 2013; 13: 1-10.

[30] Ibragimova NK, Pless M, Adolfsson M, Granlund M, Bjorck-Akesson E. Using content analysis to link texts on assessment and intervention to the International Classification of Functioning, Disability and Health - version for Children and Youth (ICF-CY). J Rehabil Med 2011; 43: 728-33.

[31] Elliott AC, Woodward WA. Statistical Analysis - Quick Reference Guidebook. 1st Ed. California - United States of America: SAGE Publications; 2007.

[32] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. Biometrics 1977; 33: 159-174.

[33] Alansari R, Bedos C, Allison P. Living with cleft lip and palate: the treatment journey. Cleft Palate Craniofac J 2014; 51: 222-9.

[34] Hyland ME, Whalley B, Jones RC, Masoli M. A qualitative study of the impact of severe asthma and its treatment showing that treatment burden is neglected in existing asthma assessment scales. Qual Life Res, 2014; 0: 1-9.

[35] Kahn LS, Vest BM, Madurai N, Singh R, York TRM et al. Chronic kidney disease (CKD) treatment burden among low-income primary care patients. Chronic Illn 2014; 0: 1-13.

[36] LeBovidge JS, Haskell S, Olney E, Hoyte L, Rachid R, et al. The psychological impact of oral immunotherapy for children with food allergy: Perceived benefits and treatment burden. Clinical Practice in Pediatric Psychology 2014; 2: 13-26.

[37] Ridgeway JL, Egginton JS, Tiedje K, Linzer M, Boehm D, et al., Factors that lessen the burden of treatment in complex patients with chronic conditions: a qualitative study. Patient Prefer Adherence 2014; 8: 339-51.

[38] Sawicki GS, Heller KS, Demars N, Robinson WM. Motivating adherence among adolescents with cystic fibrosis: Youth and parent perspectives. Pediatr Pulmonol 2014; 0: 1-10.

600

Implications for rehabilitation

- Health professionals applying the ICF should consider the negative impact of interventions on patient's life roles and self-identity, Body Functions and Structures and on valued Activities and Participation.
- Health professionals who may be concerned about the treatment burden being experienced by their patients can now use the ICF terminology to discuss this with the multidisciplinary team.
- Poor adherence to rehabilitation programmes may be explained by an increased burden of treatment. This phenomenon can now be mapped to the ICF, and coded using a framework well known by multidisciplinary teams.

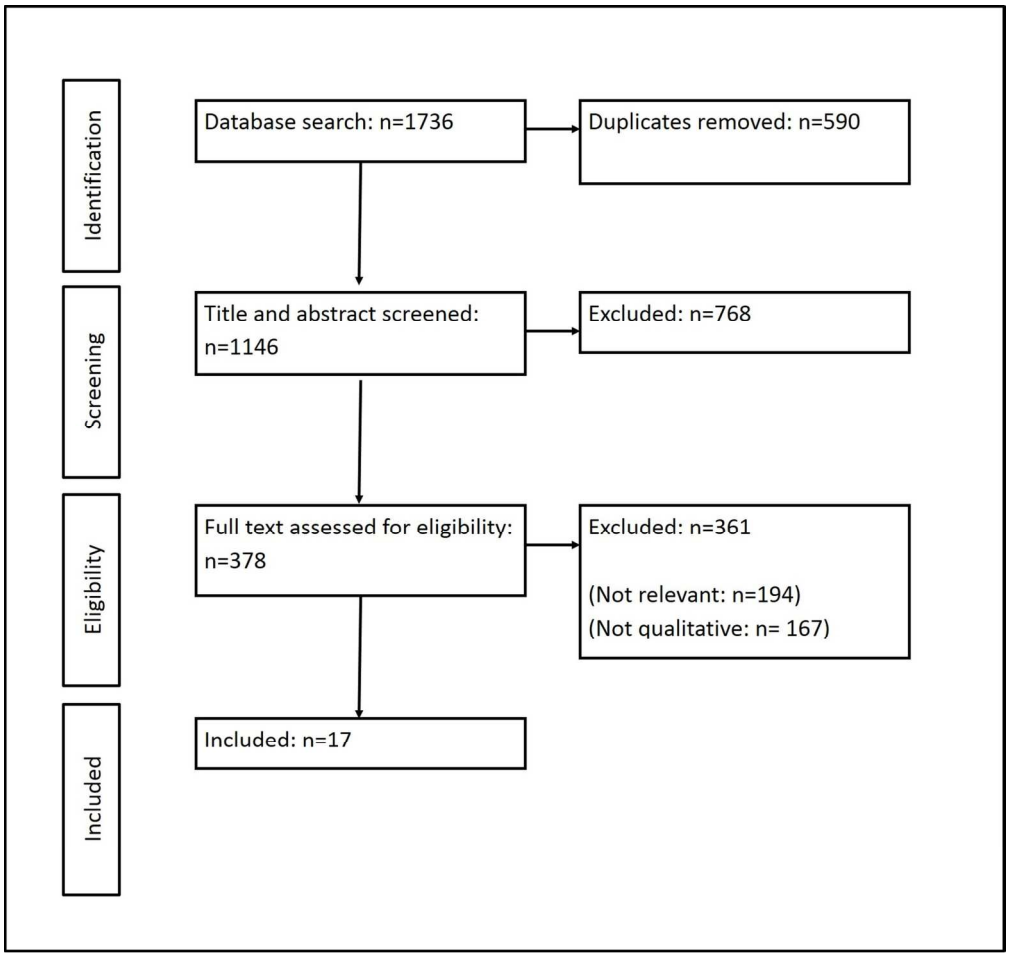

Figure 1. Study selection process.
169x160mm (300 x 300 DPI)

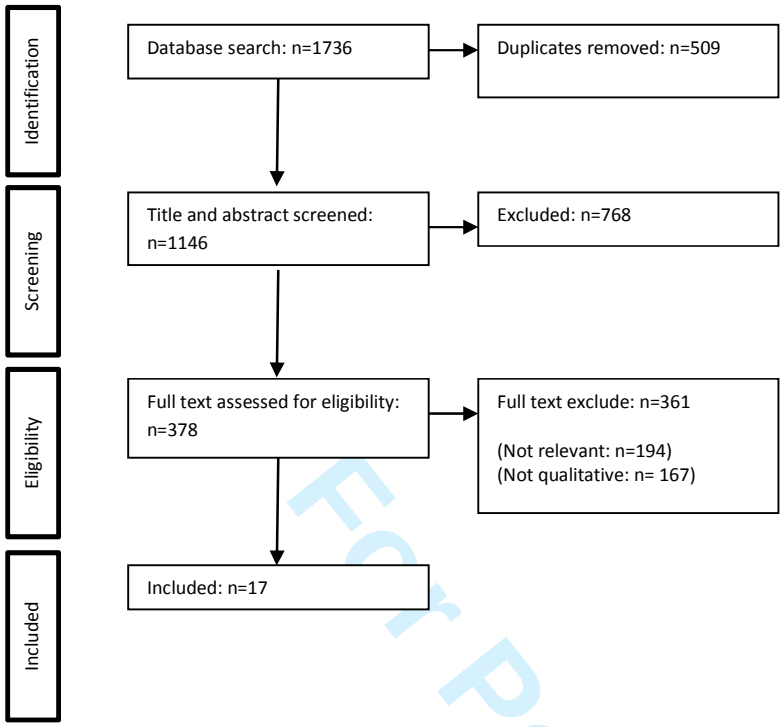

Figure 1. Study selection process.

Font: Calibri (Body)

Table 1. Characteristics of the included studies.

Study	Age range	Health condition	n	Qualitative data collection methods	Country
Alansari et al., 2014 [33]	18-60	cleft lip and palate	11	Interviews	Canada
Baylor et al., 2007 [12]	49-80	Spasmodic Dysphonia	6	Interviews	USA
Eton et al., 2012 [4]	26-85	Multi pathologies	32	Interviews	USA
Fried et al., 2003 [1]	(mean = 70)	Chronic diseases (end of life)	23	FG and interviews	USA
Gallacher et al., 2011 [5]	45-88	Chronic Heart Failure	47	Interviews (secondary analysis)	UK
George et al., 2010 [13]	16-35	Cystic Fibrosis	25	Interviews	USA
Hyland et al., 2014 [34]	28-70	Severe asthma	23	Interviews	UK
Johnston and Noble, 2012 [14]	74-96	Chronic kidney Disease	9	Interviews	UK
Jordan et al., 2006 [8]	24-84	Percutaneous Endoscopic Gastrostomies	20	Mixed methods (interviews and QoL measure)	UK
Kahn et al., 2014 [35]	(mean = 61.7)	Chronic kidney disease	34	Interviews	USA
Karamanidou et al., 2014 [6]	32-68	Renal Disease	7	Interviews	Greece
LeBovidge et al., 2014 [36]	Study 1: 9-18 Study 2: 7-15	Food allergies	Study 1: 10 children + 9 parents; Study 2: 13 children + 13 parents	Interviews	USA
Lewis and Newell, 2009 [15]	Not mentioned	Tuberculosis	23	FG and interviews	Nepal
Ridgeway et al., 2014 [37]	26-87	Chronic diseases	75	FG and interviews	USA
Sav et al., 2013 [7]	16-83	Chronic diseases	97	Interviews	Australia
Schofield and Horobin, 2014 [16]	8-15	Primary Ciliary Dyskinesia	5	Interviews	UK
Sawicki et al., 2014 [38]	16-21	Cystic Fibrosis	18	Interviews	USA

Table 1. Burden of treatment concept linked to the ICF categories.

ICF Code	ICF category title	Studies
Body Functions		
b126	Temperament and personality functions	[34]
b130	Energy and drive functions	[6, 8, 12, 13, 15, 16]
b134	Sleep functions	[4, 34]
b152	Emotional functions	[1, 4, 5, 8, 12, 13, 16, 34, 36]
b210	Seeing functions	[4]
b240	Sensations associated with hearing and vestibular function	[36]
b280	Sensation of pain	[1, 4, 6, 12, 33-36]
b310	Voice functions	[12, 16]
b420	Blood pressure functions	[35]
b435	Immunological system functions	[6, 8, 36]
b440	Respiration functions	[1, 13]
b450	Additional respiratory functions	[6, 13, 16, 34]
b455	Exercise tolerance functions	[1, 4, 6, 12, 16, 33-35, 38]
b460	Sensations associated with cardiovascular and respiratory functions	[6, 12, 13, 16, 34, 36]
b510	Ingestion functions	[8, 12, 34, 36]
b515	Digestive functions	[8]
b525	Defecation functions	[34]
b530	Weight maintenance functions	[34, 37]
b610	Urinary excretory functions	[6]
b620	Urination functions	[35]
b7	Neuromusculoskeletal and movement related functions	[8, 34]
b780	Sensations related to muscles and movement functions	[12]
b8	Functions of the skin and related structures	[6, 34, 36]
Body Structures		
s2	The eye, ear and related structures	[4]
s330	Structure of pharynx	[16, 36]
s410	Structure of cardiovascular system	[6, 16]
s430	Structure of respiratory system	[1, 12, 13, 16, 36]
s530	Structure of stomach	[8, 34, 36]
s540	Structure of intestine	[34]
s610	Structure of urinary system	[6, 35]
s7	Structures related to movement	[34]
s710	Structure of head and neck region	[12]
s720	Structure of shoulder region	[6]
s770	Additional musculoskeletal structures related to movement	[12]
s8	Skin and related structures	[34]
s810	Structure of areas of skin	[6]
Activities and Participation		
d1	Learning and applying knowledge	[4-8, 12]
d230	Carrying out daily routine	[5, 6, 13, 35, 37, 38]
d240	Handling stress and other psychological demands	[12, 33]
d3	Communication	[4-6, 14]
d330	Speaking	[12]
d4	Mobility	[8]
d455	Moving around	[13, 16]
d470	Using transportation	[5]
d5	Self-care	[7, 12, 14, 16, 35, 37, 38]
d550	Eating	[4, 8]
d570	Looking after one's health	[4, 5, 13, 37, 38]
d620	Acquisition of goods and services	[37, 38]
d7	Interpersonal interactions and relationships	[4-8, 12, 14, 33, 35, 37, 38]
d8	Major life areas	[8, 12, 13, 38]
d850	Remunerative employment	[4, 5, 7, 12, 13, 38]
d855	Non-remunerative employment	[8]
d9	Community, social and civic life	[5, 12, 36, 38]
d920	Recreation and leisure	[4, 7, 8, 13, 16, 36, 38]
d930	Religion and spirituality	[35]
Environmental Factors		

e1	Products and technology	[8]
e110	Products or substances for personal consumption	[4, 5, 7, 37, 38]
e115	Products and technology for personal use in daily living	[1, 4, 5, 7, 8, 13, 35, 37]
e245	Time-related changes	[16]
e3	Support and relationships	[4-6, 8, 12, 14, 33, 38]
e310	Immediate family	[5, 12-16, 35, 37, 38]
e315	Extended family	[5, 12, 14-16, 35, 37, 38]
e320	Friends	[4, 5, 35, 37]
e325	Acquaintances, peers colleagues, neighbours and community members	[6, 12, 13, 15, 35, 37]
e355	Health professionals	[5-8, 12-15, 33, 35, 37, 38]
e4	Attitudes	[6-8, 12, 13, 15, 16, 33, 38]
e410	Individual attitudes of immediate family members	[5, 12-16, 35, 37, 38]
e415	Individual attitudes of extended family members	[5, 12, 14-16, 35, 37]
e420	Individual attitudes of friends	[4, 5, 12, 35, 37]
e425	Individual attitudes of acquaintances, peers colleagues, neighbours and community members	[12, 13, 15, 35, 37]
e450	Individual attitudes of health professionals	[4-8, 12-15, 33, 35, 37, 38]
e460	Societal attitudes	[16]
e515	Architecture and construction services, systems and policies	[7]
e530	Utilities services, systems and policies	[5]
e540	Transportation services, systems and policies	[5, 7, 14, 35]
e580	Health services, systems and policies	[4-8, 12-16, 35, 37, 38]
e590	Labour and employment services, systems and policies	[7, 13]

The ICF codes starting with “b”, “s”, “d” and “e” indicate the components: “body functions” (b), “body structures” (s), “activities and participation” (d) and “environmental factors” (e).

Table 1. Meaningful concepts linked to the Personal Factors.

Personal Factors	Studies
Age	[1, 6, 7, 12-14, 33, 38]
Being active	[6, 15]
Beliefs about illness and treatment	[1, 5, 6, 12, 14-16, 38]
Coping strategies	[4-7, 12, 16, 37]
Desire to avoid being a burden	[1, 14]
Discipline	[13]
Disease acceptance	[6, 8, 16]
Employment	[4, 13, 35]
Empowerment	[6, 13-16, 33, 37, 38]
Ethnicity and religion	[4, 7, 13]
Family context	[12, 14, 35]
Fears	[4, 5, 12, 36]
Feeling isolated	[15, 33]
Financial Context	[4, 5, 7, 35]
Gender	[4, 13]
Hope and Faith	[6, 35, 37]
Individual judgements / decisions or choices	[1, 6, 7, 12-14, 16, 33, 35, 38]
Individual needs / characteristics	[4-7, 12-14, 16, 33]
Knowledge/ Education	[4-7, 12, 13, 15, 16, 35, 38]
Life experiences	[12, 16]
Life style	[12, 13]
Marital status	[4, 13]
Not feeling capable	[5, 14]
Organisation skills	[4, 5, 37, 38]
Perception of own health status	[4, 14, 16]
Perception of quality of life (coded as not defined – quality of life)	[1, 6, 38]
Positive/Negative mental attitude	[6, 8, 12, 13, 15, 16]
Treatment Preferences	[1, 4, 13, 16, 35, 37, 38]
Priorities and Life goals	[13, 38]
Resilience	[4-8, 12, 16, 33, 35]
Self-confidence and motivation	[6, 13, 15, 16, 33, 35, 37]
Self-image	[6, 7, 12, 13, 16, 33, 38]
Sense of normality	[6, 12, 13, 16, 33, 36-38]

Table 1. Meaningful concepts identified as not covered by the ICF

Concepts not covered by the ICF	Studies
Adherence/Non-adherence to treatment	[1, 4-7, 12-16, 33, 35, 37, 38]
Absence of empowerment	[6, 15, 16]
Burdens to others	[14]
Capacity	[4, 5, 7, 8, 12, 14, 16]
Discharge process	[8]
Time frame / time burden	[1, 4, 5, 7, 8, 13, 14, 16]
Treatment regimen	[1, 4-8, 12-16, 33-38]
Workload	[4, 5, 7, 12-14, 35, 38]
Work needed to adjust the requirements imposed by treatment	[5, 7, 12]
Performing more than one activity at the same time	[16]
Sputum production	[16]

Supplementary file: Content analysis linking subthemes emerged from the framework synthesis to the ICF

Theme 1:**Environmental factors**		
Subtheme	**Meaningful concepts**	**ICF codification**
1.1 Architectural barriers	Architectural barriers	e515
1.2 Positive and negative communication aspects with health care professionals	Positive and negative aspects of communication	d3
	Health professionals	e355; e450
1.3 Complex treatment regimens	Complexity (related to health care services)	e5800
	Treatment regimens	nc
1.4 Difficult to access to health care	Difficult to access to health care	e580
1.5 Engaging with HCP	Health care professionals	e355; e450
	Activity of engaging with others in a health care context	d5; d7
1.6 Family, friends & co-workers (social network)	Family	e310; e410; e315; e415
	Friends	e320; e420;
	Co-workers	e325; e425
1.7 Financial burden caused by health related costs	Financial context	pf
	Health related costs	d5; e580
1.8 Good health policies or services	Health care policies	e580; e5802
	Health care services	e580; e5800

1.9 Individualised treatment methods	Individual needs	pf
	Treatment regimens	nc
	Health services (provision of care)	e580
1.10 Lack of continuity and integrated health services	Health services systems and policies	e580
1.11 No supported discharge	Health services systems and policies (regarding discharge process)	e580
	Discharge process	nc
1.12 Polyphaymacy	Polyphaymacy	e110
1.13 Positive aspects of treatment	Health services (provision of care)	e5800
1.14 Positive and negative impact of treatment on relationships	Positive and negative impact	nd
	Relationships	e3; e7
1.15 Side effects or other negative consequences of treatment	Side effects and other negative consequences	nd
	Treatment regimen	nc
	Health services (provision of care)	e5800
1.16 Stigma	Stigma	e460
1.17 Time and travelling burden (related to treatment)	Travelling	e540; d470; d475
	Time frame / time burden	nc
	Health services	e580
1.18 Treatment related equipment as facilitators of	Treatment related equipment	e115

treatment and prompts of adherence		
	Adherence	nc
1.19 Unhelpful Health care professionals	Unhelpful Health care professionals	3355; e450
1.20 Unsuccessful or without benefit treatments	Treatment regimen	nc
	Non-effective provision of care	e5800
1.21 Having peer support	Peer support	e325; e425

Theme 2: **Environmental Factors linked to Personal Factors**

Subtheme	**Meaningful concept**	**ICF codification**
2.1 Absence of empowerment to undertake and be more active in the treatment	Empowerment; absence of empowerment	pf; nc
	Being active	pf
	Treatment regimens	nc
2.2 Adapting treatment regimens to individual needs	Treatment regimens	nc
	Individual needs	pf
2.3 Age influencing treatment decisions	Age	pf
	Treatment decisions	pf; nc
	Health services (provision of care)	e5800

2.4 The assessment of effectiveness considers personal factors	Assessment of effectiveness	pf
2.5 Avoiding to be a burden to others	Being a burden to others	nc
	Desire to avoid being a burden	pf
2.6 Co-existing health conditions reduce capacity to adhere	Co-existing health conditions	hc
	capacity	nc
2.7 Confusion or lack of knowledge about the treatment	Lack of knowledge	pf
	Health services (provision of care)	e580
2.8 Day time preferences for treatment	Preferences	pf
	Time-related changes	e245
	Health services (provision of care)	e580
2.9 Ethnicity and religion affects the access to health care	Ethnicity and religion	pf
	Access to health care	e580
2.10 Family context influences the impact of treatment	Family context	pf
	Treatment regimen	nc
2.11 Fear and anxiety about treatment and treatment outcomes	Fear	pf

	Anxiety	b152
	Treatment regimen	nc
	Treatment outcomes	nd
2.12 Feeling isolated due to treatment requirements, stigma or lack of knowledge	Feeling isolated	pf
	Treatment regimen	nc
	Stigma or Lack of knowledge	e4
2.13 Life-style changes to fit treatment	Life style	pf
	Treatment regimen	nc
2.14 Need for being listened by health care professionals	Individual needs	pf
	Health care professionals	e450; e355
2.15 Not feeling capable to do all treatment requirements	Not feeling capable	pf
	Treatment regimen	nc
2.16 Passive, non-intended and chosen non-adherence	Adherence	nc
	Individual choices	pf
2.17 Perception on QoL influencing treatment decisions	Perception of QoL	nd-qol
	Treatment decisions	pf

2.18 Personal beliefs about life and treatment	Personal beliefs	pf
	Treatment regimen	nc
2.19 Poor confidence or motivation for treatment	Self-confidence and motivation	pf; b130
	Treatment regimen	nc
2.20 Positive mental attitude promoting adherence	Positive mental attitude	pf
	Adherence	nc
2.21 Reluctance to approach health care professionals	Reluctance/fear	pf
	Health care professionals	e450; e355
2.22 Resilience about the disease and treatment increases the capacity to adhere	Resilience	pf
	Capacity	nc
	Adherence	nc
2.23 Self-image and sense of normality determines treatment choices	Self-image	pf
	Sense of normality	pf
	Treatment choices	pf
2.24 Self-care demands add workload to the treatment	Self-care	d5
	Workload	nc

2.25 Treatment affecting all areas of life	All areas of life	nd
	Treatment regimen	nc
2.26 Treatment choices change overtime	Treatment choices	pf
	Time frame	nc
2.27 Inability to work limits capacity to pay for medication	Employment	pf; d850
	Capacity	nc
	Medication	e110
2.28 Discrepancy in perceptions of effort between health care professionals and patient	Perception of own health status	pf
	Health care professionals	e355; e450
2.29 Having a routine as a strategy to reduce treatment workload and promote adherence	Having a routine	d230
	Coping strategy	pf
	Workload	nc
	Adherence	nc

Theme 3: **Environmental Factors linked to Activities**		
Subtheme	**Meaningful concept**	**ICF codification**
3.1 Sports as treatment	sports	d9201
3.2 Leisure activities promoting adherence	Leisure activities	d920
	Adherence	nc
3.3 Activity limitations lead to limitations on treatment adherence	Activity limitations	nd
	Adherence	nc
3.4 Adapting treatment to fit activities	Treatment regimen	nc
	Activities	nd
3.5 Choosing enjoying activities instead of treatment	Individual choices	pf
	Enjoying activities	d920
3.6 Costs of treatment limiting activities	Treatment costs	e580
	Activities	nd
3.7 Learning about treatment	Learning	d1; d5
3.8 Self-management activities	Self-management activities	d5
3.9 Treatment allowing activities	Treatment regimen / outcomes	nc
	Activities	nd

3.10 Treatment itself limiting activities	Treatment regimen / outcomes	nc
	Activities	nd
3.11 Workload by self-management activities influencing adherence	workload	nc
	Self-management activities	d5
	Adherence	nc
3.12 Family supports with organising meds appointments	Family support	e310; e315
	Organisation skills	pf; d230
	medication	e1101
	Booking appointments	d620
	Looking after one's health	d570

Theme 4: **Environmental Factors linked to Participation**

Subtheme	**Meaningful concept**	**ICF codification**
4.1 Actively seeking support from family and friends	Being active	pf
	Support from family	e310; e315; e410; e415
	Support from friends	e320; e420;
4.2 Costs of treatment stopping participation	Treatment costs	e580

	Participation	nd
4.3 Employment hindering adherence	Employment	e590; d850
	Adherence	nc
4.4 Getting support from others	Support from others	e3
4.5 Managing workload of treatment and participation in meaningful life activities	workload	nc
	Participation in meaningful life activities	d8; d9
4.6 Participation restrictions triggering adherence	Participation restriction	nd
	Adherence	nc
4.7 Treatment limiting or promoting social participation and leisure activities	Treatment regimen	nc
	Social participation and leisure activities	d920
4.8 Treatment limiting or promoting sports participation	Treatment regimen	nc
	Sports	d9201
4.9 Treatment limiting or promoting employment and career development	Treatment regimen	nc
	Employment and career development	d850; e590

Theme 5: **Environmental Factors linked to Body Functions and Structures**		
Subtheme	**Meaningful concept**	**ICF codification**
5.1 Treatment promotes coughing and lung clearance	Treatment regimen	nc
	Coughing and lung clearance	b450; b440; s4301
5.2 Dry skin due to treatment	Dry skin	b8; s810
	Treatment regimen	nc
5.3 Fatigue due to treatment, limiting treatment adherence	Fatigue	b4452
	Treatment regimen	nc
	Adherence	nc
5.4 Voice symptoms improved by treatment or caused by treatment	Voice related symptoms	b310; s3
	Treatment regimen	nc
5.5 Infections due to treatment	Infections	hc; b435
	Treatment regimen	nc
5.6 Movement restrictions due to treatment	Movement restrictions	b7; d4
	Treatment regimen	nc
5.7 Need of ventilator because of lung dysfunction	Ventilator	e115

	Lung dysfunction	b440; s4301
5.8 Not feeling well to use public transport	Not feeling well	nd
	Use public transport	d470; e530
5.9 Pain or discomfort due to treatment	Pain or discomfort	b280
	Treatment regimen	nc
5.10 Physical limitations due to not well adapted treatment technologies	Physical limitations	nd
	Treatment technologies	e1
5.11 Respiratory symptoms caused or reduced by treatment	Respiratory symptoms	b460; b450; s430
	Treatment regimen	nc
5.12 side effects	Side effects	nd
5.13 Sleep disorder due to medication	Sleep disorder	b134
	Medication	e110
5. 14 Stigma of coughing leads to cough suppression	Stigma	e460
	Coughing	b450
5.15 Stomach ulcers due to health care professionals lack of knowledge about treatment	Stomach ulcers	b515; s530

	Health care professionals	e355; e450
5.16 Swallowing issues due to treatment	Swallowing issues	b5105
	Treatment regimen	nc
5.17 Taking medication because body is missing something	Taking medication	e1101
	Body missing something	nd
5.18 Tight neck improved after treatment	Tight neck	s710
	Treatment regimen	nc
5.19 Treatment requirement is to tolerate large volumes of food into stomach	Treatment regimen	nc
	large volumes of food into stomach	s530; b515

Theme 6: **Personal Factors**

Subtheme	**Meaningful concept**	**ICF codification**
6.1 Age and gender	Age	pf
	Gender	pf
6.2 Confidence and hope	Confidence	pf
	Hope	pf

6.3 Discipline	Discipline	pf
6.4 Disease acceptance	Disease acceptance	pf
6.5 Employment	Employment	pf; d850
6.6 Empowerment	Empowerment	pf
6.7 Ethnicity and marital status	Ethnicity	pf
	Marital status	pf
6.8 Fears	Fears	pf; b152
6.9 Health status	Perception of own health status	pf
6.10 Individual needs and preferences	Individual needs	pf
	Individual preferences	pf
6.11 Knowledge about disease and treatment	Knowledge	pf; d1
	Treatment regimen	nc
6.12 Life style and life experiences	Life style	pf
	Life experiences	pf
6.13 Motivation	Motivation	pf
6.14 sense of normality	sense of normality	pf
6.15 Personal believes	Personal believes	pf

6.16 Positive and negative feelings	Positive and negative feelings	pf; b152
6.17 Resilience and coping strategies	Resilience	pf
	coping strategies	pf
6.18 Years of formal education	Education	pf
6.19 Religion and faith	Religion and faith	pf; d930
6.20 Life goals	Life goals	pf

Theme 7: **Personal Factors linked to Activities**

Subtheme	**Meaningful concept**	**ICF codification**
7.1 Imbalance between workload and capacity	Workload	nc
	Capacity	nc
7.2 Incorporate treatment in routine	Treatment regimen	nc
	Routine	d230
7.3 Organisation skills to manage treatment	Organisation skills	pf; d230
	Treatment regimen	nc
7.4 Positive attitudes associated to activities	Positive attitudes	pf; b152
	Activities	nd

Theme 8: **Personal Factors linked to Participation**		
Subtheme	**Meaningful concept**	**ICF codification**
8.1 Fears limiting adherence	Fears	pf; b152
	Adherence	nc
8.2 Personal priorities and career	Personal priorities	pf; d850
	career	pf; d850

Theme 9: **Personal Factors linked to Body Functions and Structures**		
Subtheme	**Meaningful concept**	**ICF codification**
9.1 Coping strategies for stress and pain	Coping strategies	pf
	Stress	d240
	pain	b280
9. 2 Fear of having a needle in the throat	fear	pf; b152
	throat	s3
9.3 Treatment goals change according to its effects on voice	Treatment goals	nd
	Effects on voice	s3; b310
9.4 Knowledge about respiratory system	Knowledge	pf; d1

	respiratory system	s430, b4
9.5 Perception of QoL changes with perception of fatigue	Perception of QoL	nd-qol
	Fatigue	b4552
9.6 Personal characteristics influencing perceptions of respiratory symptoms	Personal characteristics	pf
	respiratory symptoms	b450; b460
9.7 Respiratory symptoms reducing motivation	respiratory symptoms	b450; b460
	Motivation	pf; b130
9.8 Symptoms influencing self-image	Symptoms	nd
	self-image	pf
9.9 Symptoms limit sense of normality	Symptoms	nd
	Sense of normality	pf
9.10 Balancing BoT and treatment outcomes	Balancing BoT	nd; nc
	treatment outcomes	nd

Theme 10: **Activities**

Subtheme	**Meaningful concept**	**ICF codification**
10.1 Speaking	Speaking	d330

10.2 Disease limiting eating	Disease	hc
	Eating	d550
10.3 Running	Running	d455
10.4 Making sense of disease and treatment	Making sense of disease and treatment	d1; d570
10.5 Monitoring treatment and disease	Monitoring	nd
	Monitoring treatment and disease	d570
10.6 Management of own health	Management of own health	d570

Theme 11: **Activities linked to Participation**

Subtheme	**Meaningful concept**	**ICF codification**
11.1 Activity limitations lead to restrictions in community and professional life	Activity limitations	nd
	Community life	d9
	Professional life	d850
11.2 Enacting treatment activities implies engaging with health care professionals	Treatment regimen	nc
	health care professionals	e355; e450

Theme 12: **Activities linked to Body Functions and Structures**		
Subtheme	**Meaningful concept**	**ICF codification**
12.1 Running triggers voice and respiratory symptoms	Running	d455
	Voice symptoms	b310
	respiratory symptoms	b460
12.2 Finding strategies to deal with side-effects	Copying strategies	pf; d570
	Side-effects	nd
12.3 Respiratory symptoms limit the simultaneous activities of speaking and running	Respiratory symptoms	b450; b460
	Simultaneous activities	nc
	speaking	d330
	Running	d455
12.4 Treatment activities prompted by perceptions of respiratory symptoms	Treatment regimen	nc
	Respiratory symptoms	b450; b460

Theme 13: **Participation**		
Subtheme	**Meaningful concept**	**ICF codification**

13.1 Engaging with others	Engaging with others	d7; e3
13.2 Restriction of physical activities with peers	physical activities	nd
	Activities with peers	d920
13.3 Participation as a priority regarding treatment decisions	Participation	nd
	Individual priorities	pf

Theme 14: **Participation linked to Body Functions and Structures**

Subtheme	**Meaningful concept**	**ICF codification**
14.1 Functions related with eating limit recreation and leisure activities	Eating	b5105; d550
	recreation and leisure activities	d920
14.2 Pain limiting capacity to work	Pain	b280
	capacity to work	d850
14.3 Perception of symptoms depends on the extent of participation restrictions	Perception of symptoms	nd
	participation restrictions	nd
14.4 Side effects limiting social participation (playing cards with friends)	Side effects	nd

	social participation (playing cards with friends)	d9200
14.5 Speaking dysfunction influencing participation	Speaking dysfunction	b3; s3; d330
	Participation	nd
14.6 Symptoms restricting participation with peers	Symptoms	nd
	Participation with peers	d9205
14.7 Symptoms limiting volunteering	Symptoms	nd
	Volunteering	d855

Theme 15: **Body Functions and Structures**

Subtheme	**Meaningful concept**	**ICF codification**
15.1 Anxiety, frustration, distress and depression	Anxiety, frustration and distress	b152; d240
	Depression	hc
15.2 Blood	Blood	b4; s410
15.3 Chest, pharynx and lungs	Chest, pharynx and lungs	s330; s430
15.4 Coughing and sputum production	Coughing	b450
	sputum production	nc
15.5 Fatigue	Fatigue	b4552

15.6 Kidneys	Kidneys	b610; s6100
15.7 Joints and muscles	Joints and muscles	s7; b7
15.8 Pain	Pain	b280
15.9 Poor vision	Poor vision	b210; s2
15.10 Shoulder	Shoulder	s720
15.11 Shortness of breath and wheezes	Shortness of breath and wheezes	b450; b460
15.12 Stomach and bowel problems (pain, flatulence and constipation)	Stomach pain	s530; b28012
	bowel	s540
	Constipation and flatulence	b525
15.13 Vice and speaking	Vice and speaking	d330; b310; s3
15.14 Being overweight	Being overweight	b530
15.15 Absence of symptoms limits adherence to treatment	Symptoms	nd
	Adherence	nc
15.16 Skin	Skin	b8; s8
15.17 Sleep	Sleep	b134
15.18 Being irritable	Being irritable	b1263; pf

15.19 Sickness	Sickness	b510
15.20 Increased need to urinate frequently	Increased need to urinate frequently	b6201
15.21 High blood pressure	High blood pressure	b420
15.22 Dizziness	Dizziness	b2401
15.23 Allergic reactions	Allergic reactions	b4351