THE MEANING OF LIVING WITH AN OPEN SURGICAL WOUND

A thesis submitted to The University of Manchester for the degree
of Doctor of Philosophy
in the Faculty of Biology, Medicine and Health

2021

LJUBISA PADEN
SCHOOL OF HEALTH SCIENCES
Division of Nursing, Midwifery and Social Work

LIST OF CONTENTS

ABSTRACT 9
DECLARATION 11
COPYRIGHT STATEMENT 12
ACKNOWLEDGEMENTS 13
CHAPTER 1: PREFACE 14
  1.1 THE AUTHOR 14
  1.2 INTRODUCTION TO THE STUDY 15
  1.3 THESIS STRUCTURE 16
  1.4 PUBLICATIONS FROM THIS THESIS 17

2 BACKGROUND 18
  2.1 INTRODUCTION 18
    2.1.1 Research context 18
  2.2 DEFINING COMPLEX WOUNDS 22
    2.2.1 Distinction based on duration of wound healing 22
    2.2.2 Distinction based on the type of wound healing/closure 23
    2.2.3 Distinction based on wound aetiology 23
  2.3 COMPLEX WOUND EPIDEMIOLOGY 27
    2.3.1 Prevalence of complex wounds 27
    2.3.2 Prevalence of complex wounds in Slovenia 31
    2.3.3 Summary 33
  2.4 SYMPTOM BURDEN AND IMPACTS ON WELL-BEING OF PATIENTS WITH COMPLEX WOUNDS 34
    2.4.1 Burden and impacts of unpleasant symptoms 34
    2.4.2 Impact of wounds on the physical domain of well-being 37
    2.4.3 Impact of wounds on psychological domain of well-being 38
    2.4.4 Impact of wounds on the social domain of well-being 40
    2.4.5 Impact of wounds on the financial and employment domain of well-being 40
    2.4.6 Impact of treatment of wounds 41
    2.4.7 Summary 42
  2.5 CONCLUSION 42

CHAPTER 3: METHODOLOGY 44
  3.1 INTRODUCTION 44
  3.2 STUDY AIMS AND OBJECTIVES 44
  3.3 LITERATURE REVIEWS AND EVIDENCE SYNTHESIS 46
    3.3.1 Narrative reviews 46
    3.3.2 Systematic reviews 47
    3.3.3 Scoping reviews 48

3.3.4 Summary 49
3.4 STUDY 1: SCOPING REVIEW OF PEOPLE'S EXPERIENCES OF LIVING WITH COMPLEX WOUNDS – METHODS 50
3.4.1 Study design 50
3.4.2 Protocol for conducting the scoping review 57
3.5 EPIDEMIOLOGICAL POPULATION STUDIES 57
3.5.1 Routinely collected data 57
3.5.2 Bespoke data collection 58
3.5.3 Summary 60
3.6 STUDY 2: A CROSS-SECTIONAL SURVEY OF OPEN SURGICAL WOUNDS IN SLOVENIA – METHODS 60
3.6.1 Aim and objectives of the study 60
3.6.2 Study design 61
3.6.3 Study population 61
3.6.4 Study setting 61
3.6.5 Inclusion criteria 62
3.6.6 Data collection 62
3.6.7 Data analysis 64
3.6.8 Ethical issues 65
3.7 KEY QUALITATIVE METHODS AND THEIR USE IN EXPLORING "PEOPLE'S EXPERIENCE" 65
3.7.1 Grounded theory 66
3.7.2 Phenomenology 67
3.7.3 Hermeneutics 69
3.7.4 Transition from philosophy (method) to procedures 69
3.7.5 Qualitative content analysis 72
3.7.6 Summary 75
3.8 STUDY 3: QUALITATIVE EXPLORATION OF THE MEANING OF LIVING WITH OPEN SURGICAL WOUNDS – METHODS 75
3.8.1 Aim and objectives of the study 75
3.8.2 Study design 76
3.8.3 Study population and inclusion criteria 76
3.8.4 Sample size and recruitment strategy 76
3.8.5 Data collection 78
3.8.6 Data transcribing and translation 79
3.8.7 Data analysis 81
3.8.8 Ethical issues 82
3.9 SUMMARY 86

CHAPTER 4: PEOPLE'S PERSPECTIVE OF LIVING WITH COMPLEX WOUNDS – A SCOPING REVIEW 87

4.1 INTRODUCTION 89
4.2 MATERIALS AND METHODS 91
  4.2.1 Study design 91
  4.2.2 Protocol and registration 91
  4.2.3 Eligibility criteria 91
  4.2.4. Information sources 92
  4.2.5 Search 92
  4.2.6 Selection of sources of evidence 93
  4.2.7 Data charting process 94
  4.2.8 Data items 94
  4.2.9 Synthesis of results 94
4.3 RESULTS 95
  4.3.1 Selection of sources of evidence 95
  4.3.2 Size and geographical distribution of evidence base 96
  4.3.3 Nature and characteristics of included studies 98
  4.3.4 Study funding 123
4.4 DISCUSSION 123
  4.4.1 Main findings 123
  4.4.2 Implications for future research 127
4.5 STRENGTHS AND LIMITATIONS 127
4.6 CONCLUSION 128

CHAPTER 5: A CROSS-SECTIONAL SURVEY OF PATIENTS WITH OPEN SURGICAL WOUNDS IN SLOVENIA 130
5.1 INTRODUCTION 132
5.2 METHODS 133
  5.2.1 Design 133
  5.2.2 Setting 133
  5.2.3 Participants 134
  5.2.4 Data collection 134
  5.2.5 Data analysis 136
  5.2.6 Ethical considerations 136
5.3 RESULTS 136
  5.3.1 Characteristics of the study population 136
  5.3.2 Point prevalence estimate 136
  5.3.3 Nature of SWHSI 138
  5.3.4 Management of SWHSI 139
5.4 DISCUSSION 143
  5.4.1 Prevalence of SWHSI 144
  5.4.2 Nature of SWHSI 144
  5.4.3 Management of SWHSI 145

5.4.4 Unpleasant symptoms 146
5.4.5 Strengths and limitations 147
5.5 CONCLUSION 147

CHAPTER 6: A QUALITATIVE EXPLORATION OF THE MEANING OF LIVING WITH AN OPEN SURGICAL WOUND 149
6.1 BACKGROUND 151
6.2 METHOD 153
6.2.1 Procedures 153
6.2.2 Participants 154
6.2.3 Data collection 154
6.2.4 Data analysis 154
6.2.5 Language consideration 155
6.2.6 Confidentiality and ethical considerations 155
6.3 RESULTS 155
6.3.1 Enduring healing 156
6.3.2 Life disruption 157
6.3. 3 Adapting to a new reality 159
6.3.4 Striving for healing 161
6.3.5 Returning to normal life 163
6.4 DISCUSSION 164
6.4.1 Main results 164
6.4.2 Trustworthiness 168
6.5 CONCLUSIONS 169

7 DISCUSSION 170
7.1 INTRODUCTION 170
7.2 OVERVIEW OF WORK UNDERTAKEN 170
7.2.1 People’s perspectives of living with complex wounds – a scoping review (Study 1) 171
7.2.2 A cross-sectional survey of open surgical wounds in Slovenia (Study 2) 173
7.2.3 A qualitative exploration of the meaning of living with an open surgical wound (Study 3) 176
7.3 STRENGTHS AND LIMITATIONS 179
7.3.1 Scoping review 179
7.3.2 A cross-sectional survey 180
7.3.3 A qualitative study 181
7.4 IMPLICATIONS FOR RESEARCH AND CLINICAL PRACTICE 182
7.4.1 Implications for future research 182
7.4.2 Implications for clinical practice 185
7.5 CONCLUSIONS 185

REFERENCES 187
APPENDICES 236

The final word count: 63.400

LIST OF TABLES

Table 2.1: EUROSTAT indexes 20
Table 3.1: Common pitfalls, and strategies for overcoming them 60
Table 3.2: Population of Ljubljana "SI-STAT Data Portal" (2018) 61
Table 4.1: Items extracted in data charting 94
Table 4.2: Comparing epidemiological data with number of records identified 100
Table 4.3: Characteristics of included review/synthesis studies 101
Table 4.4: Studies included a sample of people with foot ulcers related to diabetes 108
Table 4.5: Studies included a sample of people with malignant fungating wounds 110
Table 4.6: Studies included a sample of people with open surgical wounds 111
Table 4.7: Studies included a sample of people with pressure ulcers 113
Table 4.8: Studies included a sample of people with venous leg ulcers 114
Table 4.9: Studies included a mixed sample of people with leg ulcers of venous, arterial, mixed aetiology or sample of people with leg ulcers of other aetiology 119
Table 4.10: Studies included a sample of people with leg ulcers of arterial aetiology 121
Table 4.11: Studies included a mixed sample of people with different types of complex wounds 121
Table 5.1: Point prevalence estimates by 10-year age categories 137
Table 5.2: Point prevalence estimates by gender 138
Table 5.3: Wound categories according to type of surgical specialty 138
Table 5.4: Treatment location and job title of health professional who completed form 140
Table 5.5: Frequency of dressing change 141
Table 5.6: Treatment objectives and used primary dressings 142

LIST OF FIGURES

Figure 3.1: Stages of study 45
Figure 3.2: Diagram of the analysis 82
Figure 4.1: Process of study identification 96
Figure 4.2: Numbers of eligible papers published per year between 1995 and 2018 97
Figure 4.3: Geographical distribution of primary study settings 98
Figure 5.1 Point prevalence estimates by age 137

ABSTRACT

Background: Complex wounds are a common, long-term and serious global health issue. Existing research shows that a considerable number of people live with complex wounds. Furthermore, it has shown that complex wounds have a negative impact on people's physical, psychological, social and financial well-being. Reviews of research show that there is a global lack of evidence on the epidemiology, nature and treatments of open surgical wounds. Furthermore there is a global lack of research about people's perspective of having open surgical wounds.

Aim: This research had three main aims. Firstly, to explore and scope the existing qualitative research on people's experiences of living with complex wounds. Secondly, to investigate the number, characteristics, management and unpleasant symptoms of open surgical wounds in Slovenia. Thirdly, to explore the meaning of living with open surgical wounds over time.

Methods: A three-stage project was designed. Study 1 was a scoping review of existing qualitative studies exploring people's perspectives of living with all types of complex wound. Study 2 was a multi-service, cross-sectional survey of open surgical wounds affecting people living in Ljubljana, Slovenia. Study 3 was a longitudinal qualitative study exploring the meaning of living with open surgical wounds.

Results: The findings of Study 1 highlighted the nature and extent of the current evidence base related to people's perspectives of living with complex wounds. A large proportion (35.6%) of the studies focus on people with venous leg ulcers. Findings from the scoping review also demonstrated that there is a lack of research about living with arterial leg ulcers, malignant fungating wounds and open surgical wounds; the latter in particular are under-researched. Study 2 identified a point prevalence of open surgical wounds in Slovenia of 0.38 per 1,000 of the population (95% CI: 0.33 to 0.44; most of these wounds were planned to heal by secondary intention, pre-operatively (76/110, 69%). 83% (92/110) of open surgical wounds were treated with wound dressings, and 6% were treated with negative pressure wound therapy. Study 3 found that the meaning of living with open surgical wounds is shaped by five subthemes: "enduring healing", "life disruption", "adapting to a new reality", "striving for healing" and "returning to normal life", all under an overarching theme of "negotiating a new normality". Findings from this study emphasise that open surgical wounds are a chronic condition with a typical 'chronicity' trajectory.

Conclusion: This study has addressed the deficit in knowledge by undertaking in-depth research on open surgical wounds. The complementary approach of undertaking three

studies has provided essential information about the nature and extent of qualitative research related to perspectives of living with wounds, essential information about the extent, nature, treatment and unpleasant symptoms of open surgical wounds in Slovenia, and in-depth description and interpretation of meaning of living with an open surgical wound. All three studies have contributed to knowledge about open surgical wounds both locally and globally. The results from these studies could be used for planning future research, health resources management, improving clinical practice and policy development.

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

COPYRIGHT STATEMENT

i. The author of this thesis (including any appendices and/or schedules to this thesis) owns certain copyright or related rights in it (the “Copyright”) and s/he has given The University of Manchester certain rights to use such Copyright, including for administrative purposes.

ii. Copies of this thesis, either in full or in extracts and whether in hard or electronic copy, may be made only in accordance with the Copyright, Designs and Patents Act 1988 (as amended) and regulations issued under it or, where appropriate, in accordance with licensing agreements which the University has from time to time. This page must form part of any such copies made.

iii. The ownership of certain Copyright, patents, designs, trademarks and other intellectual property (the “Intellectual Property”) and any reproductions of copyright works in the thesis, for example graphs and tables (“Reproductions”), which may be described in this thesis, may not be owned by the author and may be owned by third parties. Such Intellectual Property and Reproductions cannot and must not be made available for use without the prior written permission of the owner(s) of the relevant Intellectual Property and/or Reproductions.

iv. Further information on the conditions under which disclosure, publication and commercialisation of this thesis, the Copyright and any Intellectual Property and/or Reproductions described in it may take place is available in the University IP Policy (see http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=2442 0), in any relevant Thesis restriction declarations deposited in the University Library, The University Library’s regulations (see http://www.library.manchester.ac.uk/about/regulations/) and in The University’s policy on Presentation of Theses

ACKNOWLEDGEMENTS

I would like to express my deep gratitude to Professor Dame Nicky Cullum and Dr. Jane Griffiths, my supervisors. Thank you for your guidance, thoughts, wisdom and critiques which have ultimately shaped this research work. Thank you for being patient and supportive from the first email I sent to you until our last supervision. Your encouragement on the good and bad days of my PhD journey illuminated the tunnel so I was able to see the path. I will be forever grateful.

I would like to acknowledge the work of nurses who participated in collecting data and recruited participants for this research work. I would also like to thank the people with wounds, who even during times of grave illness shared their time and thoughts with me and contributed to this research work.

Thank you to all the nurses and physicians in hospitals, primary care, social care institutions and other institutions who supported me and opened doors so I could carry out this research.

Thank you to my colleagues in the Department of Nursing and the Laboratory of Clinical Biophysics at the University of Ljubljana (Slovenia) for supporting me. Special thanks to Dr. Manca Pajnič, Dr. Mirjam Ravljen and Renata Vettorazzi for all the discussions and pastoral support. Thank you to Professor Ulla Hällgren Graneheim and Dr. Elisabeth Anne Lindahl, both from the University of Umeå (Sweden), for taking an interest in my work, for inspiration and discussions.

Thank you to Sylvia Glover for proofreading my thesis and acting as my informal teacher of British English. You have become my pen friend during the years.

Special thanks to my dearest: Tanja, Rok, Luka, Sašo, Simona, Sonja, Marcel, Marizela, Rožle, Alen, Minja, Ana, David, Amy, Robert and others who have been brought into my life and have supported me.

Finally, thank you to my family: my mother, father, sister, nephew and brother-in-law, for all the support and love.

CHAPTER 1: PREFACE

1.1 THE AUTHOR

I would describe myself as an applied health researcher with an interest in experimental, epidemiological and qualitative research methods.

I completed my undergraduate degree in Nursing at the University of Ljubljana (Slovenia) in 2009 and enrolled on the MSc in Nursing program at the University of Maribor (Slovenia), where I obtained a degree in 2011.

During my studies I have worked as a nursing assistant and from 2010 as a registered nurse with specialist knowledge at the Department of Surgical Infections, University Medical Centre Ljubljana. Since 2012 I have been employed at the Department of Nursing, Faculty of Health Sciences at the University of Ljubljana, first as an assistant lecturer, and from 2017 as a senior lecturer, in nursing.

I am a co-lead of the Gerontology and Rehabilitation Nursing unit and a lead of the Wound Care Nursing unit.

My employment at the university has also involved conducting and assisting in different research projects. During this time I have learned and used different methodological approaches, i.e. surveys, qualitative research methods and experimental laboratory methods.

My ambition to do research in the field of complex wounds directed me to the path of enrolling on a PhD at the University of Manchester, where I had the opportunity to study, learn and train in various methodological approaches to research, and also had the opportunity to work with world-class researchers.

1.2 INTRODUCTION TO THE STUDY

The starting point of this PhD project was my clinical observation of wound management practice in Slovenia. As a registered nurse working daily in a wound care clinic at the Department of Surgical Infections in Ljubljana, I was impressed by “new” possibilities and ways of treating wounds, such as using wound dressings with nanosilver, applying maggots or treating with oxygen. However, as my professional background is nursing, my focus was also on patients’ needs and benefit. Frequently I asked myself what my role was in providing wound care, and what I could do to improve practice and outcomes for patients’ benefit.

The literature I reviewed made me aware that there is an increasing evidence base about estimating if and how interventions in wound care are effective, yet it seems that there is an existing knowledge gap in basics, such as estimating how many people are affected by wounds and understanding patients’ needs and “lived experience” of having complex wounds. The narrative review, which is presented in the background chapter, and a further scoping review steered this project towards focusing on open surgical wounds, as they are generally under-researched.

Therefore the overall aim of this study is to estimate the prevalence of open surgical wounds and to explore the meaning of living with open surgical wounds.

Understanding both will guide research and clinical practice to provide a foundation for further research into interventions in order to reduce the impact of open surgical wounds on people’s well-being and to provide the assets needed to deliver the best possible care.

1.3 THESIS STRUCTURE

This thesis is submitted in alternative format, as I have published already one article (Study 2), and two (Study 1 and 3) are prepared for submission. The alternative format allowed me to gain experience in how to disseminate research findings effectively.

The thesis consists of seven chapters (three of which are three articles). Each chapter has its own introduction and summary.

The first chapter is the introduction to the thesis, where my personal context, introduction to the study, and thesis structure are presented.

The second chapter is divided into three sections and contains the background. In the first section distinctions between wounds based on naming, healing and its aetiology are explained and discussed. In the second subsection, global and Slovenian data on wound prevalence are mapped and critiqued. Next, in the third section, an overview of evidence related to common unpleasant symptoms of complex wounds and their impact on daily living is presented and critiqued.

The third chapter focuses on the different methodological approaches which were considered. It introduces and justify approaches taken for conducting studies (study 1, 2, and 3).

Chapters four to six present the results of this thesis. The fourth chapter is a scoping review of patient’s perspectives of living with complex wounds. The fifth chapter is a cross-sectional survey of open surgical wounds in Slovenia, and the sixth chapter is a qualitative exploration of the meaning of living with an open surgical wound.

A final chapter (Chapter 7), draws together conclusions and discussion across all three studies. Furthermore it introduces the implications for practice and further research.

References are listed at the end of thesis.

Appendices are referred to through the text and are numbered in sequence.

1.4 PUBLICATIONS FROM THIS THESIS

This thesis is submitted in alternative format. One article was published, while two manuscripts are prepared for submission.

Pađen, L., Griffiths, J., & Cullum, N. (2019). A cross-sectional survey of patients with open surgical wounds in Slovenia. *Health & Social Care in the Community*, 27(4), e213–e222. https://doi.org/10.1111/hsc.12700

Pađen, L., Griffiths, J., & Cullum, N. (NA). A qualitative exploration of the meaning of living with an open surgical wound. *Prepared for submission*

Pađen, L., Griffiths, J., & Cullum, N. (NA). Peoples' perspective of living with complex wounds – a scoping review. *Prepared for submission*

I was responsible for contribution to the conception of studies, designs of studies, data collection, data analysis and drafting manuscripts with guidance, critical review and feedback from both of my supervisors.

2 BACKGROUND

2.1 INTRODUCTION

The aim of this chapter is to establish the background to the study, to illustrate what was known about the epidemiological burden of complex wounds in Slovenia and to emphasise the importance of understanding the impact of complex wounds on patients' lives.
This chapter consists of four sections. First, the context of the research in Slovenia is presented. In the second section, complex wounds are distinguished from acute wounds and divided into subtypes, to explore the diversity of wound aetiology. In the third section the epidemiology of complex wounds is presented, to illustrate the global burden and provide insights into Slovenian data. In the fourth section, what was known about frequent unpleasant symptoms related to wounds and the impact of complex wounds on patients' quality of life is explored. Two main subsections, 2.3 and 2.4, have their own summaries that signal the need for further study, and the chapter ends with a conclusion summarising the overall gap in the evidence base.

2.1.1 Research context

In this section, Slovenia will be presented in terms of demographic, economic development, education, and health data. Furthermore, the demographic and health data will be compared with the United Kingdom and Sweden as a large number of wound-related research studies originate from these two countries.

Demography

Slovenia (formally the Republic of Slovenia), is a central European country bordered by Italy to the west, Austria to the north, Hungary to the east and Croatia to the south. Slovenia covers 20,273 square kilometres (7,827 square miles) and has a population of 2,094 million. The capital city is Ljubljana, with a population of 292,988. Looking at general demographics, Slovenia has a low population density compared with other European countries (101 people per sq. km). Similar to other developed countries, the age profile of the Slovenian population is becoming older. The proportion of people aged 65 years and older is increasing: in 2020, the proportion was 20%, but is expected to be approximately 30% by 2060 (SI-STAT, 2020).

Economy and development

Slovenia is a partner in many international organisations and unions, such as the European Union, NATO, OECD and United Nations (CIA, 2020). Slovenia is a developed country. Its gross domestic product (GDP) ranks 82nd in the world (nominal, for 2019). GDP per capita is

21,267 EUR (33rd in the world), GDP growth in March 2020 was estimated at 1.7%, and inflation (general increase in prices) was 2.0%. Average monthly gross earnings are 1,800 EUR. Slovenia has a low unemployment rate: 4.0% in February 2020 (SI-STAT, 2020).

Education

Public expenditure on formal education is estimated at around 4.5% of GDP (compared with 5.4% in UK and 7.1% in Sweden) (EUROSTAT, 2016). Looking at data related to formal education, or schooling, it can be noted that Slovenia has a fairly high enrolment rate in formal education, comparable to other western countries: 81% enrolment in pre-school education, 91% enrolment of 18-year-olds in secondary level education, and 46.1 % enrolment of young people (aged 19-24 years) in tertiary education (SI-STAT, 2020). The literacy rate of citizens aged 15 years and older is 99.7% (UNESCO, 2020).

Health care

Health care in Slovenia is organised into three tiers, namely primary care (health care centres), secondary care (hospitals and outpatient clinics) and tertiary care (referral hospitals, university hospitals). Public providers deliver the majority of health care services, while “concession” providers (companies appointed by government or local authorities to provide publicly-funded services) can deliver some of the services, such as primary care (GP, gynaecology, paediatric and school medicine care) or at secondary level (general and specialist surgical care or general and specialist medicine care) (Ministry of Health, 2020). People could receive health care services also in private sector.

The Slovenian health insurance system is based on a single public insurer, which provides compulsory health insurance. Working people pay insurance through their taxes (deducted from gross salary). Compulsory insurance covers 85% of all services, while 15% of services are covered through voluntary insurance, which can be obtained through commercial insurance companies. Children and students up to 26 years old are insured through their parents or guardians (compulsory insurance only) (Health Care and Health Insurance Act – NPB 30, 2019).

Eurostat theme comparison

When Slovenia joined the European Union in 2004, it was also included as a state in the European, “EUROSTAT” monitoring system. Eurostat covers nine different statistical themes (including areas ranging from general and regional statistics, economy and finance to population and health and social conditions) (EUROSTAT, 2016). Some of these indexes – those which emphasise health and social-economic status – are presented in Table 1 to illustrate the differences between the Slovenian population and the populations of the UK and Sweden, where most wound prevalence and studies of patients' experiences have been carried out.

Table 2.1: EUROSTAT indexes.

Index	Slovenia	UK	Sweden
Demography			
Total population (data from January 2020)	2,080,908	66,647,112	10,230,185
Proportion of population aged 65 and over in % (data from 2019)	19.8	18.4	19.9
Health status			
Healthy life years at birth in years (data from 2018) a) Males b) Females	a) 56.3 b) 54.6	a) 61.5 b) 60.8	a) 73.7 b) 72.0
Self-perceived health and well-being in % (data from 2018) a) very good b) good c) fair d) bad e) very bad	a) 20.2 b) 45.7 c) 25.0 d) 7.2 e) 1.9	a) 33.1 b) 39.3 c) 19.8 d) 6.1 e) 1.7	a) 28.7 b) 47.2 c) 18.9 d) 3.8 e) 1,4
Health care			
Health care expenditure in EUR per inhabitant (data from 2016)	1,657	3,566	5,132
Health care resources (data from 2016) a) Number of registered nurses per 100,000 population b) Number of general practitioners per 100,000 population	a) 307.26 b) 57.38	a) 645.46 b) 76.33	a) 1,090.24 b) 64.63

Index	Slovenia	UK	Sweden
Income and Living Conditions			
Median equivalised net income in EUR (data from 2018)	13,244.00	20,991.00	25,540.00
People at risk of poverty or social exclusion % of total population (data from 2018)	15.6	21.2	12.9
Inability of households to make ends meet % of total population (data from 2013)	21.9	11.5	3.7

The data were taken from EUROSTAT statistical reports from 2016 to 2020 (EUROSTAT, 2020). Since there are some data which were not updated in 2020, the most recent data available are presented.

As for health status, the results from EUROSTAT showed that Slovenians have the lowest expectancy of healthy years at birth of the three countries compared. There are minor differences between genders. When self-perceived health was surveyed, Slovenians had the highest percentage for “very bad health” and the lowest for “very good health”. Also, two indicators (numbers of nurses and numbers of GPs) were observed in the area of health resources. Both showed that Slovenia has a lower level of health resources. Healthcare expenditure per inhabitant in Sweden is twice as high as in Slovenia. Also Slovenia has the lowest number of qualified nursing professionals (according to the definition in EU directive 36/2005) and general practitioners. The data also showed that on average Slovenians have lower income and are at higher risk of poverty than Swedes, but are still at lower risk compared to the British; however the inability of households to make ends meet in Slovenia is twice as high as in the UK and almost six times higher than in Sweden.

These data show that findings from previously published research on wounds which was carried out in other countries might not be fully applicable to Slovenia, or must be interpreted with caution. Factors such as poverty, lower numbers of qualified professionals, and fewer health care resources could make a difference prevalence and experiences of living with complex wounds, but there is no research evidence to support this.

2.2 DEFINING COMPLEX WOUNDS

A wound is the point where disruption or damage to the integrity of skin or epithelial tissue occurs. Wounds can be classified using a variety of approaches, e.g. duration (acute, chronic), cause/aetiology (surgical, traumatic, and related to disease) or how they heal (primary, secondary or tertiary intention) (Buchanan et al., 2014; Menke et al., 2007; Young & McNaught, 2011).

2.2.1 Distinction based on duration of wound healing

Acute wounds (injuries, burns and surgical wounds) normally heal in an orderly sequence of phases within days or weeks (Li et al., 2007) without any complications.

When a delay in healing occurs and a wound fails to heal within 6 - 8 weeks it is regarded as “chronic” (Menke et al., 2007). “Chronic wound” is a recognised term, but in recently published literature the terms “hard to heal” and “complex wound” are increasingly used. Pragnell and Neilson (2010, p.1248) define the concept of a “hard to heal” wound as one *“which encompasses a number of abnormal responses to the general process of healing – a defined and complex sequence of overlapping cellular and biochemical events leading to scar formation”*. In the paper the authors also use the term “chronic wounds” as a synonym for “hard to heal wounds”. Lazarus and colleagues (1994, p. 489) define complex wounds as those that *“… have failed to proceed through an orderly and timely process to produce anatomic and functional integrity, or proceeded through the repair process without establishing a sustained anatomic and functional result*”. Cullum et al. (2016; p. 1) define complex wounds as *“superficial, partial or full thickness skin loss … healing by secondary intention”.*

Looking more closely at these definitions, Lazarus et al.’s (1994) concept of a “chronic wound” only refers to the duration and time frame of healing/non-healing and the deficiency of either anatomical or physiological functions of the tissue. To some extent, Lazarus and colleagues ignore the complexity of the healing process. In contrast, Pragnell and Neilson (2010) point out the complexity of healing by stressing the biochemical and cytological processes in healing. Cullum et al.’s (2016) term “complex wound”, is a broader concept that points to the wide complexity of the healing process and not only a time delay in healing or tissue loss. In summary it can be said that all these definitions signal that these wounds are characterised by their complexity of healing and the time taken for healing.
Throughout this thesis, the broader definition of a complex wound is used: *“superficial, partial or full thickness skin loss healing by secondary intention”* (Cullum et al., 2016).

2.2.2 Distinction based on the type of wound healing/closure

Wounds can heal by primary, secondary or tertiary closure.

Primary closure, also commonly referred to as “healing by primary intention”, is a method where the healing process is accelerated by the re-approximation of wound edges with sutures, staples, glue or thin adhesive strips. This artificially decreases the wound gap to be filled and therefore it minimises scarring. Most surgical wounds heal by primary intention (Harper et al., 2014; Walter et al., 2012; Young & McNaught, 2011).

Secondary closure, or “healing by secondary intention”, occurs when a wound’s edges cannot be surgically re-approximated due to severe tissue loss, or because of infection or risk of infection. This results in a delay to normal tissue repair as an extensive defect must be filled with granulation tissue, which is later followed by wound epithelialisation and contraction. Secondary intention healing normally results in a large scar (Harper et al., 2014; Li et al., 2007; Young & McNaught, 2011).

Sometimes, a wound that has been intentionally left open can be closed after a period of days, usually when an infection has been successfully treated or when the risk of infection has passed. This is defined as “healing by tertiary intention” or “healing by delayed primary intention”. Some research has suggested that the healing process for wounds healing by tertiary intention is faster and results in smaller scars (Buchanan et al., 2014).

2.2.3 Distinction based on wound aetiology

Complex wounds have different aetiologies. The common complex wounds are: arterial and venous leg ulcers, diabetic foot ulcers, and pressure ulcers (Demidova-Rice et al., 2012; Menke et al., 2007). Less common complex wounds are surgical wounds healing by secondary intention. Surgical wounds heal by secondary intention either because this was intended at surgery (e.g., due to infection or risk of infection) or because the surgical wound broke down (dehisced) after surgery (Chetter et al., 2017). There are other complex wounds, such as connective tissue ulcers (Dabiri & Falanga, 2013) and malignant fungating wounds (Probst et al., 2013a, 2013b); however these are less common and may be regarded as atypical wounds.

In the next section the causes and characteristics of complex wounds will be presented according to frequency of occurrence, which will be further explained later in the chapter.

Pressure ulcers

Pressure ulcers (also known as pressure sores, bed sores or decubitus ulcers) are the most common type of preventable complex wound. The European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance (2019) defined pressure ulcers as “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear”. Pressure is a force which compresses skin and underlying tissue between the supporting surface and a bony prominence (Haesler, 2019). Shear forces cause deformation of tissue by force which is parallel to the surface where tissue is engaged (Reger et al., 2010). Pressure, with or without shear, impairs tissue oxygenation and blood flow (Manorama et al., 2013; Manorama et al., 2010).

It is well documented that many risk factors influence the development of pressure ulcers. Coleman and colleagues (2013) conducted a systematic review of patient risk factors for the development of pressure ulcers. A search was conducted of 14 electronic databases plus hand-searching of journals and conference proceedings. Coleman et al. contacted field experts and searched for data on relevant web pages. Fifty-four primary studies of different designs (prospective cohort, retrospective record review and randomised control trials (RCT) were eligible for inclusion. The review showed that many factors contribute to the development of pressure ulcers. According to Coleman et al. (2013) these contributing factors are complexly interrelated and it is not possible to isolate any one of these as the cause of a pressure ulcer developing. Mobility was recognised as a significant risk factor which is inversely proportional to the development of pressure ulcers; the lower the mobility/activity, the higher the risk of occurrence of pressure ulcers. In addition to this factor, Coleman et al. also concluded that impaired perfusion (for example as a result of diabetes, vascular disease, oedema, smoking or pressure) is also a significant risk factor for pressure ulcer development. Beside pressure and impaired perfusion, skin moisture, nutritional factors (BMI, general nourishment, and food intake), age and the presence of other diseases are also risk factors. There is, however, limited evidence as to the contribution of body temperature, race or gender to the development of pressure ulcers (Coleman et al., 2013).

A noticeable strength of Coleman et al.’s (2013) review is that the authors adopted a systematic and rigorous approach to searching the literature, data extraction and quality appraisal of primary studies. However, the review’s findings are limited in that almost 70% of the primary studies were regarded as low or very low quality studies, as they suffered from small sample sizes, inadequate numbers of events, poor reporting, inadequate models for predicting risk factors and/or inadequate data analysis (Coleman et al., 2013). Another drawback of Coleman et al. (2013) review is that they did not follow recommended methods and approach for prognostic factor reviews. Therefore, Including findings from Coleman et al. (2013) could have resulted in the assumption that a specific risk factor has a more important impact than it actually has.

Shi et al. (2018a) conducted a systematic review and meta-analysis with the specific aim of assessing the independent prognostic value of skin status for predicting pressure ulcer development. Forty-one studies with 15 skin descriptors (such as blanchable erythema, non-blanchable erythema, current pressure ulcers, history of pressure ulcer, dry skin, moist skin, oedematous skin, etc.) were included in the review. Shi et al. (2018a) suggested that the skin descriptors analysed are low predictors for developing pressure ulcers. Non-blanchable erythema may be more likely to be associated with developing pressure ulcers; however, the included primary studies were graded as low certainty.

Leg ulcers

Leg ulcers most frequently occur on the lower leg, below the knee (González-Consuegra & Verdú, 2011). The majority of leg ulcers have some kind of vascular aetiology, which can be venous, arterial or a combination (Gohel & Poskitt, 2010; Nelzén, 2010). Briggs and Closs (2003), in their literature review on leg ulcer prevalence and aetiology, concluded that although a number of other conditions could lead to ulceration, such as arterial disease, vasculitis, pyoderma gangrenosum, rheumatic disease and others (Meyer et al., 2011; Short & Bull, 2009), most (between 37% and 76%) were due to venous disease. The underlying pathology of venous leg ulcers is chronic venous insufficiency (Nelson & Jones, 2008), which is characterised by insufficient drainage of venous blood from the lower limbs due to failure of venous valves. This process starts with venous hypertension, which additionally damages the valves and vascular wall (Gohel & Poskitt, 2010). The consequent oedema means that even small wounds, e.g. due to mechanical injury, can lead to chronic ulceration (Shai & Halevy, 2005). The pathogenesis of arterial ulcers is reduced perfusion through arterial lumen, which leads to reduced peripheral (distal) oxygenation and ischemia, resulting in tissue loss or necrosis (Metcalfe & Brooks, 2010).

Foot ulcers associated with diabetes

Diabetes is a chronic disease with high and rising prevalence in developed countries (Agardh et al., 2011; King et al., 1998). Chronically high blood sugar levels can lead to several different complications involving vessels and nerves. Foot ulcers associated with diabetes often start with a small injury to the foot, or callouses on the feet due to ill-fitting footwear, or other physical injuries such as those due to foreign objects in the shoe, punctures, and pedicure injuries (Prompers et al., 2007). Other factors such as co-morbidity, mobility and infections influence the healing of diabetic ulcers (Iraj et al., 2013). Foot ulcers associated with diabetes can be classified by their underlying aetiology as ischaemic, neuropathic or neuro-ischaemic (Apelqvist et al., 2008). Peripheral neuropathy is one of the complications of diabetes which results in insensitivity to pressure and pain (Oyibo et al., 2001). Ischemia and necrosis can be attributed to angiopathy and atherosclerosis, which are complications of diabetes (Hammes, 2003). Consequences of foot ulcers associated with diabetes include the risk of gangrene, which can lead to amputations (Gemechu et al., 2013; Nather & Wong, 2013). It has also been found that people with diabetes have a more than twenty-fold risk of lower limb amputation compared to people without diabetes (Holman et al., 2012).

Atypical wounds

There are several less common types of complex wound, which, together, could be labelled as "atypical". Atypical wounds are caused by systemic diseases with complex pathophysiology and therefore their diagnosis and management are very complex. These wounds might be divided into two main groups, i.e. connective tissue wounds and malignant, fungating wounds.

Connective tissue ulcers

Connective tissue ulcers are a consequence of connective tissue disorders (Dabiri & Falanga, 2013). Connective tissue disorders are heritable (Van Laer et al., 2013) or have autoimmune aetiology; these include rheumatoid arthritis, lupus erythematosus, Sjogren's syndrome, Hughes Syndrome, scleroderma, myositis and various other connective tissue diseases (Dabiri & Falanga, 2013; Rao & Bowman, 2013). The development of connective tissue ulceration is a complex process which cannot be attributed to one isolated factor, but to a range of complex factors, such as systemic disease (connective tissue disorders and other diseases such as renal impairment), inflammation, and local wound factors (Dabiri & Falanga, 2013; Shanmugam et al., 2008, 2010).

Malignant wounds

Cancer presents a global burden to health. The number of new cases is continuously rising due to population aging, lifestyle risks and environmental cancer risk factors (Jemal et al., 2011). Malignant wounds develop either as primary skin cancer or as cutaneous metastases, i.e. the spreading of another primary cancer into the skin e.g. fungating breast cancer (Alexander, 2009; Maida et al., 2012). Malignant wounds typically present as proliferating wounds (which can be cauliflower-like in appearance) or in the form of shallow craters or ulcers (Grocott et al., 2013; Lo et al., 2012).

2.3 COMPLEX WOUND EPIDEMIOLOGY

Epidemiology is defined as the *"study of the occurrence and distribution of health-related events, states, and processes in specified populations, including the study of the determinants influencing such processes, and the application of this knowledge to control relevant health problems"* (Porta, 2014; p. 95).

Two measurements of the number of cases in a population are used in epidemiology: prevalence and incidence. According to Porta (2014; p. 144) incidence is *"the number of instances of illness commencing, or of persons falling ill, during a given period in a specified population",* whilst prevalence is defined as *"a measure of the occurrence of any type of health condition, exposure, or other factor related to health: the total number of individuals who have the condition at a particular time (or during a particular period) divided by the population at risk of having the condition at that time or midway through the period"* (Porta, 2014; p. 223). Furthermore, when using prevalence, the concepts of "point" and "period" prevalence must be understood. Point prevalence relates to the number of cases at a particular point in time, while period prevalence relates to the number of cases over a particular time period, as, for example, lifetime prevalence, which is the occurrence of a condition at any time in someone's life (Porta et al., 2014). Prevalence is useful when the aim is to estimate the overall burden of the condition. Incidence might be used if the aim is to assess the probability of occurrence, the causes of the condition or the risk factors which predispose individuals to developing a condition.

In the following section I will present an overview of the current knowledge of complex wound epidemiology, with an emphasis on prevalence since the overall "burden" of complex wounds is the variable of interest. In the second part of this section I will present the available data for Slovenia.

2.3.1 Prevalence of complex wounds

A large corpus of epidemiological studies has aimed to estimate the prevalence of complex wounds. Leg ulcers are probably the most researched type of all. In 2003, two systematic reviews of epidemiological data focusing on leg ulcer prevalence were conducted by Graham et al. (2003) and Briggs and Closs (2003). However, there was a lack of comprehensive data on the prevalence of all types of complex wounds which remained the case for more than 10 years. Cullum et al. (2016) overcame this knowledge gap by publishing a systematic review of the existing data on prevalence of all subtypes of complex wounds.

In this section I will focus on findings from three literature reviews, namely: Graham et al. (2003), Briggs and Closs (2003) and Cullum et al. (2016). Furthermore, two original studies which were published in 2014 will also be critiqued as Cullum et al.'s review included only original studies published up until 2012.

Graham et al. (2003) carried out a systematic review of literature published on the prevalence of lower-limb ulcers. Twenty one prevalence studies (cross-sectional or longitudinal) on open or healed leg and/or foot ulcers were included in their review. Prevalence rates of validated cases in the total population varied according to whether only open lower limb ulcers (0.12-1.8%) or both open and healed ulcers (1.8%) were included; by comparison, the prevalence rate in the absence of validation was between 0.12% and 0.32%. Furthermore, in five original studies the samples used were of people who were in contact with health care services. In those studies the prevalence of open leg ulcers (when validation had occurred) was between 0.06% and 1.97%, whereas the prevalence of both open and healed ulcers was greater (1.3-3.6%).

Similarly to Graham et al. (2003), Briggs and Closs (2003) also carried out a review of research on leg ulcer prevalence. Sixteen studies were eligible for inclusion in the review. Authors reported that the estimated prevalence of active or open ulceration was between 0.11% and 0.18%, and that of open and previous (healed) ulcers was between 1 and 2%. Briggs and Closs also concluded that the burden of leg ulcers might be higher since there are populations which might not be represented in those figures, such as self-treating people.

Findings from both reviews have shown a high rate of variation in the reported prevalence of lower limb ulcers. This variation might be due to heterogeneous studies not reporting clear inclusion/exclusion criteria, especially when defining the population, the condition and the type of prevalence (especially in cases when healed ulcers were included in reported prevalence rates). Furthermore, the variation in prevalence rates might be due to the samples used in the original studies, e.g. the total population or randomly selected source population. Some studies were even designed to collect data from the caseloads of medical professionals. Both reviews indicate that careful selection of the source population, clear inclusion criteria and rigorous data collection are all essential in these kinds of studies. Dale (1983) and Nelzén (1996) have shown that there were a high number of false positive cases (up to 64%) when the technique of self-reporting was used. This indicates that case validation is necessary in order to provide reliable prevalence estimations, although it is costly.

Both reviews suffer from minor limitations which must not be neglected in the interpretation of findings. Graham et al. (2003) and Briggs and Closs (2003) had approached the search process systematically, but neither of the reviews had searched grey literature, which might have provided additional data on leg ulcer prevalence. Furthermore, the findings from both reviews are limited to reports published in the English language. Despite these issues, it is unlikely that these limitations could invalidate the findings of Graham et al.'s and Briggs and Closs' reviews; however, reported prevalence might be under- or over-estimated.

Cullum et al. (2016) reviewed studies estimating the prevalence rates of a range of complex wounds. This was the first systematic review to explore prevalence rates comprehensively, i.e. to include relevant data about all subtypes of complex wounds in one review. Forty eight studies were included in the review. Most of the studies were carried out in high-income countries such as the United Kingdom, United States, Sweden and Canada, and were based on sample sizes of between 551 and 1,000,000 people. The estimated prevalence rate for complex wounds was between 0.24 and 1.4% of the population. Reported estimated prevalence rates of leg ulcers were in the range 0.039 to 0.48%; leg and foot ulcers from 0.1 to 12.8%; non-diabetic foot ulcers between 0.02 and 3.39%; foot ulcers associated with diabetes between 1.3 and 5.9%. The prevalence of pressure ulcers was in the range between 0.056 and 23%.

The variation of reported prevalence rates in the case of leg and foot ulcers and pressure ulcers is quite high. This is likely to be due to the fact that some of the original studies had focused on populations at very risk of developing ulcers, such as elderly people or patients with spinal cord injuries. Furthermore, the variation is largely explained by the different denominators used in the original studies. For example, original studies which estimated prevalence in the total population (defined geographical population) found lower prevalence rates, while, on the other hand, whereas those which used current caseloads as the denominator estimated higher prevalence. This can be observed in outliers in pressure ulcer prevalence, where the maximum was 23% (99 out of 427 people with spinal cord injury treated in a Spinal Cord Injuries unit). A similar pattern can be seen in the prevalence of leg and foot ulcers, where the outlier stands at 12.8%; in this case a retrospective analysis of the medical records of 671 elderly people (aged over 65) in Hong Kong was used to estimate prevalence (Cullum et al., 2016).

Cullum et al. (2016) also pointed to under-researched areas, namely, at that time, no study had addressed the prevalence of complex wounds in hard-to-reach populations such as drug users; no data on surgical wound healing by secondary intention were found, and therefore some populations were globally under-represented – or even not represented at all – in the prevalence studies. The same team then went on to conduct a prevalence survey for all types of complex wounds (data from this study is published in Hall et al., 2014 and later in Cullum et al., 2016). The original study was reported before the full report of the project was published. Therefore in this thesis I refer to data published in Hall et al. (2014).

Since research in wounds is expanding it was possible that new epidemiological data were available, so I conducted another search in 2014 (using an adapted version of Cullum et al.'s search strategy) to identify any newly published literature. Beside Hall et al. (2014) study, the study carried by Coull et al. (2014) was also identified.

Coull et al. (2014) carried out a survey to estimate the prevalence of skin conditions and leg ulcers among young injecting drug users. A convenience sample of 200 drug users (21-44 years) across Glasgow (UK) was recruited for the study. Findings from this study showed that a significant proportion of those studied had, at that time, a complex wound of one type or other. The study showed that 30% of the source population reported that they had had a leg ulcer at least once during their life, and 7% of the recruited participants had an active ulcer. Furthermore 23% of all interviewees reported that they had, at the time that they were recruited, other types of complex wounds; however the authors did not report wound types. These figures show that prevalence of leg ulcers and other types of complex wounds amongst drug users is high compared to the general population; Cullum et al. (2016) have shown that the prevalence of leg ulcers is in a range between 0.039 and 0.48%, and that of complex wounds is between 0.24 and 1.4%.

The findings of the study conducted by Coull et al. (2014) should be treated with caution however as some weaknesses were identified. Firstly, the sampling technique had the potential for selection bias, because participants were recruited via a worker at the methadone clinic; this might lead to more participants with wounds or other skin conditions being recruited. Also, participants were excluded if they appeared to be under the influence of drugs or alcohol, because the authors judged they would not be able to give full consent; in addition the authors failed to quantify how many of the participants were excluded or refused to be interviewed. Also, the findings which related to lifetime prevalence might be prone to recall bias. Finally, no cases were validated, so false reporting or misclassification of the skin conditions might have occurred. Nevertheless the strength of the study was that it drew attention to the occurrence of complex wounds in this population group and the need for further, more robust research.

Hall et al. (2014) aimed to estimate the point prevalence of complex wounds in Leeds (United Kingdom), a city with a population of 751,485. They included into the cross-sectional study all health care providers in the area. The study measured a prevalence of all complex wounds of 1.47/1,000 of the population. The prevalence of complex wounds was higher in older people and females, which is similar to the findings of Graham et al. (2003). Hall et al. (2014) were the first to conduct a prevalence study of all subtypes of complex wounds, namely: malignant fungating wounds (0.02/1,000), pressure ulcers (0.31/1,000), foot ulcers associated with diabetes (0.13/1,000), non-diabetic foot ulcers (0.9/1,000) and leg ulcers (0.44/1,000). Furthermore, it was probably the first study which has quantified the prevalence of surgical wounds healing by secondary intention, which was estimated at 0.21 per 1,000 population (CI: 0.18-0.24). These findings suggest that surgical wounds healing by secondary intention occur as commonly as other types. What must be taken into account is the fact that only patients who were receiving treatment through health care services were included in the study, so the actual prevalence for specific types of wounds could be higher. Findings from some previous research have shown that 44% of people with leg ulcers had reported self-caring for ulcers without routine follow-up by health care professionals (Nelzén et al., 1996).

2.3.2 Prevalence of complex wounds in Slovenia

It is possible that findings from the three systematic reviews of prevalence of complex wounds conducted by Briggs and Closs (2003), Graham et al. (2003) and Cullum et al. (2016), are not transferable to the Slovenian population, since the Slovenian general population differs from other, previously researched, target groups in many respects, such as socio-economic status, environment, area of living (rural, urban), state of health and access to health care services. Moreover, none of the reviews reported any prevalence studies in countries close to Slovenia (such as Austria, Italy, or Hungary) or other former Yugoslavian countries.

In this section I present the available data on the prevalence of complex wounds in the Slovenian geographical area. For the purpose of estimating the burden, a search was conducted using the local database, COBIB.SI, using the terms (ran* ALI poškodb* ALI kronič* ran*) IN (epidemiolog* ALI prevalenc*). Only three publications were identified as relevant to the topic of complex wound epidemiology. One study addressed the prevalence of leg ulceration (Franks et al., 2007) while two studies were designed as surveys of pressure ulcers in hospital (Jelen, 2013; Kadivec, 2000). No other evidence estimating the prevalence of other subtypes of complex wounds in Slovenia was found.

Franks et al. (2007) aimed to determine the prevalence of leg ulceration in two geographical regions (Novo mesto and Krško, population 165,000) in Slovenia. All patients who were being treated by local health care providers were included in the study. The eligibility criteria were that individuals should have “breakdown of dermis anywhere in lower limb or foot, present for at least two weeks regardless of aetiology of ulcer”. Data were collected by health care professionals. To avoid double counting when a patient’s health care was shared between different providers a unique code was given to each participant.

The authors concluded that the estimated prevalence of lower limb ulceration was 1.81 per 1,000 of the population. Prevalence was higher among female (2.33/1,000) than male participants (1.24/1,000) and there was proportional correlation with increased age; however no attempt was made to statistically quantify these associations (gender or age).

The study by Franks et al. was the first to provide data on the prevalence of lower limb ulceration in Slovenia. However, there are two unexplained inconsistencies within the report which might have influenced the results. Firstly the diagnostic unit for eligibility required a lower limit of ulcer duration of 2 weeks. This seemed to change to 6 weeks when the results were presented. Furthermore, because of this change of inclusion criteria the authors excluded 55 cases from the sample, yet no rationale was given for this decision. In addition, there had clearly been some non-clarified issues with the denominator, which was the population in the geographical area. The authors initially stated that the population size was 165,000; later in the results it showed 68,810 males and 70,062 females (a total of 138,872) living in the Novo mesto and Krško region, which is fewer than first reported. The prevalence rate was estimated to be 1.81/1,000, but it is not clear which denominator was used to calculate prevalence. According to the authors 254 cases were identified as having lower-limb ulceration for 6 weeks or more. If the calculation was based on the denominator which was reported as being used in the calculation (138,872), the prevalence rate would be higher: 1.83/1,000 instead of 1.81/1,000. Another issue is that the authors overlooked the fact that there might be people who were not treated, or who were unknown to healthcare professionals, especially those who treated themselves, persons without health insurance or hard-to-reach groups like drug users or homeless people. However, although there are some minor flaws within the report, the prevalence rate is comparable to other previously published studies (Briggs and Closs, 2003; Graham et al. 2003, Cullum et al., 2016).

In the past, only two surveys of pressure ulcer prevalence have been conducted in Slovenia. Both investigators, Kadivec (2000) and Jelen (2013), aimed to estimate the point prevalence in the hospital environment.

Kadivec (2000) conducted a survey using a specially designed tool for collecting data on the risk of pressure ulcer development and nursing assessment of pressure ulcers. The survey was carried out at the University Clinic of Pulmonary and Allergic Diseases in Golnik, and 214 patients were recruited and examined by registered nurses. Kadivec (2000) reported that the point prevalence of pressure ulcers was 6%.

The findings of Kadivec (2000) might be challenged on the basis of sub-optimal study reporting and study conduct. First, Kadivec did not report their definition of pressure ulcer; furthermore the study analysed the data according to the stages of development of the pressure ulcers, but did not describe how those stages are defined and differentiated. Secondly, the author developed an assessment tool but did not report how this tool was designed or whether it was validated. Another weakness of the study is that the author does not report how the clinical examinations were performed; moreover, since the assessments in each department were carried out by different registered nurses per department, this might raise some uncertainty about proper distinction between pressure ulcer stages, as some previous studies reported misclassification, especially in stage 1 (Kottner et al., 2009). Kadivec (2000) made no attempt to quantify the pressure ulcer stages, which again might have an impact on increased prevalence. Another weakness of the study is that Kadivec did not provide other important data, such as comorbidity of participants, which could illustrate the wider context of the reported rate.

More than a decade later, in 2013, Jelen carried out a survey (audit) of pressure ulcers (all stages) in the largest university hospital in Slovenia. The aim of the study was to estimate the point prevalence of pressure ulcers. Jelen used adapted European Pressure Ulcer Advisory Panel questionnaire for data collection. Each patient was clinically examined by two registered nurses who were trained in pressure ulcer assessment. 1,224 adult patients who were hospitalised in a specific time period (one day) in different departments (surgical, internal medicine, nursing hospital, neurology, orthopaedics or infectious diseases) were included in the audit. Jelen (2013) concluded that the point prevalence of pressure ulcers (all stages) was an estimated 11.3%. If the first stage (non-blanchable erythema) is excluded from the cumulative prevalence, then the prevalence rate decreases to 6.4%, which is within the range of findings from other countries (Cullum et al., 2016).

Jelen's (2013) findings are limited to a typical tertiary referral hospital environment. First, prevalence was assessed at a hospital, where is a concentration of sick patients with reduced mobility and other risk factors. Secondly, in the hospital departments where the duration of hospital stay is longer, the concentration of patients with pressure ulcers might again influence a higher prevalence. Thirdly, it is not clear whether the observed department had any policy about discharging patients with pressure ulcers to the home environment, or whether the patient stayed in hospital until pressure ulcer was healed. Furthermore only adult participants were recruited into the study, which again fails to provide a clear picture of overall pressure ulcer prevalence in Slovenia.

2.3.3 Summary

In this section I have shown that there are still challenges in estimating the prevalence of complex wounds. Previously published research which focused on estimating the prevalence of complex wounds differs and is limited in various aspects, such as inclusion of different types of wounds and providing clear definitions of included wound types; sample and sampling strategy; study design; data collection technique; confirmation of cases. Furthermore it has conclusively been shown by three systematic reviews that methodological problems with the existing prevalence studies can be overcome by well-planned study design, which will make research comparable and findings valid (Graham et al., 2003; Briggs and Closs, 2003; Cullum et al., 2016). Although the volume of wounds research is growing, there is still a lack of generally accepted guidelines for designing prevalence studies in wound research.

The evidence presented suggests that apart from possibly unreliable prevalence data, epidemiological studies show that patients with complex wounds represent a major and non-negligible health problem. Findings from studies suggest that the prevalence rate of complex wounds is highly variable (range 0.02 - 23%) and varies according to various factors. However these studies also highlight the need for new, well-designed studies. In this chapter I have also highlighted that the majority of studies are focused on the prevalence of leg ulcers, pressure ulcers and foot ulcers related to diabetes, and apart from Hall et al. (2014), there is a general (global) lack of research into the prevalence of surgical wounds healing by secondary intention. In addition, no research was found that had surveyed surgical wounds healing by secondary intention in Slovenia.

2.4 SYMPTOM BURDEN AND IMPACTS ON WELL-BEING OF PATIENTS WITH COMPLEX WOUNDS

I will now discuss what was known from pre-existing research about the symptom burden and impact on patients of different complex wounds. The discussion is organised thematically, by the major domains that emerge, namely: 1) burden of unpleasant symptoms, 2) physical impact, 3) psychological impact, 4) social impact, 5) financial impact, and 6) the impact of treatments of wounds (including patient adherence).

2.4.1 Burden and impacts of unpleasant symptoms

Unpleasant symptoms related to the wound, such as pain, exudate, malodour and pruritus, are commonly experienced by people with various types of complex wounds. Furthermore, these symptoms have been identified in many studies as distressing, and interfering with people’s everyday living and daily activities.

Pain

Pain is the dominant unpleasant symptom of complex wounds, and probably the most researched. Researchers have studied pain from four different aspects: the prevalence of wound-related pain, pain and its impact on daily living, pain related to wound care procedures, and interventions for pain relief. Several systematic reviews and meta-syntheses have synthesised the available data on wound-related pain to provide some insight into this complex phenomenon; however, their findings focus on certain types of complex wounds, most frequently pressure ulcers (Girouard et al., 2008; Gorecki et al., 2011) and leg ulcers (Briggs & Flemming, 2007; Herber et al., 2007; Persoon et al., 2004), and little evidence is available for other types of wounds such as malignant wounds (Lo et al., 2012; Maida et al., 2009; Probst et al., 2013a: 2013b).

By looking at evidence related to pain, it can be noted that the occurrence, type, intensity and duration of wound-related pain varies depending on the type of complex wound. The common ground for all subtypes of complex wounds is that they are painful. Pain affects a large number of people with wounds, namely from 25 to 100% of the study sample (Bengtsson et al., 2008; Bradbury & Price, 2011a; Girouard et al., 2008; Maida et al., 2009; Persoon et al., 2004; Ribu et al., 2006). It appears that pain occurrence varies by type of wound: for example, self-reported pain occurs more frequently with pressure ulcers (Girouard et al., 2008) and diabetic foot ulcers (Bengtsson et al., 2008; Bradbury & Price, 2011a; Ribu et al., 2006) than with malignant wounds (Maida et al., 2009) and venous leg ulcers (Persoon et al., 2004); meanwhile there is no quantitative data for surgical wounds healing by secondary intention.

Studies reported that self-reported pain occurrence, intensity and duration varied a great deal depending on other factors, such as the timing of assessment, wound-related procedures, patient mobility, condition of wound (swelling, infection), weather, season of the year, analgesia etc. (Girouard et al., 2008; Persoon et al., 2004; Ribu et al., 2006; Bradbury and Price, 2011a, b; Bengtsson et al., 2008; Maida et al., 2009).

Malodour and exudate

Other unpleasant symptoms such as malodour and exudate have also been reported in various studies, which mostly involved people with leg ulcers, malignant wounds and pressure ulcers (Persoon et al., 2004; Briggs and Flemming, 2007; Herber et al., 2007; Gorecki et al., 2009; Probst et al., 2013a, 2013b; Lo et al., 2008; Maida et al. 2009). However there is a limited evidence base on the occurrence of these symptoms and their impacts on quality of life: indeed only one study was identified which attempted to explore what it is like to live with wound-related malodour and exudate, regardless of wound type (Lindahl et al., 2007), while findings from others studies report malodour and exudate as part of the general experience of having wounds, and how wounds affect people’s lives (Persoon et al., 2004; Briggs and Flemming, 2007; Herber et al., 2007; Gorecki et al., 2009; Probst et al., 2013a, 2013b; Lo et al., 2008; Maida et al. 2009).

A qualitative study by Lindahl et al. (2007) focused on exploring what it is like to live with malodorous exuding wounds. Phenomenological hermeneutic method was used to illuminate the experiences of living with ulcers from the patient's perspective. In total, nine patients with various types of wounds (leg ulcers, malignant wounds, infected dental wounds, and infected surgical wounds) were involved. Data were collected using a narrative interview technique and analysed using a qualitative content analysis approach.

The overall findings from Lindahl et al. (2007) showed that malodour and leakage had a major impact on patients' everyday lives and their quality of life. Malodour and exudate were reported to have impacted people's physical, psychological and social domains of life. It was suggested that the persistent smell and exudate evoked negative emotions and feelings, and furthermore led people to have feelings of losing themselves (their body, mind and personality). However, beside negative impacts, this study has also shown that people develop positive strategies to overcome the daily challenges.

Findings from other studies have emphasised that people with different types of complex wounds frequently experience unpleasant symptoms, such as malodour and exudate. In case of leg ulcers, Persoon et al. (2004) reported that exudate occurs in 20 to 79% of cases, while Herber et al. (2007) reported that malodour and exudate occur in 60% of cases, which illustrates the high frequency of the symptoms. Gorecki et al. (2009) suggested that odour and exudate were also commonly experienced by people with pressure ulcers. In contrast to leg ulcers and pressure ulcers, the occurrence of malodour and exudate appears to be less frequent in malignant wounds: Maida et al. (2009) reported that malodour or exudate affects approximately 10 to 20% of patients. In case of surgical wounds healing by secondary intention, there are no quantitative data related to occurrence of symptoms.

When looking at the impact of malodour and exudate on people's quality of life, the findings from studies are conclusive: these symptoms affect the physical, psychological and social domains of quality of life (Persoon et al., 2004; Briggs and Flemming, 2007, Herber et al., 2007). It appears that experiencing malodour and exudate is associated with higher risk of depression and anxiety (Herber et al., 2007); furthermore it affects body image, as evidenced by people often using extreme or graphic descriptors such as "impure", "dirty" or "horrible" (Persoon et al., 2004; Briggs and Flemming, 2007, Herber et al., 2007).

Pruritus

Pruritus (commonly referred to as "wound itch") seems to be one of the unpleasant symptoms which is particularly under-researched. There are only few studies which have reported the occurrence of pruritus (Maida et al., 2009; Paul, 2013) or its impact on people's lives (Briggs & Flemming, 2007; Herber et al., 2007; Lo et al., 2008; Lund-Nielsen et al., 2005a,b; Persoon et al., 2004; Probst et al., 2013b).

Compared to other unpleasant symptoms, wound-related pruritus appears to be less frequent and varies widely depending on the wound type. Paul (2013) estimated the occurrence of wound-related pruritus at 27.6 % of the sample (n=199). Furthermore, it was noted that the highest reported rate of pruritus sensation was in the “venous leg ulcers” group (45.2%) while the lowest was in the neuropathic diabetic foot ulcers group (16.2%). Similarly, to Paul (2013), Persoon et al. (2004) also concluded that pruritus affects people with venous ulcers more frequently: they suggested that pruritus occurs in up to 58% of cases; however, these suggestions were not supported by associated statistics or details of the primary studies. When looking at the occurrence of pruritis in malignant wounds, it appears that it is lower compared to other subtypes of complex wounds, affecting 6% of people (Maida, 2009). No evidence related to occurrence is available for pressure ulcers and surgical wounds healing by secondary intention.

Herber et al. (2007) noted that pruritus interferes with patients’ daily living; it restricts normal quality of sleep. Moreover, Briggs and Flemming (2007) found that patients perceived pruritus as a distressing symptom which they could not control. Probst et al. (2013b) suggested that pruritus also affects patients with malignant wounds.

Suggestions from Persoon et al. (2004), Herber et al. (2007) and Briggs and Flemming (2007) are of limited value due to poor reporting of the studied phenomenon, which might be due to the fact that there is an existing gap in the current evidence base on wound-related pruritus (quantification and description of the nature of the pruritis). Furthermore these suggestions are mostly limited to findings from qualitative studies where the studied phenomenon was experiences of living with leg ulcers, and pruritus was not the primary focus of study. It was noted that pruritus was a distressing symptom, but further research was needed to explore the nature of pruritus (Persoon et al., 2004; Herber et al., 2007; Briggs & Flemming, 2007). No other studies exploring pruritus related to other types of complex wounds, such as pressure ulcers, foot ulcers associated with diabetes, malignant wounds or surgical wounds healing by secondary intention were found. This indicates that further research is needed.

2.4.2 Impact of wounds on the physical domain of well-being

The physical domain of quality of life is affected by multiple factors, namely unpleasant symptoms, the wound itself, perceived health, and treatment strategies.

It has been well documented that unpleasant symptoms such as pain are associated with reduced mobility (Byrne & Kelly, 2010; Mudge et al., 2008; Palfreyman et al., 2007; Taverner et al., 2011, 2014). People have reported that wounds and wound-related symptoms such as pain have reduced their participation in outdoor activities, such as walking and shopping, and indoor activities including those of daily living, for example climbing stairs, housework, preparing meals, taking care of personal hygiene (washing and bathing) and putting on clothes (Briggs & Flemming, 2007; Byrne & Kelly, 2010; Herber et al., 2007; Mudge et al., 2008; Palfreyman et al., 2007; Persoon et al., 2004; Taverner et al., 2011, 2014). In general, people with wounds often develop sedentary behaviour and do not achieve a sufficient level of physical activity, i.e. 30 minutes per day (Heinen et al., 2007).

Wounds and wound-related pain also results in reduced sleep, namely in the duration and quality of sleep (Persoon et al., 2004; Herber et al., 2007 and Briggs & Flemming, 2007). Lack of sleep often results in profound fatigue and inability to be physically active (Fagerdahl et al., 2013).

Wound location could also influence the perceived level of impact on the physical domain. It seems that patients' mobility is affected to a greater extent by leg and foot ulcers (Bradbury & Price, 2011b; Heinen et al., 2007; Hjelm et al., 2002a) than by other types of wounds, such as surgical wounds healing by secondary intention or pressure ulcers (Gorecki et al., 2010; McCaughan et al., 2018). However, it must be emphasised that there is a lack of empirical (quantitative) evidence to support such claims. Furthermore it seems that younger people experience greater impact on their physical activity than older people (Franks & Moffatt, 1998).

Perceived health and self-limitation could also be two of the factors which affect people's mobility. Some studies (Bolas & Holloway, 2012; Edwards, 2003; Fagerdahl, 2014; Fagerdahl et al., 2013; McCaughan et al., 2015; Upton & Andrews, 2013) have found that people have reduced mobility and physical activity due to wounds, wound-related symptoms (mostly pain) or treatment strategies (for example bandages, NPWT or larval therapy). Furthermore it seems that comorbidities could exacerbate the impact on physical quality of life (Firth et al., 2011, 2013; Gorecki et al., 2012; McGinnis et al., 2015).

2.4.3 Impact of wounds on psychological domain of well-being

Wounds and wound-related symptoms (mostly exudate and malodour) have a profound and multilayered negative impact on people's psychological well-being (Lindahl et al., 2007). They affect people's emotions and produce negative emotional reactions (Briggs & Flemming, 2007; Gorecki et al., 2009; Herber et al., 2007; Lo et al., 2008; Lund-Nielsen et al., 2005a; Persoon et al., 2004; Alexander, 2010) in terms of generally negative feelings, feelings of depression, anxiety, anger, despair, fear, worrying, feelings of being controlled by the ulcer, loss of self-confidence, mood change and frustration.

Qualitative studies have shown that people with wounds report that they experience anxiety and depressive symptoms; however the severity of the symptoms varies (Briggs & Flemming, 2007; Gorecki et al., 2010; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018).

Findings from studies suggest that unpleasant symptoms such as pain and odour often cause feelings of “being controlled by the wound” or “losing control” and being “constantly reminded that they have a wound”. Losing control means that people with wounds feel that they are losing the certainty in their lives which they take for granted, that they become uncertain about the outcomes of healing and treatment, for example. It can also mean that people develop fears related to their future. All these feelings undermine people’s psychological well-being (Herber et al., 2007; Lernevall et al., 2017; Lindahl et al., 2007; Turner & Kelly, 2000). The depth of impact on psychological well-being is also reflected in the findings of Charles (1995), where it is reported that people with wounds even had suicidal thoughts.

The concept of altered body image is also well described in the literature. Wounds, wound-related symptoms (mostly exudate and odour that can be noticed by others) and treatment have produced feelings of embarrassment and shame, which are interrelated with negative social behaviour such as social withdrawal and isolation (Bolas & Holloway, 2012; Lindahl et al., 2007; Lo et al., 2008; Lund-Nielsen et al., 2005a; Ottosen & Pedersen, 2013; Paton et al., 2014). Furthermore, wounds and unpleasant symptoms are associated with negative general feelings, mostly related to self-esteem, perception of one’s appearance, and sexuality, though this seems to affect females (Hareendran et al., 2005; Hjelm et al., 2002b; Lindahl et al., 2007; Lund-Nielsen et al., 2005a; Paton et al., 2014) and younger people with wounds (Lo et al., 2008; Lund-Nielsen et al., 2005a; McCaughan et al., 2018) more frequently.

On the other hand, besides negative emotional impact, it has been reported that patients develop adapting and coping strategies, such as accepting their condition as a psychological reaction, i.e. their focus changes from a negative to a positive attitude and they regain control over their everyday life (Fagerdahl, 2014; Herber et al., 2007; Hopkins, 2004; Lindahl et al., 2007; Persoon et al., 2004; Phillips et al., 2018). Expectations related to outcomes changed and often became realistic. People reported the need to be (stay) positive which encouraged them through the experience of having a wound (Persoon et al., 2004; Lindahl et al., 2007; Herber et al., 2007, Philipps et al., 2018).

Qualitative research studies indicate that the magnitude and variety of emotional impacts might be related to people’s resilience to the fact of having a complex wound; however there is a lack of quantitative psychological evidence in the area of wound research to make a definite association.

2.4.4 Impact of wounds on the social domain of well-being

The social domain, especially interpersonal relations (partner, family, friends, others) and social activities seems to be impacted by complex wounds. Social impact is related to and intersects with the impact of wounds, wound-related unpleasant symptoms, treatments, and the overall experience of having a wound.

One major concern related to social impact is the visibility of the condition. The wound, symptoms such as malodour, swelling or exudate, and some of the treatments such as compression, maggots and topical negative pressure wound therapy, can be noticed by others in social settings and can produce negative feelings such as embarrassment and shame (Green et al., 2017; Herber et al., 2007; Hopkins, 2004; Jones et al., 2008; Lindahl et al., 2007; Paton et al., 2014; Persoon et al., 2004; Phillips et al., 2018). The “visibility” of the wound, symptoms, treatment or the patient’s perception of the experience can become a trajectory of self-stigma or public stigma. People with wounds reported often feeling unclean or dirty which induced negative social behaviour, mostly by reducing social contacts – social isolation or even social alienation (Jones et al., 2008; Lindahl et al., 2007; Lo et al., 2008).

The reduction of social activities and social isolation might also be due to physical limitations, as mobility is affected. People are not able to travel, or to participate in social activities (Lindahl et al., 2007; Lo et al., 2008).

Wounds, wound-related unpleasant symptoms and treatments have a negative impact on social relations with loved ones and others. It is well documented that people experience strain in their relationships (Lund-Nielsen et al., 2005a; Jones et al., 2008; Probst et al., 2013b). Furthermore, women who had malignant wounds reported avoiding close physical contact and also reported reduced sexual desire (Lund-Nielsen et al., 2005a; Probst et al., 2013b) which illustrates the magnitude of the impact on people’s social well-being.

2.4.5 Impact of wounds on the financial and employment domain of well-being

Having a wound affects people’s employment and has a negative financial impact on them. People with wounds have reported being concerned about their current and future financial stability, for example how to maintain their employment or, in case of self-employment, how to make ends meet (Briggs & Flemming, 2007; Franks et al., 2006; Kapp et al., 2018; Kirupa, 2014; Palfreyman et al., 2007).

Furthermore, in many studies it was reported that people with wounds had additional financial strain: often treatments such as wound dressings, over-the-counter medicines, and alternative therapies were additional expenses in countries where patients pay for prescriptions. Furthermore, many people who were not insured or had to pay some of the cost of services (prescriptions, follow-ups, dressing changes, nursing and GP care, etc.) faced increased outgoings and significant financial impact (Kapp et al., 2018; Lindahl et al., 2007; Upton & Andrews, 2013).

2.4.6 Impact of treatment of wounds

Impacts of treatment of wounds were reported in many papers. It encompassed various aspects, namely: physical, psychological and social impacts of treatments (as described in previous sections of this chapter), and cognitive and behavioural aspects such as adherence and compliance with and knowledge about treatment.

People’s cognitive and behavioural perception of treatment seems to affect the general experience of having complex wound. Themes related to adherence and compliance with treatment were often raised in the findings of qualitative research. Adherence and compliance appear to be complex processes that are affected by geographical location and culture of patients (Hjelm & Apelqvist, 2016; Hjelm & Beebwa, 2013), personal values and beliefs (Crews et al., 2016; Edwards, 2003; Fagerdahl, 2014; Hjelm & Apelqvist, 2016; Hjelm & Beebwa, 2013), physical and psychological tolerance (including other illnesses or conditions) (Firth et al., 2011, 2013; McCaughan et al., 2015; McGinnis et al., 2015; Palfreyman et al., 2007), knowledge and education (Edwards, 2003; Fagerdahl, 2014; Wellborn & Moceri, 2014), outside support (Lindahl et al., 2007; Ottosen & Pedersen, 2013), health care accessibility and relationship with health care professionals (Edwards, 2003; Mudge et al., 2006), and general personal experiences.

Knowledge about treatments was often described as important for people with wounds. Knowledge and education can improve patient outcomes and engagement (Bolas & Holloway, 2012; Fagerdahl, 2014). Findings from studies suggest that information given by health care professionals helped patients to understand the nature of their condition and treatment; however, the information was often difficult to comprehend (Herber et al., 2007; Lindsay & Hawkins, 2003; Van Hecke et al., 2011a). Furthermore, some studies illustrated the need for health education interventions which would support people in everyday living (Lindsay & Hawkins, 2003; Lo et al., 2008; Lund-Nielsen et al., 2005a; Van Hecke et al., 2011a; Van Hecke et al., 2011b).

2.4.7 Summary

There is a body of research which aims to explore the impact of complex wounds and how these interfere with patients' daily activities and quality of life.

Overall, the findings suggest that patients commonly experience unpleasant symptoms such as pain, malodour, exudate and pruritus, although most of the research is focused on exploring the nature of pain, while the nature of other unpleasant symptoms such as malodour, leakage and pruritus is still under-researched.

Findings from qualitative research exploring the experiences of living with wounds conclude that wounds and their symptoms interfere with patients' daily activities and have a negative impact on all aspects of quality of life including physical, psychological, social and economic well-being. However, most research has focused on people with leg ulcers, wounds related to diabetes, pressure ulcers and malignant wounds, while there is an overall lack of evidence on what is like to live with surgical wounds healing by secondary intention.

2.5 CONCLUSION

In this chapter I have provided the background of this thesis; specifically, I have described the research context, defined complex wounds, and explored the epidemiology and impacts of complex wounds on people's well-being, with the aim of contextualising and supporting the further studies which I carried out as part of this PhD.

By compiling evidence from published studies, I have demonstrated that:
1) There is only a limited evidence base for understanding the epidemiology of wounds in Slovenia and at a global level. Studies have aimed to estimate the prevalence; however it may be suggested that, from the research currently available, wound prevalence is hard to estimate as many studies suffer from poor quality. Nevertheless, it has been identified that a considerable proportion of people suffer from complex wounds. Furthermore, it appears that the prevalence of leg ulcers has probably been the most researched of all types of complex wounds, while data on the prevalence of certain other types of complex wounds, such as surgical wounds healing by secondary intention, is limited to only one study from the UK (Hall et al., 2014). Knowing more about surgical wounds healing by secondary intention is important for several reasons, including assessing the burden of this condition, and improving care planning in acute settings and community and health resources management, and by these means enabling health care professionals to identify effective treatments and improve patient care. Therefore, I have addressed this deficit in knowledge by undertaking in-depth research on the prevalence, nature and management of surgical

wounds healing by secondary intention by conducting a cross-sectional survey. By conducting the survey in Slovenia I have also provided an important perspective for overall global data.

2) Complex wounds have a profound impact on people's well-being. The evidence base is focused on understanding the patient perspective of unpleasant symptoms and living with wounds in patients with leg ulcers, pressure injuries and malignant fungating wounds, while it seems that for surgical wounds healing by secondary intention the evidence base is limited and particularly under-researched, even though it seems that they are relatively common (Hall et al., 2014). Further understanding of the patient perspective of living with surgical wounds healing by secondary intention will contribute to the current evidence base on wound research and enable researchers to explore strategies and develop better interventions to improve patients' quality of life. Furthermore it will allow clinicians to understand people's experience and their specific needs in depth in order to provide competent and compassionate care.

Narratives related to people's experiences of having complex wounds, which I presented earlier in this background chapter (section 2.4), have directed me to further investigate people's perspectives of living with surgical wounds healing by secondary intention. However, based on the fact that the background chapter was written as a traditional review with the aim of contextualising the body of research, I decided first to undertake a scoping review of qualitative research of people's experiences of living with complex wounds, which would identify knowledge gaps, i.e. the experiences of people who suffer from specific types of complex wounds. The scoping review would also provide insight into the methodological approaches which were used in previous studies, and allow me to target knowledge deficits by approaching under-researched (potentially under-represented) populations and tailoring the research design of the subsequent qualitative study.

In the next chapter I will introduce the structure of this three-stage project. I will state the study aims and objectives, discuss the methodological approaches considered for carrying out each study and provide a rationale for the approach taken in this research.

CHAPTER 3: METHODOLOGY

3.1 INTRODUCTION

This chapter outlines the methodology and study design for all three studies. First the aims and objectives for each study are presented. Secondly, methodologies related to each study are discussed in depth and procedures of each study are explained and argued.

Due to the nature of this thesis, which is submitted in the alternative format, some parts of this methods chapter are repeated in later chapters. However this chapter offers the opportunity to explain methodological choices in more detail and give the underpinning rationale for the approaches taken in each study.

In this and following chapters I use the term ‘surgical wounds healing by secondary intention’ interchangeably with ‘open surgical wounds’. Both are defined as “superficial-, partial-, or full-thickness skin loss wounds healing by secondary intention”. The reason for using ‘open surgical wounds’ lies in the fact that people who had such wounds have used it and as this project focuses on people with open surgical wounds, I decided to use their term.

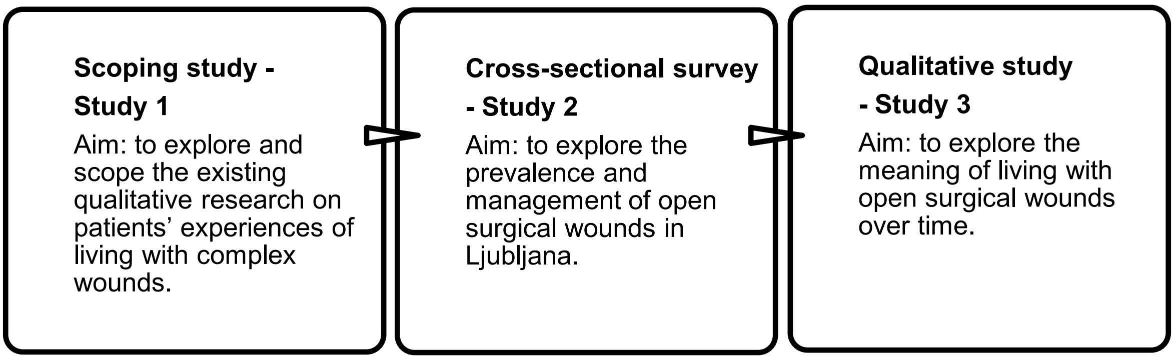
3.2 STUDY AIMS AND OBJECTIVES

I have illustrated in the background chapter (Chapter 2), that there is an existing evidence base on the subject of estimating the prevalence of certain types of complex wounds, and on understanding what is like to live with those wounds.

Findings from published systematic reviews on complex wound prevalence directed me towards further exploration of the prevalence, nature and management of open surgical wounds, as there was a general lack of epidemiological data about open surgical wounds. Furthermore, I was unable to identify any comprehensive reviews exploring the extent and nature of the evidence related to understanding the peoples perspective of living with any type of complex wound, which would direct further research.

In response to this lack of evidence I constructed a three-stage project (Figure 1). Stage 1 is a scoping review (in this thesis referred to as Study 1) which directed me towards further exploration of open surgical wounds. Stage 2 is a cross-sectional survey of open, surgical wounds affecting people living in Slovenia (referred to as Study 2). Stage 3 is a qualitative study exploring the meaning of living with open surgical wounds.

Figure 3.1: Stages of study.



Aim

The overarching aim of this thesis was to explore the meaning of living with open surgical wounds over time. The first two studies (Study 1 and Study 2) informed and contextualised the qualitative study (Study 3). Each study had specific aims and objectives, given below.

Objectives

<u>Study 1</u>

The aim of Study 1 was to explore and scope the existing qualitative research on patients' experiences of living with complex wounds, with the following objectives:

a) Investigate and describe the nature, extent and variety of the published research about patients' experiences of living with complex wounds.
b) Map the body of published qualitative research about patients' experiences of living with complex wounds in terms of the wounds studied and the approaches taken.

<u>Study 2</u>

The aim of Study 2 was to explore the prevalence and management of open surgical wounds in Ljubljana, (Slovenia), with the following objectives:

a) Estimate the point prevalence of open surgical wounds in people of all ages.
b) Explore the natural history, characteristics and unpleasant symptoms of open surgical wounds.
c) Explore where and by whom people with open surgical wounds are treated.
d) Explore the management of such wounds.

Study 3

The aim of Study 3 – the qualitative study – was to explore the meaning of living with open surgical wounds over time.

3.3 LITERATURE REVIEWS AND EVIDENCE SYNTHESIS

There are different types of literature review, which differ in purpose, approach and depth (Chalmers et al., 2002; Noble & Smith, 2018). In the field of health research there are three dominant types of review which have been traditionally used to synthesise evidence, namely: narrative reviews, scoping reviews and systematic reviews (Noble & Smith, 2018); however, there are also other types of evidence synthesis, such as overviews of reviews, prognosis reviews and diagnostic test accuracy reviews (Chandler et al., 2019).

One of the objectives of this thesis was to explore the nature and extent of research about people’s perceptions and views of their everyday experience of having complex wounds (Study 1), and therefore only relevant types of reviews (narrative, systematic and scoping) were considered. The purpose of this section is to critique the different types of review, presented in order of when the methodologies were developed, and to present a rationale for undertaking a scoping review.

3.3.1 Narrative reviews

Narrative reviews are reviews where researchers comprehensively summarise, interpret and critique qualitative and/or quantitative research evidence with the aim of reporting current knowledge on a topic (Greenhalgh et al., 2018; Greenhalgh, 2014; Gasparyan et al., 2011). Traditionally they have often been used for introducing a topic (setting the context) or for educational purposes (Green et al., 2006; Ferrari, 2015). On the other hand, narrative reviews can be used for highlighting controversies in the existing evidence base, for interpreting complexities in the evidence base or for facilitating discussion (Greenhalgh et al., 2018; Faggion et al., 2017).

Narrative reviews have been criticised for being prone to bias, as they often have an unclear and unsystematic methodology (Faggion et al., 2017; Green et al., 2006; Littell, 2008; Roundtree et al., 2009). An unsystematic search strategy and bias in selection of studies limits reproducibility and introduces risks related to the internal validity of findings (Faggion et al., 2017; Green et al., 2006; Littell, 2008; Roundtree et al., 2009). In contrast to systematic reviews, narrative reviews usually do not involve systematic appraisal of bias in the primary studies which are included in the review, which again could result in biased review findings (Faggion et al., 2017; Green et al., 2006; Littell, 2008; Roundtree et al., 2009).

As my study aimed to explore the variety and extent of the evidence, the limitations related to the methods involved in narrative reviews (e.g. the search strategy and risks related to missing studies) led me to reject this approach.

3.3.2 Systematic reviews

Systematic reviews are probably the most well-known in health research. In contrast to narrative reviews, systematic reviews were developed in response to the need for high quality summaries of existing relevant research, to answer specific and focused questions about the effectiveness of interventions (if, how and why interventions are effective) (Greenhalgh et al., 2018; Greenhalgh, 2014; Cullum & Dumville, 2015). Nowadays, systematic reviews are also used for other reasons, such as for developing and informing clinical guidelines and providing trustworthy information for making clinical decisions. Systematic reviews can also be used for identifying areas for further research and informing policy makers. Furthermore, systematic reviews can provide guidance to improve the design of primary research (Lasserson et al., 2019).

Systematic reviews are characterised by a systematic, complex, and reproducible methodological process aiming to minimise bias when answering a study question (Cullum & Dumville, 2015). High quality systematic reviews have clear objectives and pre-specified criteria for study inclusion. Secondly, systematic review methodology is designed in a systematic way, which is scientific and allows replication. Thirdly, systematic reviews involve a systematic search strategy which attempts to be comprehensive and identify all eligible studies. Eligible studies are assessed for risk of bias using a systematic approach (which refers to the assessment of risks related to the design or conduct of an individual study - internal validity). Lastly, the findings are presented in a structured and systematic way (Chandler et al., 2019). Systematic reviews also feature a high level of transparency (Moher et al., 2009) which reduces the risk of bias associated with the procedures (methods) for conducting the review (Boutron et al., 2019).

Systematic reviews are limited by having specific questions to answer (Cullum & Dumville, 2015), most frequently concerning intervention efficiency, and are not intended to explore, for example, patient perspectives of living with wounds or to advance the interpretative understanding of phenomena (Greenhalgh et al., 2018). Therefore I rejected a systematic review for Study 1, as my goal was to summarise the qualitative approaches taken and gaps in our understanding of the impact of complex wounds.

3.3.3 Scoping reviews

Scoping reviews are an alternative to narrative and systematic reviews (also known as a scoping study, scoping exercise, or evidence mapping) and I selected this approach for Study 1.

Arksey and O'Malley (2005) were the first to publish a framework for conducting scoping reviews, and identified the purposes of scoping reviews as: 1) "*to examine the extent, range and nature of research activity*"; 2) "*to determine the value of undertaking a full systematic review*"; 3) "*to summarise and disseminate research findings*" and 4) "*to identify research gaps in the existing literature*" (Arksey & O'Malley, 2005, p. 21).

Later on, definitions of scoping reviews were developed and progressed in other publications (Anderson et al., 2008; Colquhoun et al., 2014; Daudt et al., 2013; Davis et al., 2009; Levac et al., 2010). The main objectives, which appear across different definitions of scoping reviews, are generally the same, i.e. that scoping reviews answer broad scope questions (are exploratory in their aim and nature), identify relevant evidence in a systematic way, select evidence from different sources (for example by design e.g. quantitative, qualitative or by type of evidence e.g. grey literature, published peer-reviewed articles) and group evidence by key concepts (mapping evidence) (Anderson et al., 2008; Colquhoun et al., 2014; Daudt et al., 2013; Davis et al., 2009; Levac et al., 2010).

Comparing scoping and systematic reviews, it can be concluded that both use rigour and transparent methods in their procedures, although the aims and objectives are different.

A scoping review is usually conducted for general exploration of literature or concepts of interest (Arksey & O'Malley, 2005), which is the opposite of the very focused, narrow questions which are usually associated with systematic reviews (Gough et al., 2012). The objective of this thesis was exploratory in two senses; namely the extent (how many studies, from where) and the nature (what kind of methodological approaches) of the existing research related to the patient perspective of having complex wounds, so a scoping review method was deemed fit for the purpose.

Scoping reviews, similarly to systematic reviews, use a systematic and comprehensive approach to searching for research (Arksey & O'Malley, 2005). Comprehensive and systematic identification of studies allows the existing evidence base to be scoped and key themes – or in the case of this specific study (Study 1), mapping and research targets (directing a qualitative study: the third stage of this thesis) – to be identified. A systematic search, in contrast to an unsystematic search (often used in narrative reviews), minimises the risk of potentially missing studies and promotes reproducibility (Lefebvre et al., 2019).

Another key distinction between scoping and systematic reviews is the risk of bias assessment. Systematic reviews require a risk of bias assessment as bias in primary studies can lead to risks related to over or under-estimation of the true intervention effect, or uncertainty (Boutron et al., 2019), whereas a scoping review does not require a risk of bias assessment as it is not seeking to summarise the findings of the research and the confidence we can have in the findings. By contrast, scoping reviews are more oriented towards exploring the spectrum of the concepts used in research, the types of research and the areas under-served by research (Arksey & O'Malley, 2005). This has been debated more recently and it has been suggested that critical appraisal of studies should be carried out in scoping reviews as it reduces risk of bias in the findings; thus scoping reviews could inform research (exploring the need for further systematic review), policy and practice (Brien et al., 2010; Daudt et al., 2013; Davis et al., 2009) rather than only scoping the extent and nature of evidence. Later PRISMA-ScR recommendations for reporting scoping reviews by Tricco et al. (2018) suggest that the decision whether to undertake critical appraisal should be in line with the research aim and objectives.

This scoping review had two objectives, which were specifically exploratory in nature, and associated with three main concepts; the extent, nature and mapping of research, and did not aim to produce a meta-synthesis of findings (i.e. content analysis of themes). I aimed to conduct a review which would help me direct future qualitative research (the third stage of this thesis) by identifying areas under-served by research approaches, methods, geography, characteristics of included participants and wound types. Therefore I concluded that critical appraisal of the included studies would not increase the validity of the findings from this scoping review.

3.3.4 Summary

I considered three different types of review when selecting the methodological approaches to this thesis. Based on the methodological merits of each and to support the aim of Study 1 (to explore the extent and nature of evidence related to patients' perspectives), the scoping review method was deemed to fit the purpose, as it is on the one hand rigorous and transparent, which allows the extent of research studies (i.e. study mapping) to be identified, and on the other hand can answer a broad questions where interpretation of specified concepts is needed (i.e. nature of studies).

3.4 STUDY 1: SCOPING REVIEW OF PEOPLE’S EXPERIENCES OF LIVING WITH COMPLEX WOUNDS – METHODS

In this section, I explain and justify the methods and approaches followed in this scoping review (Study 1).

3.4.1 Study design

There are a few ways of conducting scoping reviews. Arksey and O’Malley’s (2005) framework was the first to conceptualise procedures for conducting scoping reviews. In their framework, they often draw parallels with the methodology of systematic reviews. Methods for scoping reviews have been enhanced since then (Daudt et al., 2013; Levac et al., 2010; Pham et al., 2014) and mostly relate to clarification of concepts and proposed additional steps in procedures, which would increase the validity of findings and make scoping reviews more useful. Some of these, such as critical appraisal, have been already discussed above; rationales for the procedures followed in this review are given below.

I decided to use Arksey and O’Malley’s (2005) framework for conducting the scoping review, and also drew from some procedures related to identifying primary studies and selecting primary studies using the systematic review methodology. I have justified the decisions taken during the procedures with the aim of achieving transparency in this study.

The framework is designed to comprise five stages:

1. Identifying the research question,
2. Identifying relevant studies,
3. Selecting studies,
4. Charting the data,
5. Collating, summarising and reporting results (Arksey & O’Malley, 2005, p. 22).

1) Identifying the research question

To design a review question Arksey and O’Malley (2005) recommend specifying parameters to maintain the focus of the scoping review. Furthermore, they recommend that parameters should be set wide enough to achieve a broad scope. Research questions related to qualitative research can be formulated using the PICO framework, which relates to: Population (describing participants), Interest (describing the phenomenon of interest, such as experience, event) and Context (describing the perspective of the related context i.e. setting or distinct characteristic) (Lockwood et al., 2017).

Based on the discussion in background chapter (Chapter 2) I formulated the question as: "What is the nature and the extent of research on people's perceptions and views of their everyday experience of having complex wounds?"

I conceptualised the following objectives:

1) to investigate and describe the nature, extent and variety of the published research about people's experiences of living with complex wounds,
2) to map the body of published qualitative research about people's experiences of living with complex wounds in terms of the types of participants and wounds studied.

2) Identifying relevant studies

I developed eligibility criteria based on the research question and objectives (Arksey & O'Malley, 2005). Studies were eligible for inclusion in this scoping review if they met the following inclusion criteria:

1) Studies written in English

I excluded studies published in other languages due to the available resources – I had no specific funding for translating papers or for performing specific searches in national databases.

2) Peer-reviewed journal papers

I excluded grey literature and student theses, as processing these would not be feasible within the available resources, including time. Furthermore, there is extremely limited empirical evidence related to patterns of publishing qualitative research compared with quantitative studies. Petticrew et al. (2008) have suggested that only 44.2% of qualitative studies presented at conferences were later published. The reason for such a pattern might be related to the poor quality of studies or poor reporting of studies: for example, only 50% of abstracts include details on context/setting, whereas 57.9% details on the sample or sampling procedures, and 55.3% contained details related to study findings. As the objective of the scoping review was to explore the nature of evidence (in particular the tradition, methods and context), it seemed that including grey literature would not increase the validity of the findings.

3) Studies that focused on participants with complex wounds defined as: superficial, partial-, or full-thickness skin loss wounds healing by secondary intention;

4) Studies that aimed to explore the impact on everyday life of having complex wounds (including treatments), or to explore how unpleasant symptoms associated with complex wounds interfere with daily living;

5) Studies that focused on the lived experience in a home (community) setting (exploring everyday living and not experience in hospital);

6) Studies with one of the following study designs: qualitative studies (regardless of philosophical background or data collection or analysis method), mixed-method studies, systematic reviews of qualitative and/or quantitative studies, meta-synthesis of qualitative studies.

Constructing the search strategy

I developed the search strategy in a comprehensive and systematic way, which minimised the risk of missing potential studies and made the strategy possible to replicate (Lefebvre et al., 2019). A Cochrane information specialist peer-reviewed the search strategy and advised me how to amend it to achieve high sensitivity across databases.

Search terms were formulated according to set eligibility criteria (Centre for Reviews and Dissemination, 2009). I used MeSH -Medical Subject Headings (version 2015) to identify other relevant terms alongside the main term; for example: “pressure ulcer” was the main heading, but it has also synonyms such as “bed sore”, “pressure sore”, and “decubitus” (U.S. National Library of Medicine, 2015). Since there are many types of complex wounds, additional search terms were used to narrow the hits and to avoid the possibility of missing relevant studies.

In part I used Shaw et al.’s (2004) search strategy to identify qualitative studies as the search terms were already built. I used thesaurus terms, for example “qualitative research or phenomenology”, free-text terms such as “experience” and broad based terms such as “interview”. Free-text terms were used due to the use of subject headings for qualitative research, which varies across databases (for example, MEDLINE introduced the heading of “qualitative research” in 2003) (Centre for Reviews and Dissemination, 2009). To broaden the fields captured, additional commands were used, such as the truncation symbol (*/$), which retrieves terms with various endings. The “explode” command was used with the aim of including all the narrower terms which are under the tree of the subject heading (Baumann, 2016). To narrow down the selection I also used the Boolean logic operator “AND” (Centre for Reviews and Dissemination, 2009).

The search of electronic databases was designed in three steps. In the first step, search terms related to different types of wound were combined, then in the second step terms related to the phenomenon of interest (experience of having complex wound) were combined. Hits resulting from the first and second steps were then combined with methods search terms using “AND” (see the example of a search strategy below).

As I expected to identify an extensive evidence base related to the search terms, I restricted the search to titles and abstracts, which would help reduce the number of hits.

Example of search strategy via OVID

Example of the search strategy used in Ovid MEDLINE (Literature search performed July 10 2018).

1 exp Skin Ulcer/
2 (pressure adj (ulcer* or sore* or injur*)).ab,ti.
3 (decubitus adj (ulcer* or sore*)).ab,ti.
4 (bedsore* or bed sore*).ab,ti.
5 (varicose ulcer* or venous ulcer* or leg ulcer* or stasis ulcer* or crural ulcer* or ulcus cruris or ulcer cruris).ab,ti.
6 ((arterial or ischemic or ischaemic) adj3 (ulcer* or wound*)).ab,ti.
7 (diabet* adj3 (ulcer* or foot or feet or wound*)).ab,ti.
8 (rheumatoid adj3 (ulcer* or wound*)).ab,ti.
9 (connective adj3 (ulcer* or wound*)).ab,ti.
10 (malignant adj3 (wound* or ulcer*)).ab,ti.
11 (fungat* adj3 (wound* or tumor* or tumour* or ulcer*)).ab,ti.
12 ((smelly or malodorous) adj3 (wound* or ulcer* or tumor* or tumour*)).ab,ti
13 exp Surgical Wound/
14 exp Surgical Wound Dehiscence/
15 ((surg* adj5 wound*) or (surg* adj5 dehisc*)).ab,ti.
16 ((unpleasant or pain or painful or malodo?r or odo?r or smell* or itch* or pruritus or leakage or exudate*) adj3 (wound* or ulcer*)).ab,ti.
17 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18 exp “Quality of Life”/
19 exp Adaptation, Psychological/
20 exp Attitude to Health/
21 exp “Activities of Daily Living”/
22 (quality of life or QoL or wellbeing or well-being).ab,ti.
23 ((patient* or people*) adj3 (experience* or perspective* or perception* or view?)).ab,ti.
24 18 or 19 or 20 or 21 or 22 or 23
25 exp qualitative research/
26 exp Grounded Theory/

27 exp Interviews as Topic/
28 Focus Groups/
29 exp Narration/
30 (qualitative or focus group* or interview* or discourse analysis or content analysis or thematic analysis or narrativ* or ethnograph* or ethnolog* or ethnonurs* or field stud* or phenomenolog* or hermeneutic* or grounded theory or life experience or lived experience or data synthesis or metasynthesis or meta-synthesis or synthesis).ab,ti.
31 25 or 26 or 27 or 28 or 29 or 30
32 17 and 24 and 31

Information sources

Arksey and O'Malley (2005) recommend developing a comprehensive search strategy. Researchers are recommended to search through different sources (databases, reference lists, journals). Such procedures should reduce or minimise the risk of publication bias (Lefebvre et al., 2019) and enable a wide range of primary studies and reviews to be identified.

I carried out a systematic literature search through three electronic databases, MEDLINE (with the option "In-Process & Other Non-Indexed Citations and Epub Ahead of Print"), EMBASE and CINAHL, as it was expected that these databases would index the majority of journals where studies related to wound care are published. No date restrictions were applied to the search process as I aimed to identify all available evidence. In addition to the electronic search, I conducted a manual search in the latest issues of specialised wound care journals (Journal of Tissue Viability, Journal of Wound Care, and International Wound Journal) to identify possible studies which had not yet been indexed in the databases. Furthermore, I used the snow-ball technique to check the reference lists of identified reviews to identify potential relevant primary studies which had not been identified by the searches.

5) Selecting studies

Selection process

Arksey and O'Malley (2005) recommend an approach to study selection where two reviewers independently assess potential studies against inclusion criteria. This is important to minimise bias and errors related to selection – it reduces the risk of discarding relevant studies (Lefebvre et al., 2019). Another aspect to consider when making decisions related to selection is the transparency of those decisions. I made the decisions as transparent as possible: for example for each study that was excluded the reason was given.

Cochrane issued recommendations that reference (review) managers could be used when producing Cochrane systematic reviews (Lefebvre et al., 2019). However, there are no specific recommendations for managing the process of study selection for scoping reviews, so I used Microsoft Excel, as Arksey et al. (2002) did.

Procedures

I combined all citations from all sources into one file (using Microsoft Excel) and then de-duplicated the references. A hired research assistant (E.B.) and I independently screened all the studies retrieved by the search for eligibility against the inclusion criteria. All irrelevant references were rejected immediately, while if one met or appeared to meet the inclusion criteria it was identified for further assessment.

In the second phase, I attempted to obtain full text copies of potentially relevant studies through electronic databases, through the University of Manchester Library, the Library of the Faculty of Health Sciences – University of Ljubljana, The British Library, or directly (journal publishers). In cases where a full copy of the study could not be obtained, the citation was excluded from further assessment. I assessed all retrieved full-text copies of publications against the inclusion criteria and documented the reasons for exclusion.

Charting the data

I developed a data charting protocol, which I used to chart the data, with adherence to the research question and objectives of review. My co-researcher/supervisor (J.G.) and I piloted a draft of the data extraction form on five studies, as recommended by Levac et al. (2010). The data extraction form was clear and was confirmed by consensus (me and my co-researcher, J.G.) for use for data extraction.

A minimal set of data (a mixture of general and specific data) for extraction from studies seemed to fit the aim and objectives of this scoping review. Therefore, I extracted the next items from primary qualitative studies:

1. Author; title; year of publication and source of reference.
2. Aims of the study.
3. Study setting.
4. Study design (including approach to data collection and data analysis).
5. Recruitment and sample size.
6. Inclusion/exclusion criteria.
7. Age and gender of participants.

8. Wound type.
9. Whether any funding declared and nature of funding.

From systematic reviews and meta-syntheses of qualitative studies I extracted the items given below:

1. Authors' details; year of publication and source of reference.
2. Review objectives.
3. Search strategies.
4. Study inclusion and exclusion criteria.
5. Included settings.
6. Included populations (age of participants, gender of participants, sample).
7. Included wound type (definition).
8. The number of included qualitative studies or mix method studies.
9. Whether any funding declared and nature of funding.

It is recommended that two people independently extract data from interventional studies as it minimises the risk of bias related to effect estimates (Lefebvre et al., 2019); however, in the case of this scoping review I extracted the data and my co-researchers (J.G., N.C.) confirmed the accuracy of data extraction for 10% of the records. The decision to take this approach was based on the fact that as this scoping review did not aim to answer questions related to treatment effectiveness and had extracted a limited data set (mostly associated with general data), the risks related to errors were estimated as low. Similar approaches had been taken in other reviews, for example in Shi et al. (2018b). Another reason lay in the limited availability of human and financial resources.

5) Collating, summarising and reporting results

I used a PRISMA flow diagram (Moher et al., 2009) for reporting the number of identified records, and excluded and selected studies.

The results are presented in narrative format, and also in tables, charts and figures (Arksey & O'Malley, 2005). I have grouped studies based on the types of publication (primary or reviews/synthesis studies) and by wound type. A summary of the characteristics of included studies and reviews/synthesis studies is presented in table format. Some of the data, such as the numbers of screened and included studies, are presented in a flowchart and line charts. The geographical locations of included primary studies are presented as a map.

3.4.2 Protocol for conducting the scoping review

Arksey and O'Malley (2005) do not explicitly require protocol development or registration. The Joanna Briggs Institute has suggested that a protocol could be optional (Peters et al., 2017). I developed an *a priori* protocol (Appendix 1) for the purpose of outlining the scoping review by defining the methodological and analytical approaches. Furthermore, it allowed these approaches to be peer-reviewed in advance (for example, the search strategy was peer-reviewed by a Cochrane information specialist). It also ensured that I documented relevant definitions and criteria to aid the study selection and data extraction.

At the time of development I did not register the protocol, as it was not eligible for registration with PROSPERO, although it was peer-reviewed by my supervisors and a Cochrane information specialist. I registered it later with the Open Science Framework.

3.5 EPIDEMIOLOGICAL POPULATION STUDIES

The objectives of Study 2 of this thesis were to estimate the point prevalence of open surgical wounds, explore the natural history, characteristics and unpleasant symptoms of open surgical wounds and to explore the management of such wounds. Therefore two types of approach to population research, namely routine and bespoke data collection, were considered for use in this study. In this section both types are discussed, with reference to the advantages and limitations of each approach. Furthermore, a rationale for undertaking bespoke data collection is presented.

3.5.1 Routinely collected data

Routinely collected data means secondary data collected from various sources, such as censuses, registries, community service data, hospital data, laboratory data and others. Routine data sets (health information passively collected prior to developing a research question or conducting a study) can be divided into three main groups, namely: demographic data (national census, civic registries), health disease data (morbidity registries, hospital registries, prescribing data, infectious disease surveillance) and population based health information (health surveys, secondary data sets, data on the environment) (Bruce et al., 2008). Routine data are valuable for assessing the health of a population, planning and evaluating health services and informing decisions in clinical medicine (including health technology assessment) and public health (Benchimol et al., 2015; Kane et al., 2000). The main advantages of routinely collected data are availability and low cost, as the data have already been collected. Another advantage is comprehensiveness: the data are often more comprehensive than simple data sets. Furthermore, if the definition of a case is the same across different services or countries (for example, the case of hospital acquired infections and antimicrobial use), comparison by time and population can be carried out (Bruce et al., 2008; Kane et al., 2000; van Hauwermeiren et al., 2019). However, there are also limitations to routinely collected data, which are related to the validation and standardisation of data (issues related to inconsistences and reliability of data – misclassification bias), the reporting of data (incomplete or inadequate reporting, including errors), the population sample (selection bias) and limited scope of data (not matching the aim of the study) (Benchimol et al., 2015; Bruce et al., 2008; Kane et al., 2000).

In beginning this work I sought to establish whether there any routinely available data on complex wounds, for example a wounds registry, in Slovenia; however based on my communication with the stakeholders (medical chiefs of clinics and chief nursing officers of clinics) there is no existing registry. I also considered obtaining data from the national disease registry (which is based on the International Classification of Diseases) run by the National Institute of Public Health of Slovenia; however, data about complex wounds, including open surgical wounds, are not systematically collected. As there is no existing population data on open surgical wounds in Slovenia I decided to use bespoke data collection for conducting Study 2.

3.5.2 Bespoke data collection

Another approach taken in epidemiological research is bespoke data collection, which typically uses a survey – a questionnaire of some kind – to collect data. Population surveys (prevalence or incidence studies) aim to determine the burden of disease cases (or risk factors) in a defined population (Bruce et al., 2008; Pearce, 2012; Thrift, 2010). A case (or risk factor) is usually specified with statistical, clinical, prognostic or operational definition. A clear definition of case makes it possible to detect whether people are or are not affected by the observed disease or condition (Coggon et al., 2003). Another key feature of population surveys is that the population is defined by a numerator (proportion of people with the characteristic) and denominator (reference population), as otherwise the epidemiological measures such as incidence, prevalence or mortality would be at risk of bias (Coggon et al., 2003; Pearce, 1999; Thrift, 2010).

In estimating epidemiological measures, two types of study are used, namely incidence and prevalence studies (Pearce, 2012; Thrift, 2010). The objective of incidence studies is to measure the rate of new cases of a disease or a condition in a population, whereas prevalence studies aim to identify all cases existing at a single time point, or over a specified period, in a defined population (Bruce et al., 2008; Coggon et al., 2003; Pearce, 2012).

As the aim of Study 2 was to explore the number (point prevalence), nature and management of open surgical wounds in Ljubljana (Slovenia), a prevalence study was the type of epidemiological study that best fitted the aim. I decided to use a cross-sectional design as I aimed to identify all the people who suffered from an open surgical wound during the specified period of time in Ljubljana.

Before designing the cross-sectional study (Study 2) I considered the methodological challenges in epidemiological studies of complex wounds reported in reviews conducted by Cullum et al. (2016), Briggs & Closs (2003) and Graham et al. (2003).

It is well documented that the currently available literature on complex wound prevalence is heterogeneous and the findings are very difficult to compare (Briggs & Closs, 2003; Cullum et al., 2016; Graham et al., 2003). Challenges related to two main areas were identified, namely methodological rigour and reporting.

Studies aiming to estimate wound prevalence should clearly define the objectives of the study, present the study design and describe the setting. It is crucial to provide clear eligibility criteria for participant inclusion (the definition of a “case”) in a study and define the methods of sampling (Briggs & Closs, 2003; Cullum et al., 2016; Graham et al., 2003) as both could increase the risk of selection bias. Furthermore, the diagnostic criteria (wound, healed, open, location, confirmed/validated cases, etc.) must be well defined, along with all other variables of interest (such as demographics), as by such means the risk of misclassification and selection bias is reduced (Briggs & Closs, 2003; Cullum et al., 2016; Graham et al., 2003). Appropriate data collection techniques must be considered carefully, as some are or can be prone to selection bias (such as routine data from registries) (Bruce et al., 2008; Kane et al., 2000). The selected population (denominator) must be clearly described, and information must be provided as to whether the sample is representative of the geographical population. This is important if making associations or even proposing causal relationships (Yu & Tse, 2012a, 2012b). When reporting prevalence studies the statistical analysis must be well described. Furthermore, the precision of estimates must be given, e.g. confidence intervals. Risk of bias should be clearly reported (Briggs & Closs, 2003; Cullum et al., 2016; Graham et al., 2003).

The table below lists strategies that I used in Study 2 to overcome the identified challenges.

Table 3.1: Common pitfalls, and strategies for overcoming them.

Common pitfalls	**Strategy**
Inappropriately reported or the wrong epidemiological measure used (point, period or lifetime prevalence)	Study was designed as a cross-sectional prevalence survey (exploring the number of wounds at a defined (particular) point in time)
Undefined denominator	Denominator was defined relative to a specific geographical area – population of the city of Ljubljana; data from census.
Undefined diagnostic unit	Clear definition of open surgical wound
Case validation	Confirmation of existence by health professional
Poor reporting of how data was collected	Use of paper questionnaire filled out by health care professionals
Reporting of study	Use of STROBE guidelines

3.5.3 Summary

I considered two approaches (routine data collection and bespoke data collection with a survey) to epidemiological population research and two types of studies (prevalence and incidence) when selecting how best to answer the aim and objectives of Study 2. Based on the merits of each approach I decided to conduct a prevalence cross-sectional survey as I aimed to identify all the people with open surgical wounds in Ljubljana at a specific point of time.

3.6 STUDY 2: A CROSS-SECTIONAL SURVEY OF OPEN SURGICAL WOUNDS IN SLOVENIA – METHODS

In this section I will present the methods and procedures used in the cross-sectional survey (Study 2 of this thesis).

3.6.1 Aim and objectives of the study

The aim of Study 2 was to explore the prevalence and management of open surgical wounds in Ljubljana, (Slovenia), with the following objectives:

a) Estimate the point prevalence of open surgical wounds in people of all ages.

b) Explore the natural history, characteristics and unpleasant symptoms of open surgical wounds.
c) Explore where and by whom people with open surgical wounds are treated.
d) Explore the management of such wounds.

3.6.2 Study design

I carried out a cross-sectional survey out to identify the point prevalence, nature and management of open surgical wounds.

3.6.3 Study population

The study population was the residents of the city of Ljubljana, Slovenia.

Table 3.2: Population of Ljubljana "SI-STAT Data Portal" (2018).

Age (years)	Size of population
0-9	29,730
10-19	24,688
20-29	38,274
30-39	43,898
40-49	40,580
50-59	38,639
60-69	35,422
70-79	22,148
80-89	13,033
90-99	2,452
100+	55

3.6.4 Study setting

In Slovenia, people with complex wounds are usually treated in wounds referral centres which are hospital based. In most cases the care of complex wounds is managed by a medical practitioner; typically a general surgeon or dermatologist. In practice this means that patients visit their surgeon every two to three months, when future wound management is prescribed. Subsequently the wound is managed by the local general practitioner (GP) who prescribes treatment, while registered nurses (or nursing assistants) working with the GP or community health nurses (primary care providers) perform procedures such as dressing change, topical treatment, debridement, etc. If wound complications occur, the GP refers the patient back to the surgeon/dermatologist.

A health care network is well developed in the city of Ljubljana, and to ensure the reliability of the prevalence estimates, all institutions where a primary care provider or referral surgeon is available were considered for inclusion in the study. Hospital settings were also included in the study, as people who receive care there could have open surgical wounds.

Moreover, social care providers and free clinics were also considered for inclusion as local GPs visit and treat patients with wounds who live in those institutions. The Administration of the Republic of Slovenia for enforcement of judicial sanctions has their own medical practitioner offices, and therefore prisoners would usually be treated by those institutions.
I also considered military personnel who are serving in Ljubljana. However, based on a telephone conversation with a military officer from Medical Unit of the Slovenian Armed Forces, military personnel with wounds would in "peace time" seek care from civilian hospitals/GPs.

3.6.5 Inclusion criteria

All people known to health and social care providers were eligible for inclusion in the survey if they had at least one active open surgical wound, the existence of which was clinically confirmed by a GP or registered nurse.

The studied diagnostic unit is a person with one or more open surgical wounds, which is defined as "superficial-, partial-, or full-thickness skin loss wounds healing by secondary intention" (Hall et al., 2014).

3.6.6 Data collection

I carried out data collection as follows:

Gaining access
Firstly I obtained approval from the Ethics Committee of The University of Manchester and the Ethical Committee of the Republic of Slovenia.

Slovene public health care providers (similar to the British NHS) and social care services are organised as independent legal entities with complete autonomy (Ministrstvo za zdravje/ *Ministry of health, 2020*). The process of gaining access was time-consuming, as all the institutions (20 institutions) in the city of Ljubljana were asked for permission for their patients to take part in the proposed study.

I sent the application letter to the medical directors and principal nursing officers. In the case of the Clinic of Administration of the Republic of Slovenia for the enforcement of judicial sanctions, the office of the secretary general was asked for cooperation in identifying the key person. I organised meetings with managers (ward manager, principal nursing officer, medical directors) to explain further and to motivate them to take part in the study.
When I gained access, the timetable for data collection was sent, with detailed information about when the study will be carried out. I ensured that there was enough time to prepare for data collection.

Data collection technique

Anonymised data relating to all people with open surgical wounds were collected by health professionals using a questionnaire devised for this study (Appendix 2). People were not identifiable from the data collected, ensuring full anonymity therefore people with wounds were not asked to give their informed consent, as they were not directly involved in this survey. Requesting individual patient consent, apart from being resource intensive, disproportionate and potentially off-putting for the participants, would probably also introduce selection bias such that the results would not be truly representative of the problem. The same approach to data collection had been used in previous research in the UK (Hall et al., 2014).

A guide to questionnaire completion (Appendix 3) was given to health professionals (in hard copy and electronic form). Data collection (form completion) was carried out away from peoples' bedsides to ensure the anonymity of the data and that the data collectors did not involve patients in questionnaire completion (ensuring people's identities stayed anonymous).

Pilot study

Firstly, I carried out a pilot study in various settings for the following reasons:

- To establish good communications and a rapport between researcher and institutions and health personnel,
- To test whether the data collection instrument was clear, readable and understandable,
- To test whether the guide was clear, readable and understandable,
- To identify any barriers to completion of the data collection forms.

(Hertzog, 2008) calculations were followed in estimating the appropriate sample size for the pilot study. As the aim of the pilot study was to gain information regarding the clarity of the form, timing, communication, etc., I estimated that a pilot with a sample size of up to 10 people with open surgical wounds from five different settings and filled out by up to five different health personnel (GP or RN) was appropriate to achieve the pilot study aims. After the pilot study, I refined one question on the form and I added additional explanation to the guide. In addition, I assessed communication as good and provided the explanations needed to improve participants' understanding of how the study will be carried out. I also organised a debriefing meeting with the nurses to review common issues with data collecting.

In some institutions (e.g. community health care centres, some departments at the University Medical Centre, Ljubljana) I organised training sessions to ensure that data collectors (registered nurses or medical doctors) were familiar with the data collection form. I also used these sessions as an opportunity to motivate the data collectors to take part in the study.
A month before the start of the survey and again a week before, I informed contact persons by email or telephone about the exact date that the study was to begin. A reminder was also sent by email on the day the study started and at the end of the study. I collected the data forms from the principal nursing officer of each institution and then carried them to my office at the University of Ljubljana, where they were safely stored.

3.6.7 Data analysis

I used the R statistical package and Microsoft Excel for the data analysis. Descriptive statistics (frequencies, proportions, means, mode, minimum [min] and maximum [max] values, standard deviations [SD] and interquartile range [IQR]) were used to calculate the prevalence and other data on the natural history and treatment of the wounds. I calculated confidence intervals (C.I.) by using the Wilson score . Because of the low number of missing values and the exploratory nature of the study, I did not use any formal statistics to deal with missing values.

I used the standard formula to calculate the overall prevalence (Bruce et al., 2008): the number of people with wounds was divided by the population of the city of Ljubljana (288,919) and then multiplied by 100.

$$\text{Prevalence} = \frac{\text{Persons with a wound during a specified time period}}{\text{Population of the city of Ljubljana (data from census)}} \times 100$$

3.6.8 Ethical issues

First I obtained approval from the University of Manchester Research Ethics Committee (Appendix 4) and then from the Medical Ethical Committee of the Republic of Slovenia (Appendix 5). I considered following ethical issues related to this cross-sectional survey:

Voluntary participation:

The cross-sectional survey of people with open surgical wounds was designed to collect anonymous data about patients and their wounds. Patients were not directly involved in the study (they did not have to provide any information, neither did they have fill out data collection forms). Data were collected away from patients' bedsides.

Providing information – informed consent:

Anonymised data were collected away from patients. This means that it was not necessary to obtain informed consent or provide study information to the patients.

Ensuring privacy and confidentiality:

No identifiable data were collected. This ensured that patients' identities were private and undisclosed. Full anonymity was guaranteed.

Data safety management:

A strategy for data handling and ensuring safety was developed. The collected data (the data collecting forms) were stored at the office of the researcher at the University of Ljubljana in a locked storage cabinet. An electronic database of collected data was stored on the researcher's computer and encrypted. The data were accessed exclusively by the researcher personally and both supervisors. Data will be kept in locked storage at the researcher's office at University of Ljubljana for 10 years after the completion of the research and then it will all be confidentially destroyed.

3.7 KEY QUALITATIVE METHODS AND THEIR USE IN EXPLORING "PEOPLE'S EXPERIENCE"

This section provides a brief overview and critique of the alternative qualitative approaches most frequently used in complex wound research (grounded theory, phenomenology and hermeneutics). I do not address the fundamentals of each approach in an in-depth, philosophical way, but instead consider the key concepts from a pragmatic viewpoint. This seems to be important, as an insight into the approaches can illuminate the horizon of theoretical and research work related to the use of philosophical approaches in researching people's experience. Furthermore conducting an overview of different approaches has helped me to understand the reason why qualitative content analysis (Graneheim & Lundman, 2004) was considered the most suitable approach for addressing the objective of Study 3, namely: to explore the meaning of living with open surgical wounds over time. The discussion in this section also contextualises the reasons for rejecting other approaches. Firstly I discuss grounded theory, which is followed by a discussion of phenomenology, hermeneutics and their translation to research methodology. The reason for such an approach lies in the need to illuminate how approaches develop, and how each previous approach (e.g. Husserl's phenomenology) influenced the development of the next (e.g. Heidegger's hermeneutics). Furthermore, it is vital to define and discuss the concepts related to phenomenology and hermeneutics as they contextualise Graneheim and Lundman's (2004) approach to qualitative content analysis, which I used in the present qualitative study (Study 3).

3.7.1 Grounded theory

Grounded theory has its roots in symbolic interactionism. This is oriented towards interpretation of what meaning things have for people, and the "symbols" used to describe meaning. In contrast to a quantitative paradigm, grounded theory aims to collect rich descriptions of the meaning and to understand the context of these. The main aim of grounded theory is the generation and development of theory. Grounded theory uses inductive techniques for collecting data (interviews, observations) (Chen & Boore, 2009; Starks & Brown Trinidad, 2007).

Three main approaches have been frequently used in health research, namely the original Glaser and Strauss (1967) approach, Charmaz's (2006) and Strauss and Corbin's (1990) approach. Glaser and Strauss' (1967) approach is conceptualised by the maxims: theory generation, comparative analysis and theoretical sampling. Glaser and Strauss' approach has been criticised for objectivism, rigour, procedure and neglecting the researcher's role in the research process (researcher as a co-creator of data) (Allen, 2010; Evans, 2013; O'Connor et al., 2018; Rieger, 2019). The later approach derived by Strauss and Corbin (1990) emphasises the researcher's role and the role of existing literature in developing theoretical sensitivity. Furthermore it is distinguished by its different approach to data analysis, which is more structured, has roots in induction, deduction and verification, and leads to rigid analysis. The main critique of Strauss and Corbin's (1990) approach is that it departs from the original sense of grounded theory, by moving the focus away from people through rigid systematic procedures of analysis (Allen, 2010; Evans, 2013; Rieger, 2019). A third approach has been developed by Charmaz (2006) and is embedded in social constructivism. Charmaz (2006) emphasises that social constructivist grounded theory does not only focus on understanding constructs of people but also allows researchers to build constructs about the factors influencing people's situations. Charmaz's (2006) grounded theory is often criticised for introducing a major change in methodology – i.e. changing it into a form of qualitative data analysis and neglecting the positivist concepts employed by classical grounded theory (Allen, 2010; O'Connor et al., 2018; Rieger, 2019).

The research question for the qualitative study was related to the lived experience of people with wounds, with a specific study objective to explore the meaning of living with open surgical wounds. I was not aiming to generate or develop a substantive theory through exploring the relations between concepts or further hypothesising. Furthermore grounded theory is associated with a more linear approach to method (Strauss & Corbin, 1990) and does not fit with the aim (exploring the phenomenon in depth) or the nature of data collection in my study (a longitudinal study, with two interviews per participant); therefore the grounded theory approach was not suitable for use in this qualitative study (Study 3).

3.7.2 Phenomenology

Phenomenology comes from the old Greek *phainomenon,* meaning "which appears" and *logos,* meaning "study". It is about the study of phenomena (Hribar, 1993). Merleau-Ponty (1995) defines phenomenology as "the study of essences". Husserl was the founder of the German phenomenological school and is often referred to as the father of phenomenology. Husserl built phenomenology as a method of understanding and obtaining the essence of a phenomenon (van Manen, 2017). The origin and *raison d'etre* of phenomenology is "*to things themselves*" (German: *zu den Sachen selbst*), meaning from a philosophical aspect to get to know things from the things themselves, which is perceived as the highest level of transcendental philosophy (Hribar, 1993). Phenomenology comprises several concepts, namely: *intentionality, phenomena, description, reduction, epoche, transcendental subjectivity, evidence, and constitution*. These concepts are described in the next section, as the development of the phenomenological research method and the hermeneutics approach are built on them.

Intentionality can be described as consciousness of something and should not be understood as an intention to do something. It emphasises the relation between something/s <thought, object, subject, world>. It relates and co-relates thought with what is meant; and within this relation we deal with intentionality, which is a bond (relation) between both, and is therefore seen as a third thing. Besides being psychological, a *phenomenon* is also considered as physical: it is to be understood as the experience of something/s. A phenomenon is considered from three aspects, namely: intention, intentional object, and intentionality. If we want to achieve a full *phenomenological description* of a phenomenon, all three elements have to be described and also lines have to be drawn between each, i.e. intention – tendency to; intentional object – object of; and intentionality – relation between. In the conceptualisation of *reduction*, Husserl argues that a pure phenomenological description would reflect the degree of positivism, which is in opposition to idea of phenomenology itself (i.e. reflection and critique of empirical psychologism); therefore in achieving the depth of reflexion of phenomena (which leads to the essence), Husserl describes three levels of reduction, namely: phenomenological reduction, eidetic reduction and transcendental reduction, with the aim of achieving the conception and theologisation of a phenomenon and, through them, the real world itself or scientific findings about it. The concept of *epoche* reflects the process of reduction (exclusion, suspension) as well, and, similar to *reduction*, it is also described at three levels, namely phenomenological, eidetic and transcendental epoche, which are reflected in the bracketing together of reality, the area of being and the mental experiential self (Hribar, 1993). Gradually applying reduction and epoche leads, according to Husserl, to pure consciousness, named as *transcendental subjectivity*, which in one part reflects pure lived experience (understood as the details of being) and in another the transcendent being (understood as the present main facts of being) (Baruch, 2004). Before the *constitution* of the horizon of a phenomenon, *evidence* reveals the phenomenon in its own nature. Husserl's work does not conceptualise evidence only as "seeing something", but also as "insight into" (Ströker, 1997). Principles of evidence are interconnected with concepts previously mentioned, namely reduction and epoche (cleared of assumptions or theory) and also others, such as intentional objects, which shape the nature of "seeing" and "insight" (Hribar, 1993). When reaching the basis of transcendental subjectivity and evidence, this basis is a catalyst of the *constitution* of meaning, which is reflected in the genesis of meaning without the actualiser (pointing the passivity of genesis), and furthermore it leads to the understanding of the horizon of meaning (Held, 2003).

Phenomenology is oriented towards the conscious experience of the world: for example, perception, bodily awareness, memory, emotions, sensations, *et cetera*. It is about questioning the essence of consciousness. The essence is the reality, which stays the same, while circumstances around the essence are changing (Moran, 2000). Although Husserl's phenomenology is oriented towards the essence of phenomena, this does not mean that phenomenology is seeking the full objective truth or to provide "strong" evidence for this truth; it is more oriented to the intuitive acceptance of that truth. For Husserl the lived experience is an acceptance of reality in which experiences are changing. Husserl argues that if the researcher wants to "see" the purest natural reality of studied phenomena he has to "bracket" his own natural reality and preconceptions of the world of studied phenomena. This would mean that all researchers' preconceptions are neutralised. In terms of the conceptualisation of a phenomenological reduction, Husserl argues that, when researching a phenomenon, all previous knowledge must be rejected – e.g. all previous theories and hypotheses – with the goal that the phenomenon should express only present givens (Bondas, 2011; Moran, 2007; Vogrinc, 2008).

3.7.3 Hermeneutics

Hermeneutic phenomenology is built on phenomenological philosophy described by Husserl (Moran, 2007; Sokolowski, 2006). Heidegger expands Husserl's ideas to "interpretative hermeneutics", and introduces the concept of being from another perspective, asking what being is, how it interacts, and whether it is being involved in the world (in German: *Dasein*). This is explained as follows: that being itself (in nature as subject or object) cannot manifest in isolation, but is always involved, i.e. "*being-in-the-world"*. Heidegger's introduced authenticity (refers to in German as *eigentlich*) as a concept and claims, that it refers to being able to choose – i.e. "*Dasein*" has possibilities related to existence, they can think and express for themselves (Moran, 2000). Heidegger sets the human lived experience apart from the traditional "historical" perspective of ontology (Moran, 2007; Smythe et al., 2008). Furthermore, Heidegger contests the need for reduction and epoche, and accepts pre-understandings as natural (Hribar, 1993). Hermeneutic phenomenology researches how people understand the world in which they live, and in addition it represents the interpretation of a phenomenon and not its structure, as is the case in Husserlian phenomenology. Heidegger's idea of world experience can be understood as people experiencing the world with the influence of a broader social, cultural or even political context. In addition to the previous concept, a person (an individual) cannot be separated from the world (Dowling, 2004; Pascal, 2010; Caelli, 2001). The researcher has to understand the context of the participant's lived experience. Hermeneutics aims to describe meaning, including not only the manifest but also the latent content, and also the meaning which goes beyond the author, the researcher and the context (Graneheim & Lundman, 2004). Wojnar and Swanson (2007) argue that because of Heidegger's concept of being and his orientation towards interpreting phenomena, hermeneutics is a useful method for interpreting human experiences of caring and healing within all domains (spheres), and can influence the shaping of experience.

3.7.4 Transition from philosophy (method) to procedures

Philosophical approaches (especially phenomenology), due to their nature, have often been criticised for their difficulty of application in health and caring science research, as they are complex, were developed in a philosophical context and were not intended for use in research. Moreover they frequently probe a single philosophical idea or concept (e.g. ethics, aesthetics, logics, time, mind, body, existence, authenticity or death) and often lack detailed descriptions of procedures for carrying out research. However, the question arises as to whether the works of Husserl, Heidegger and others (Gadamer, Ricoeur, Merlau-Ponty), which are by their own nature philosophy, can be applied as methodological procedures to carry out research, and if so to what extent. Some researchers, such as van Manen (1990) and Lindseth and Norberg (2004), have attempted to overcome this challenge by developing guidance (or explaining procedures) for exploring lived experience with phenomenology and/or hermeneutics based on their research work.

Van Manen (1990) developed "guidance" on how to conduct hermeneutic phenomenological research – research of lived experience (also termed *human science*). His work was developed in the context of pedagogy and human science research. Phenomenology is, according to van Manen (p. 25), "*a pure description of phenomenon*", whereas hermeneutics is the "*interpretation of experience via some text or via symbolic form*". This can be understood as meaning that "description" relates to the description of "living" (the life-world as it is) and to the meaning of ways of expressing the "living". Van Manen describes his approach to hermeneutic phenomenology, which consists of six activities, namely: "*investigating the phenomenon as we live it rather than as we conceptualize it; investigating experience as we live it rather than conceptualize it; reflecting on the essential themes which characterize the phenomenon; describing the phenomenon through the art of writing and rewriting; maintaining a strong and oriented pedagogical relation to phenomenon and balancing the research context by considering parts and whole"* (van Manen, 1990, p. 30, 31). All these phases are reflected in the tradition of phenomenology or hermeneutics to one degree or another. For example, "bracketing" is taken here into deeper consideration, as it is one of the very basic principles of phenomenology. It seems that van Manen follows Heidegger's argument: the possibility of bracketing is itself questionable, as a phenomenological enquiry is itself always part of subject – researcher. Furthermore, he suggests that hermeneutic phenomenology does not seek a single (fully objective) interpretation and that there can always be another interpretation.

Lindseth and Norberg (2004) developed a so-called "phenomenological hermeneutical method" for researching lived experience. The method itself has its background in phenomenology as described by Husserl, and hermeneutics as described by philosophers including Dilthey, Heidegger, Gadamer and Ricoeur in their works (Lindseth and Norberg, 2004; p. 145-6). The context in which the method was developed was that the authors sought a suitable method to do research in the field of ethics, specifically in the field of health sciences. Due to the specific topic, Lindseth and Norberg (2004) argue that a mixed approach of phenomenology and hermeneutics suited the research aim to explore lived experience, as it describes and interprets experience. The authors applied different research techniques which reflect the philosophical principles of phenomenology and hermeneutics; for example, narrations were understood as a technique to achieve reduction and epoche (though it is not explained at what levels), as through narrations about lived experience the researcher cannot judge the nature of experience (Lindseth and Norberg, 2004). However, they assert that judgements should be "bracketed" later, especially in analysis. This would seem to be in direct conflict with idea of phenomenology, namely purifying the phenomenon, so in achieving the transcendental subjectivity, which is later exposed in evidence (Hribar, 1993), however, the principles of hermeneutics are applied, i.e. pre-understandings are accepted, as according to Lindseth and Norberg (2004, p.148) pre-understandings cannot be bracketed, as "*meaning and essence would also disappear*", so this is accepted as a postulate and not problematised to the extent that is in Husserlian phenomenology (Husserl, 1997). This could be critiqued in a way, as although the authors' mixed approach would seem to fit for applying techniques to achieve the principles of each approach, the analysis process (where interpretation occurs and meaning is attributed) is subjected only to hermeneutics, and it is not clear what level or degree of phenomenology or hermeneutics is achieved within the analysis.

The use of pure phenomenology and/or hermeneutics in the qualitative study (Study 3) could have led to two main challenges, namely whether the study, as it progressed, would fit exactly with either of the philosophical approaches (either phenomenology or hermeneutics), and whether using either the first or second would be suitable for answering the aim of the qualitative study (Study 3). This latter challenge is related to the method of doing phenomenological or hermeneutic research.

To answer the first, I decided not to use pure phenomenology (Husserl, 1997) as the aim of this study was to explore the meaning of the lived experience of having open surgical wounds. I was not interested in exploring the essence of the phenomenon, i.e. providing a full phenomenological description. Through writing this thesis I was well aware of the research field and findings from qualitative studies of other types of complex wounds; moreover I could not explore the essence, as I, as a researcher, would become a part of their world (i.e. through interviewing them) with my preconceptions, and therefore it would be difficult to achieve the appropriate phenomenological stance (epoche and reduction; all three levels of each are further described in 3.5.2).

As it explores the lived experience, it could seem that hermeneutics would be a better fit to answer my study's aim, to explore the meaning of living with open surgical wounds over time (Study 3), as, firstly, there would be no need to achieve a phenomenological stance since (Heidegger, 2005) believes that preconceptions do not have to be suspended, as the researcher is already *being-in-the-world*. Furthermore, hermeneutics deals with interpreting people's experiences rather than describing them. However, I was not aiming to explore people's lived experience in terms of contextualising their experience in the broader sense of *dasein* or Heidegger's other philosophical concepts relating *dasein* to *authenticity*, *being-*

with, care, death or *temporality*. Therefore I decided to reject Heidegger's hermeneutics as an approach for the qualitative study.

The second challenge is related to actually doing a phenomenological or hermeneutical study (i.e. methodology). This has been the subject of much discourse in recent years (Giorgi, 2017; Paley, 2017; Petrovskaya, 2014; van Manen, 2017), which reflects the *pro et contra* arguments that researchers typically do not have the required basic knowledge of philosophy to underpin their research, that the methodology is distanced from basic principles of philosophy (i.e. phenomenology or hermeneutics) and the procedures for doing it should be questioned in depth (e.g. levels of description versus interpretation, meaning attribution, the plausibility of analysis, *et cetera*).

Based on the overall discussion in the section above, I decided to follow another approach, namely pragmatism, to explore people's experiences of living with open surgical wounds. Pragmatism includes various techniques and procedures that have been developed under different theoretical frameworks (or inspired by philosophy). I decided to use qualitative content analysis, which is discussed and critiqued in depth in the next section.

3.7.5 Qualitative content analysis

The origin of qualitative content analysis is in content analysis, later referred to as quantitative content analysis. Content analysis developed in communication and media studies (social sciences), where it aimed to analyse large amounts of text systematically. Later its use became more widespread, often due to criticism that the meaning of data was too complex to be merely "counted". Furthermore, there was also a need to establish the data context to better understand the effects of media messages (for example, in propaganda messages during the war, which reflects the time when content analysis evolved) and to understand the text more in depth and not only as it is manifested; thus the development of qualitative content analysis began (Schreier, 2012).

Qualitative content analysis is a method for systematically describing the meaning of data (text, visual data, verbal data) (Downe-Wamboldt, 1992). Krippendorff (2004, p.18) defined qualitative content analysis as "*a research technique for making replicable and valid inferences from texts (or other meaningful matter) to the context of their use*".
Qualitative content analysis developed over time, and there are different approaches (Bengtsson, 2016; Elo et al., 2014; Elo & Kyngäs, 2008; Graneheim et al., 2017; Graneheim & Lundman, 2004; Krippendorff, 2004). The alternative approaches can mainly be differentiated by their different ontological and epistemological perspectives, analytic (methodological) process (differences of coding framework or the nature of codes) and procedures for or understanding of achieving trustworthiness (Hsieh & Shannon, 2005).

However all the approaches are united by having a systematic method that is flexible and reduces data. The method involves the attribution of manifest and latent meaning to data (content), and then classifying the data to establish the degree of description and interpretation (Schreier, 2012).

Graneheim and Lundman's (2004) approach would seem one of the most frequently cited in a health and nursing research context (cited more than 18,000 times), so it will be looked at more closely. I will briefly discuss and contextualise the concepts of qualitative content analysis related to an onto-epistemological perspective (i.e. phenomenology and hermeneutics). Furthermore I will address the concepts which were previously questioned in Section 3.5.4.

Firstly, I will contextualise qualitative content analysis within descriptivism and interpretivism. This is important to understand, as qualitative content analysis seeks to understand the *manifest and latent content*, and there is a range of degrees of each (Graneheim & Lundman, 2004). The question of what the epistemological nature of qualitative content analysis is can be explained as follows. Firstly, *manifest content* reflects the specificity and description of meaning, which is similar to phenomenological description. Secondly, *latent content* reflects the degree of abstraction and hermeneutic interpretation (Graneheim et al., 2017), so the onto-epistemological nature of qualitative content analysis is within the horizon of descriptive phenomenology and interpretative hermeneutics. The horizon can be interpreted in such a way that the results of qualitative content analysis can be very descriptive, for example, what informants have actually said (actual words, sentences) or what is visible, (concrete content of photos or video); on the other hand the results can be interpretative, where the underlying meaning of what was said or is visible is attributed (researchers' understanding). Graneheim et al. (2017) argue the position that qualitative content analysis does not postulate; that one or another aspect should be completely achieved. However, the study's aim should direct which aspect should be achieved. For example, if the aim were to explore only experience, descriptivism would be needed. However as the aim of the qualitative study (Study 3) was to explore the meaning of living with open surgical wounds, interpretation was also expected to be achieved in the analysis. Such understanding again reflects the flexible nature of qualitative content analysis.
I also considered the analytic process and the application of qualitative content analysis concepts. The analytic process starts with reading the text as a whole, as this reflect the naïve understanding of text. It answers the question, "*what is going on?"* (Bengtsson, 2016, p. 11). This is followed by the processes of decontextualisation and recontextualisation (Graneheim & Lundman, 2004). In each phase of the analytic process, as the analysis progress to the next step, I was aware of and understood the concepts and postulates.

In the decontextualisation stage, units of meaning are formed and condensed, and codes are assigned (Graneheim & Lundman, 2004). Breaking text into meaning units is perceived as critical, as meaning units are the unit of analysis. Meaning units are conceptualised as "*words, sentences or paragraphs containing aspects related to each other through their content and context*" (Graneheim & Lundman, 2004, p.106) and were understood as such in the qualitative study (Study 3).

There have been certain critiques of the understanding of what a meaning unit is: for example, Paley (2017) writes that phenomenologists (for example, van Manen or Giorgi) who use the term "meaning unit" often do not operationalise it to such a level that it could be objectively attributed to a unit of analysis. Furthermore, he conducted a linguistic and "mathematical" analysis of the attribution process where he emphasised the need to conceptualise "meaning" and its attachment to phenomena. This could be critiqued in a way, in that such quantification of meaning and attempts at attribution exceed the nature of "qualitative" (regardless of the approach) and are more embedded into positivism. Understanding the philosophy (i.e., phenomenology) could also explain what the true nature of meaning is. Meaning itself exists as human beings exist, and therefore we are always involved with meaning (from the position of informant or researcher) (Dahlberg & Dahlberg, 2019). Van Manen (2017) emphasises that meaning is not attached and cannot be attached to content, as researchers seeks to evoke and understand meaning.

In decontextualisation we also deal with establishing the difference between content and meaning (Dahlberg & Dahlberg, 2019; Elo et al., 2014; Graneheim & Lundman, 2004). Graneheim & Lundman (2004) and Graneheim et al. (2017) argue that one unit of content could resolve into one or more meanings; however, researchers should reflect on their position related to the understanding of meaning. Schreier (2012) argues that context can clarify the meaning of content and facilitate breaking text into analysis (coding) units.

In recontextualisation, subthemes and a theme are formed. During this process we deal with concepts such as: *concrete and abstract*; *manifest and latent content* and *degree of description and interpretation*. The concepts are interrelated. Graneheim et al. (2017) position in a two-dimensional model a degree of concreteness (for example, category) with manifest content and a high degree of description; on the other hand, sub-themes are positioned with a higher degree of abstraction with the reflection of latent content, where both are associated with a higher degree of interpretation. The position of these concepts is reflected in the hierarchy of analysis. Subcategories and categories are considered to reflect the degree of description, while subthemes and a theme (or themes) reflect the degree of interpretation. Although this could be critiqued as drawing an arbitrary line between the levels of analysis, it could be argued that it is not arbitrariness which is sought, but rather consistency during the analysis and plausibility.

3.7.6 Summary

In this section I present the different research approaches in terms of how their nature and procedures were interrogated. I considered using grounded theory, phenomenology and hermeneutics as each deals with people's perspectives, however each from a different angle. I expose and critique the complexity, challenges, and potential inexactness of the approaches, with emphasis on phenomenology and hermeneutics. I discuss the basic concepts and principles of procedures (methodology) for phenomenological and hermeneutical enquiry and explain the reasons for rejecting each approach for this qualitative study (study 3).

Based on reflection on the complexity and challenges related to achieving the principles of phenomenology and hermeneutics, a pragmatic approach e.g. qualitative content analysis was considered as an option. Qualitative content analysis was discussed in depth and broadly, and the concepts were sequentially analysed and interrogated. Furthermore I contextualised qualitative content analysis as a method lying somewhere between phenomenology and hermeneutics, as has the same onto-epistemology and draws principles from both.

Qualitative content analysis was chosen for conducting the qualitative study based on its systematic and flexible nature, including clearly described procedures which contribute to achieving trustworthiness in the study, the directness and focus of the method itself, and matching the method with the aim of the study (i.e. to explore the meaning of living with open surgical wounds over time).

3.8 STUDY 3: QUALITATIVE EXPLORATION OF THE MEANING OF LIVING WITH OPEN SURGICAL WOUNDS – METHODS

In this section the methods and procedures involved in qualitative study (Study 3 of this thesis) will be presented. Furthermore, the rationale for selecting the approaches taken will be argued.

3.8.1 Aim and objectives of the study

The aim of the study was to explore the meaning of living with open surgical wounds over time. This stage of the qualitative study deals with questions such as the nature of peoples' experiences of living with open surgical wounds, how these wounds affect them in everyday life, and why, and what their perspectives are on wounds and wound treatment.

3.8.2 Study design

The aim of the qualitative study is to explore the meaning of living with open surgical wounds over time and the study was designed as a longitudinal qualitative study (with follow-up interviews), as I sought to explore the journey of living with wounds from the initiation of the wound over a few weeks or months.

3.8.3 Study population and inclusion criteria

I sought to include people in the study who had at least one open surgical wound, defined as "superficial, partial, or full-thickness skin loss surgical wounds healing by secondary intention", which had been clinically confirmed by an medical doctor or registered nurse. Eligible people had to be at least 18 years old, living at home and being treated in the community. Because resources for translation were not available, people needed to understand and communicate in Slovene. All people were required to give informed consent.

I excluded people with impaired cognitive capacity or if they had pre-existing, documented severe mental illness, or who had any other complex wounds besides an open surgical wound, as this might influence their experience of the observed phenomena. People who had a terminal illness or were in emergency situations were also excluded.

3.8.4 Sample size and recruitment strategy

Careful consideration of the sample is essential to qualitative studies. Non-probability techniques, for example: convenience sampling (sampling people who are easy accessible to researcher), purposive sampling (sampling people based on characteristics and study objectives) or snowball sampling (identification of further sample through study subjects) are often used in qualitative studies (Robinson, 2014) aiming to give a description of broader concepts and theoretical understandings (rich and rigorous presentation) rather than ensuring generalisable findings with random sampling which reduce risks for selection bias (Flick, 2007; Steeves, 2000).

I considered, but rejected, using snowball technique as I did not expect that people with open surgical wounds could help with further recruitment of new subjects to study, based on the heterogeneity of the phenomenon (affecting young, older, both genders) unlike, for example, a characteristic that might be more general (e.g. LGBT population who socialise in the community). I could not use a convenience-sampling technique, as at the time of recruitment for the qualitative study (Study 3) I was not involved in providing direct care to people with open surgical wounds. Therefore I decided to use a purposive sampling technique in order to provide the required richness and achieve an in-depth exploration of the studied phenomenon. Purposive sampling fitted with the objectives of qualitative study i.e. exploring specifically the meaning of living with open surgical wounds, and fitted with sampling based on people's characteristics i.e. having open surgical wounds.

There are no specific recommendations to follow on how to determine the appropriate sample size. Sample size is often part of the discussion related to trustworthiness (reduced risk of bias, achieving internal and external validity) in quantitative research, whereas it is discussed much less in qualitative research probably because findings from qualitative studies are not intended to be generalised (Palinkas et al., 2015). The main challenge is to take the necessary measures to achieve trustworthiness. Some concepts, such as data saturation, have been well described in the literature, mostly in relation to grounded theory (Strauss, 2003) and other approaches such as thematic analysis. Saturation refers to the point where data are being repeated and where there are no more advances in phenomenon description (i.e., no new codes and themes are coming forth from new informants), however there is a lack of methodological guidance as to how to assess and justify saturation (Carlsen & Glenton, 2011). Two recent methodological studies have addressed how many interviews are needed to achieve thematic saturation. One study suggested that saturation is achieved at between 7 and 12 interviews (Guest et al., 2006), whilst another suggested saturation occurs at the point of the ninth interview (Hennink et al., 2017). Over the years some recommendations related to numbers of interviews have been published. It is recommended that for grounded theory 20-30 single interviews be conducted (Charmaz, 2006), while for phenomenological studies up to 10 (Starks & Brown Trinidad, 2007); however these recommendations are not empirically based. Clearly the point at which saturation occurs is likely to be affected by various factors, including the aim of study; the narrowness of the research question; how the interviews are carried out and what type of interview has been used; the quality of the data; how homogeneous the sample is; and the research tradition/approach (Hennink et al., 2017; Vasileiou et al., 2018). I did not use data saturation as a concept to increase validity because it is not in line with the philosophical background and tradition of this study. The aim of the qualitative study was to explore the meaning of living with open surgical wounds and I sought rich and in-depth interpretation of the phenomenon rather than only descriptions.

I recruited 10 participants for my study. The selection of this number of participants was based on reasons related to the tradition (interpretative) of the study (Boyd, 2001; Creswell, 1998; Sandelowski, 1995), and for pragmatic reasons, as the study employed longitudinal techniques so produced a large volume of data. This is in line with previous phenomenological or hermeneutic wound care research (Green et al., 2013; Hopkins et al., 2006; Kapp et al., 2014; Lindahl et al., 2007; Probst et al., 2013b). Furthermore it is in line with recent empirical evidence related to thematic saturation (Guest et al., 2006; Hennink et al., 2017). A sample size of 10 was feasible given that the aim of the study (Graneheim &

Lundman, 2004) was to explore the meaning of living with open surgical wounds in depth (by conducting two interviews with each participant).

Recruitment was carried out in two phases. First, health professionals who were providing health care services to eligible participants approached potential participants and informed them briefly about the study (Guide for health care professionals is in Appendix 6). Potential participants were provided with a Participant Information Sheet (Appendix 7) which explained the study and then asked if they were willing for their contact details to be shared with me (researcher). If so, participants were asked to give formal consent for their contacts details to be shared.

In the second phase, I contacted people who had consented to their details being shared and asked for their verbal agreement to participate in the study. After this, a meeting with each participant was set up (time and place), where I provided a brief explanation about the study; I answered any questions, and then I asked the participant to sign the consent form for participating in the study (participating in both the first and follow-up interviews). After informed, written consent had been provided, I conducted the interview.

3.8.5 Data collection

The objective of this qualitative study was to explore people's perspectives of the studied phenomenon and therefore interviews were identified as the appropriate data collection technique.

I used semi-structured interviews as the aim of the study was to explore the meaning of a phenomenon, i.e. the lived experience (Cohen, 2000). Semi-structured interviews follow the same approach to questioning each participant, which increases trustworthiness (credibility, dependability). Open-ended questions allow participants to talk about their experiences in more depth (Kvale & Birnkmann, 2009; Kahn, 2000).

I developed a topic guide, which was used for interviewing. The topic guide identified key themes and opening open-ended questions designed to encourage people to share their experiences with me (Appendix 8). The main advantages of using a topic guide were that the list of topics was pre-defined, covered all areas of interest and helped me to navigate the conversations/interviews. The topic guide that was developed for achieving the aims of the study was short and concise, which was important since its purpose was to guide me away from asking closed questions (Arthur & Nazroo, 2003). All people were interviewed according to the same pattern by covering all pre-determined topics; however, by using subsequent questions, the depth to which each topic was explored might have varied as informants related experiences from their lives, which were – or have might been – unique.

Furthermore, through using a topic guide, I was able to return to the topics which were addressed only superficially (or were later revealed to be relevant through interviews with other people) in the follow-up interviews.

I collected demographic details with a short demographic questionnaire that I developed (Appendix 9), which people completed after their first interviews.

3.8.6 Data transcribing and translation

All interviews were audio recorded and then I transcribed them. This ensured closeness and familiarity with the data, which was important so that I (i.e. the data analyst) could obtain an overall naïve understanding of the narratives (Lindseth & Norberg, 2004; Temple & Young, 2004; Vogrinc, 2008). Field notes were recorded in the interview protocol during or at the end of each interview (Vogrinc, 2008). This helped me when I conducted the second interviews as some topics could be addressed again with people.

As the interviews were carried out in the Slovene language (the native language of both the participants and the interviewer), I did the first two phases of analysis in Slovene; meanwhile, I developed codes, subthemes and an overarching theme in English. Furthermore, I translated quotations used for the purpose of research dissemination into English.

Carrying out the recontextualisation phase in English ensured that my co-researchers (supervisors) became familiar with the content and were able to help with the data analysis and interpretation.

There has been extensive discussion in recent years related to translation and cross-language qualitative studies, predominantly concerning whether and, how translation affects the trustworthiness of findings (Al-Amer et al., 2015; Chen & Boore, 2010; Santos et al., 2015; Squires, 2008; Tsai et al., 2004; Twinn, 1997). Translation from a source language (the original language used in interviews) to another (a non-source language used for the purpose of dissemination) is a complex process and can be resource intensive. The complexity of the process is highlighted by the fact that researchers do not only translate the meaning (semantic aspect): understanding the context is also important, for example when certain phrases have the same or different meaning in two different languages (cultures) (Chiumento et al., 2018; Tsai et al., 2004).

There are different ways of translating qualitative data. Firstly, one has to consider *who* will do the translation (the researcher or a professional translator). Secondly the precise nature of the translation (i.e., complete/literal or partial) needs to be decided and finally the point in time at which the translation will be carried out must be decided (Regmi et al., 2010; Santos et al., 2015).

In the methodological literature, certified, professional translation into a non-source language has been argued to be more valid, mainly due to suggestions that non-professional translators, i.e. researchers, might translate less accurately (mostly related to losing meaning, semantics, the complexity of sentences, etc.) (Squires, 2008; Squires, 2009; Temple, 2005; Temple & Young, 2004; Van Nes et al., 2010). On the other hand, researchers are often well aware of the epistemology of research, and the context, and therefore presumably can also relate more to the content of what was spoken about. Therefore translation by the researcher could be more trustworthy (Temple & Young, 2004; Larkin et al., 2007). Another challenge in professional versus researcher translation lies in technical translation, where words are translated in a technical way, without a deeper understanding of function, versus sociolinguistic and strategic competence, where linguistic function (including transliteration) has been taken into account in translation and therefore could increase trustworthiness (Bradby, 2002; Larkin et al., 2007; Regmi et al., 2010; Squires, 2008; Temple & Young, 2004). Some of the researchers argue that a bilingual researcher might be a third and effective way of carrying out translation, namely because such a person would be proficient in the source and second languages, and furthermore would understand the research perspective (epistemology, context, concepts, etc.) (Chen & Boore, 2009; Temple, 2005).

Opting for literal translation means translating data from the raw form verbatim, including other comunication such as pauses, etc. Such translation is highly resource-and time-consuming. If it is carried out to an adequate standard (including back translation, translation consultation, review panel and discussion among researchers) it should not diminish trustworthiness, but rather increase it (Chen & Boore, 2010; Regmi et al., 2010). On the other hand, partial translation where main themes are translated is less time consuming; however it could lead to losing information or distorting the meaning (Regmi et al., 2010).

Another aspect of translating data is the timing of translation. Translation could be carried out at different stages of the research, namely prior to data collection, during data collection, after data collection (before or after transcription in the source language), during data analysis, or just for research dissemination purposes (Chen & Boore, 2010; Santos et al., 2015).

I decided to conduct translation during analysis in this study. This meant that the processes of coding and sorting codes into subthemes and generating themes were carried out in English. There were two main reasons for this decision. As mentioned, translating complete interviews, due to the volume of data (two in-depth interviews per participant), was too time consuming, and furthermore, due to limited funding and ethics permission (protecting privacy), professional translating services were not a possibility. On the other hand, it was important that I (the researcher) translated (i.e., directly assigned) the last unit in the decontextualisation phase of the analysis (i.e. code) into English to ensure the trustworthiness of the analysis and interpretation. The main rationale for this was that assigning a code to a condensed meaning unit is the first step in the abstraction process and any error here could be promulgated throughout the analysis. These codes are tools for labelling meaning units and can influence how a meaning unit is perceived. According to Graneheim and Lundman (2004) “labelling a condensed meaning unit with a code allows the data to be thought about in new and different ways”. This indicates that a process of finding a proper code occurs in this phase regardless of whether the code is assigned in the source language or, as in this case, in English, and that the true content/meaning of what participants narrated has not been lost or misinterpreted. This has been proven as manageable and less time consuming. Furthermore, with such a procedure we could achieve understanding of data and discussion among co-researchers and therefore increase the trustworthiness of the findings.

3.8.7 Data analysis

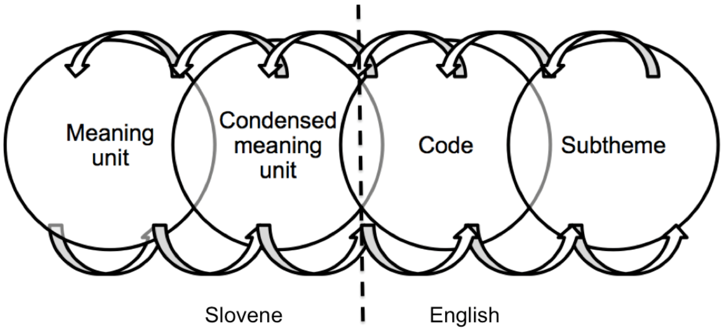
I have carried out an inductive qualitative content analysis (Graneheim & Lundman, 2004). The theoretical underpinnings of the approach were discussed in depth in section above (3.7.5), so this part will focus on the practical decisions which were taken in data analysis.

I divided the transcribed text into meaning units. Meaning units are words, sentences or phrases associated with the context (for example, unpleasant symptoms associated with wounds). Then I condensed each meaning unit by removing from it words which were not related to the context. I carried this out in Slovene (dividing the narratives into meaning units and the condensation process). Then I abstracted the condensed meaning units and labelled them with codes. I sorted the various codes into subthemes based on similarity. At the end I formed an overarching theme which reflected the link between latent meaning of the subthemes. I carried out the recontextualisation phase of the analysis in English.

According to Graneheim and Lundman (2004), the unit between a code and a subtheme is a category which reflects the bundle of manifest content. In this study, I have grouped codes directly into subthemes. The rationale for this decision lies in the richness and expressiveness of codes. Such a procedure is in line with standard qualitative content analysis practice. Graneheim et al. (2017) emphasise that “development of themes does not always require categorisation during the analysis”; therefore the codes become a unit for further interpretation.

As the structure of the analysis is complex, the diagram below provides a clearer insight into how the analysis was carried out. The analysis process in the diagram must not be understood as a linear process, as it is cyclic i.e. “backwards and forwards”.

Figure 3.2: Diagram of the analysis.



3.8.8 Ethical issues

I considered ethics at all stages of this qualitative study, not only in relation to the research process, but also in relation to the participants, as well as me as the researcher. During this study, I followed fundamental principles of good research practice (Holloway & Jefferson, 2013; Orb et al., 2001; Parry & Mauthner, 2004; Smith, 1999), such as:

Voluntary participation: people were given enough information to decide freely whether to participate voluntarily (informed consent). They were given the opportunity to decline involvement in any part of the research without suffering any consequences.

Providing information: people were provided with ample information about the qualitative study; however when questions arose about the treatment of the wound I advised them to seek that information from their GP or other health care professional involved in their treatment.

Protecting personal identity: during the research process, as well after, the identity of the individual people was protected. In order to achieve anonymity, people were coded. The code was used on all documents, including audiotapes. Only I (the researcher) know the identity of the people involved in the study. Privacy and anonymity were upheld and will continue to be upheld always and everywhere, to the extent that I, as a researcher, would not even disclose the identity of an individual in an oral report or conversation with a colleague.

Data safety management: I developed a strategy for data handling and ensuring safety. Electronic data were encrypted for security reasons (the code is known only to me – the researcher). All data are stored in a safe place (a locked storage cabinet in the University of Ljubljana, where I work). Data management strategy is in line with University of Manchester Research Data Management Policy. Ten years after the study ends, the data will be securely destroyed.

Participant support: I developed a protocol in case a participant might suffer emotional distress; however no additional support for participants was needed.

Identification of bad practice: I developed a step-strategy in case any instance of bad clinical care or practice was identified during the study; however people did not reveal any practice that might not be in line with the standards of care in Slovenia.

My safety during the study: I stayed in touch with supervisors at the University of Manchester through Skype meetings. In order to reduce the lone worker risk I have abided by the University of Manchester lone researcher policy. I developed a protocol for the fieldwork (declared in the ethical review application) and filled out the official university community-based research checklist. The Police Directorate of Ljubljana was informed that I was carrying out the study in Ljubljana and were notified of the lone worker policy by email.

Ethical approval: the study obtained approval from the Ethical Committee of The University of Manchester (Appendix 4) and the Ethical Committee of the Republic of Slovenia (Appendix 5).

3.8.9 Trustworthiness

Issues in achieving quality in qualitative (as opposed to rigour in quantitative) research have been raised and discussed within the “qualitative research community”. The criteria for determining the quality of “bias-free” findings which appear in research must come from the paradigm to which that research belongs (Morse et al., 2002; Rolfe, 2006; Sandelowski, 1993). It is also considered that it is not possible to apply the positivistic criteria of internal/external validity and reliability to qualitative research as they answer on a question by relating interpretation to a single objective reality (looking at a phenomenon from a distance with objectivity) where the qualitative paradigm understands the phenomenon from a position where multiple realities are possible and is not concerned with seeking full objective truth (Giorgi, 2017; Graneheim & Lundman, 2004; Sandelowski, 1993; Van Manen, 2017).

Key concepts for achieving trustworthiness in qualitative research are credibility, dependability, confirmability and transferability (Rolfe, 2006; Sandelowski, 1993).
I considered different approaches to achieving and maintaining the trustworthiness of the research findings and settled on the methods identified in section 3.6.

Credibility

The concept of credibility reflects and refers to how plausible research findings are. It answers the question of whether we can believe the results of study from two perspectives, namely, illustrating how the analysis covers the data obtained from participants, and the overall quality of study (Bengtsson, 2016; Elo et al., 2014; Schreier, 2012). In the literature, there are procedures and strategies for increasing the credibility of research findings (Sale & Brazil, 2004), which also differ in how applicable they are to certain approaches. Furthermore, the strategies are related to specific stages of research, including reporting, which enables the reader or user to judge the credibility of the study (Graneheim et al., 2017).

I have reported the study process from the planning to the reporting stage in a transparent way. I have discussed the main concepts related to the process of conducting inductive content analysis and how this reflects the credibility. Furthermore, I maintained the focus on paradigm, tradition and method when I was conducting the qualitative study (Bengtsson, 2016; Graneheim and Lundman, 2004; Lindseth and Norberg, 2004; Elo et al., 2014; Graneheim et al., 2017).

I have included directs quotes from study participants (hearing people's voices in the results), and added descriptions of the related context, which is described in language as close as possible to that of the participants (Lindesth and Norberg, 2004). I believe that with a rich and in-depth presentation I have illustrated how well the findings (i.e. subthemes and overarching theme) cover the data. Furthermore I included all the data, relevant to the study objective (Graneheim and Lundman, 2004). I selected quotes connected to all the main concepts and reflect people's narratives overall, as suggested by Elo et al. (2014).
I was aware that there could be more than one interpretation of the data (multiple realities) (Sandelowski, 1993); however, based on discussion between me and my co-researchers (supervisors), I believe that I have pursued the most plausible one.

Confirmability

Confirmability refers to the objectivity and neutrality of data. This means that the results represent the data provided, for example, by informants, and are (the results) not prone to researcher bias or researcher subjectivity (Elo et al., 2014; Graneheim & Lundman, 2004).

Though that it could be argued that qualitative research is susceptible to its own subjective nature, facilitating a degree of confirmability increases the trustworthiness of the findings. I aimed to increase confirmability by using quotations from the transcribed text, which links the data and the analysis (by reflecting what informants actually said) (Graneheim & Lundman, 2004). Furthermore, to demonstrate neutrality, I have described my own personal perspective related to studies carried out and reported within this PhD thesis (Sale & Brazil, 2004).

Dependability

The criterion of dependability is related to the stability of the analysis. It refers to understanding that data (for example, codes) might change through time, for example during coding or if decisions are changed during the analysis, so dependability reflects the methodological consistency over time (Graneheim & Lundman, 2004; Elo et al., 2014; Bengtsson, 2016).

There are several strategies to increase or achieve dependability, such as an audit trail, stepwise replication and a code-recode strategy (Anney, 2014). Ensuring transparency of the research process through keeping an audit trail increases dependability. Researchers should document and reflect on decisions, for example if there are changes later in the process (for example in interviews or later coding) (Bengtsson, 2016). Inductive qualitative content analysis is often carried out by a single researcher; therefore Elo et al. (2014) suggest that the research process should be as transparent as possible; furthermore Graneheim and Lundman (2004) suggest discussion among the research team as a strategy for achieving dependability. I have reported this study in depth and in open manner, so I believe that a high degree of transparency in the qualitative study has been achieved. Furthermore, the recontextualisation stage of the analysis was carried out in English, so discussion between me and my co-researchers (supervisors) was possible.

Stepwise replication refers to double data coding – two researchers coding the data with a high level of inter-coder match would indicate dependability being achieved. However, as I carried out the interviews in Slovene and the decontextualisation stage of the inductive content analysis in Slovene, double coding was not an option in this study. Another strategy to increase dependability is coding-recoding. Code-recode refers to the data being coded again after two weeks (Anney, 2014). Another tactic within code-recode is that the researcher returns to, for example, two pages of plain text coded previously and repeats the analysis by recoding and then checking for accuracy (Schreier, 2012). Though I did not opt for a formal code-recode strategy, I returned to the transcriptions of the interviews during the data collection (before conducting the follow-up interviews), and later during the data analysis, as the data analysis was performed in a cyclic, not linear way, as suggested by Graneheim and Lundman (2004).

Transferability

Transferability refers to the applicability of research findings to other groups of people or to other contexts (Elo et al., 2014; Polit & Beck, 2011). This is linked to the concept of quantitative generalisibility; however it must be emphasised that qualitative research does not aim to produce generalisable findings; qualitative research focuses on the deep study of phenomena from an “inside” perspective rather than seeking a definite and objective truth (Bengtsson, 2016). Decisions on transferability are left to the consumer of the research (Graneheim & Lundman, 2004). I employed different strategies to achieve transferability, such as ensuring the research process has a high level of transparency (Sale & Brazil, 2004), and clear and detailed description of the characteristics of the participants, culture and context (Graneheim & Lundman, 2004).

3.9 SUMMARY

In this chapter I have provided an insight into the methodology and methods used in this thesis. At the beginning I outlined the aims and objectives for each study (Studies 1, 2 and 3). I discussed the methodology and methods considered for addressing the aim of Study 1, the objective of which was to investigate and describe the nature, extent and variety of published research about patients’ experiences of living with complex wounds, including the nature of the different wounds studied. I argued for the decision to conduct a scoping review, following Arksey & O’Malley’s (2005) approach. In the following section I discussed the methodology and methods used in prevalence studies. Bespoke data collection fitted the aim of this study; therefore I designed a cross-sectional survey to explore the prevalence, nature and management of open surgical wounds in Slovenia (Study 2). I scrutinised the methodology and methods used for exploring people’s perspective of living with wounds. I considered four different approaches, i.e. grounded theory, phenomenology, hermeneutics and qualitative content analysis, and I argued the case for using the latter. I introduced and provided the rationale for the approaches taken in the qualitative study (Study 3), where I aimed to explore the meaning of living with open surgical wounds over time.

In the following three chapters (i.e. Chapters 4, 5 and 6) three individual studies are presented in the form of manuscripts.

CHAPTER 4: PEOPLE’S PERSPECTIVE OF LIVING WITH COMPLEX WOUNDS – A SCOPING REVIEW

Manuscript prepared for submission.

Ljubiša Pađen [a], Jane Griffiths [a], Nicky Cullum [ac]

[a] Division of Nursing, Midwifery and Social Work
The University of Manchester
Oxford Road
Manchester, M13 9PL, UK
E-mail: ljubisa.paden@postgrad.manchester.ac.uk

[b] Department of Nursing, Faculty of Health Sciences
University of Ljubljana
Zdravstvena pot 5
1000 Ljubljana, Slovenia

[c] Research & Innovation Division, Manchester University NHS Foundation Trust Research Office
1st Floor, Nowgen Building
29 Grafton Street
Manchester, M13 9WU, UK

Correspondence:
Ljubisa Paden (Ljubiša Pađen)
Division of Nursing, Midwifery and Social Work
The University of Manchester
Oxford Road
Manchester, M13 9PL, UK
E-mail: ljubisa.paden@postgrad.manchester.ac.uk
Phone: +38640187949

ABSTRACT

Background: Complex wounds are a common long-term and a serious global health issue. They are unpleasant for people and are a burden for health care systems, as treating them is costly. Many studies have aimed to illustrate how complex wounds and their care affect people's quality of life and daily living; however, there are limitations to current evidence about living with them.

Objectives: To explore and scope the nature and extent of the published qualitative research about people's perspectives and experiences of living with complex wounds.

Design: This study was carried out using Arksey & O'Malley's (2005) framework for conducting scoping reviews and is reported in line with PRISMA-ScR guidance for scoping reviews. A comprehensive search was conducted through electronic databases (CINAHL, MEDLINE and EMBASE) in June 2018, using a predefined search strategy to identify studies for potential inclusion. Following the removal of duplicated studies, two reviewers independently screened 1,787 relevant records. In total, 103 records were included in this scoping review.

Results: 79 primary studies (90 records) and 13 reviews or synthesis studies published between January 1995 and June 2018 were included in this scoping review. The nature and extent of the included studies vary. A large proportion (35.6%) of the studies focus on people with venous leg ulcers. There is a lack of research about people's perspectives of living with arterial leg ulcers, open surgical wounds and malignant fungating wounds. No studies have included children or adolescents with complex wounds. Most of the studies were carried out in the United Kingdom, Sweden and the United States.

Conclusions: This scoping review of qualitative research about people's perspectives of living with complex wounds has illuminated the nature and extent of the current evidence base. The findings from this study can inform researchers in terms of identified evidence gaps and future research targets.

4.1 INTRODUCTION

Having a wound at some point in life is probably a common experience for the majority of people. Most people have wounds as a result of injury or surgery; these are called acute wounds. Acute wounds normally heal in an orderly sequence of phases within days or weeks (Li et al., 2007) without any complications. The second large group of wounds is complex wounds (often also known in the literature as “chronic” or “hard to heal” wounds). These are wounds with superficial, partial or full thickness skin loss, healing by secondary intention, i.e. healing by the growth of granulation tissue from the wound bed (Hall et al., 2014; Menke et al., 2007; Pragnell & Neilson, 2010). Complex wounds have various underlying aetiologies, such as peripheral vascular disorders (venous, arterial or mixed), neuropathy due to diabetes or other systemic diseases such as malignancy and connective tissue disorder, or are the result of local factors such as long-term pressure (with a combination of shear force and friction) on the skin (Armstrong et al., 2017; Coleman et al., 2013; Grey et al., 2006; Alexander, 2009; Dabiri & Falanga, 2013).

Complex wounds are one of the common long-term conditions that affect people. Prevalence studies from the UK have shown that the point prevalence of complex wounds was estimated at between 1.47 and 1.64 per 1,000 of the population (Gray et al., 2018; Hall et al., 2014). As for subtypes of complex wounds, the most common are leg ulcers (0.44 per 1,000 population), pressure injuries/ulcers (0.31 per 1,000 population) and foot ulcers (0.22 per 1,000); the least common are malignant fungating wounds (0.02 per 1,000 population) (Hall et al., 2014). A further type of complex wound is surgical wounds healing by secondary intention, the prevalence of which has been estimated at 0.41 per 1,000 of population (Chetter et al., 2017).

A high prevalence of complex wounds impacts the health care sector as various resources are allocated for their management (Gray et al., 2018), indicating that complex wound management is resource intensive. When looking more closely at what care is delivered, and how and where, it can be noted that the majority of people with wounds are treated in the community (at home, in GP surgeries or at wound clinics), often by nurses with expertise in wound care (Cullum et al., 2016; Gray et al., 2018; Pađen et al., 2019). Various topical treatments are used in their management. Research has shown that a wide variety of wound dressings are used along with advanced treatments such as negative pressure wound therapy (Chetter et al., 2017; Gray et al., 2018; Pađen et al., 2019). People with wounds have frequent consultations and follow-ups with health care professionals – on average two to three appointments per week for dressing changes – where the mean duration of each is approximately 13 minutes (Pađen et al., 2019).

It has been suggested that the annual cost of wound care in the UK is between £4.5 and £5.1 billion (Guest et al., 2015), while in USA the costs are estimated at 25 billion US dollars (Sen et al., 2009). Furthermore, recent studies have suggested that there is a difference in the costs related to the type of wounds (Guest et al., 2020; Guest, Fuller, & Vowden, 2018a; Guest, Fuller, Vowden, et al., 2018b); however, the findings from these studies are limited, as the data source register might not reflect the true number of people who are affected by wounds, and furthermore the cost estimates do not include indirect costs; therefore the true overall cost is yet to be estimated.

Current research is oriented towards various aspects of wound care, such as: exploring the nature of wounds and wound epidemiology (Hall et al., 2014; Chetter et al., 2017; Gray et al., 2018; Pađen et al., 2019; Chetter et al., 2019); testing interventions that might work in promoting wound healing or preventing wounds (Dumville et al., 2015; Atkinson & Cullum, 2018; Lavallée et al., 2017; Westby et al., 2016; Norman et al., 2016; Shi et al., 2018b); and economic evaluations such as cost-effectiveness analysis (Tricco et al., 2015; Allen et al., 2018); moreover, it seems that a large corpus of studies has explored the experience of having complex wounds from the people's perspective, and how wounds affect people's quality of life and their well-being (Briggs & Flemming, 2007; Girouard et al., 2008; Gorecki et al., 2009; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018).

Apart from the large and still growing number of studies, it seems that clinicians in wound care still face challenges and uncertainties related to wound management. To our knowledge, there are only two studies which have aimed to identify research priorities in the field of wound care. One was conducted in the UK (Gray et al., 2017) and one internationally (Cowman et al., 2012). Both found that practitioners/responders reported a need for evidence related to impacts on peoples' quality of life and patient-centred care (Cowman et al., 2012; Gray et al., 2017). As we were to design a study project which would target the identified uncertainty related to the impact wounds have on people, we decided to conduct a scoping review with the aim of exploring and scoping the qualitative research literature on peoples' experiences of living with complex wounds, and informing researchers and clinicians about potential knowledge gaps and research targets.

The question which guided this scoping review was: "What is the nature and the extent of research about peoples' perceptions and views of their everyday experience of having complex wounds?" The two objectives were:

3) to investigate and describe the nature, extent and variety of the published research about peoples' experiences of living with complex wounds,
4) to map the body of published qualitative research about peoples' experiences of living with complex wounds in terms of wounds studied.

4.2 MATERIALS AND METHODS

4.2.1 Study design

This study was carried out using Arksey & O'Malley's (2005) framework for conducting scoping reviews. Scoping reviews (also termed scoping studies) are used to address a broad range of research questions and to scope the available literature. Arksey & O'Malley (2005) defined four common reasons for undertaking scoping reviews, namely: exploring the extent, the range and the nature of available research evidence, determining the value of undertaking a full systematic review, summarising and disseminating research findings, and identifying gaps in the existing research. Arksey & O'Malley's (2005) framework has been further developed, mainly in building clear guidance about how to conduct and report scoping reviews (Davis et al., 2009; Levac et al., 2010; Tricco et al., 2018). The Arksey & O'Malley (2005) framework has six stages: 1) identifying the research question, 2) identifying relevant studies, 3) selecting studies, 4) charting the data, 5) collating, summarising and reporting results and 6) a consultation exercise, which is optional. In this study we will conduct the first five stages only, as a consultation exercise would exceed our aims and objectives.

4.2.2 Protocol and registration

An *a priori* protocol was developed for this scoping review and registered at Open Science Framework Registration (osf.io/pk5ny).

4.2.3 Eligibility criteria

Papers were eligible for inclusion in this review if they met the following inclusion criteria:
1) papers written in English;
2) studies that focused on participants with complex wounds defined as: superficial-, partial-, or full-thickness skin loss wounds healing by secondary intention (Hall et al., 2014);
3) studies that aimed to explore the impact on everyday life of having complex wounds (including treatments), or to explore how unpleasant symptoms associated with complex wounds interfere with daily living;
4) studies that focused on the lived experience in a home (community) setting;
5) studies with one of the following study designs: qualitative studies (regardless of philosophical background or data collection or analysis method), mixed-method studies, systematic reviews of qualitative and/or quantitative studies, meta-synthesis of qualitative studies.

We excluded all other studies which did not fulfil these inclusion criteria. Furthermore, we excluded some quantitative or mixed-method studies that aimed to report some qualitative data. We sought rich descriptions of phenomena, and not descriptions of open-ended answers in surveys. We also excluded narrative reviews, as the majority of those were not systematically reported (methods and results).

4.2.4. Information sources

A comprehensive search was conducted through electronic databases: Ovid MEDLINE (1946 to 10 July 2018), EBSCO CINAHL Plus (1938 to 10 July 2018) and Ovid EMBASE (1974 to 10 July 2018). Also, the snow-ball technique was applied to reference lists of previously published reviews (Briggs & Flemming, 2007; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018) and used to identify potentially relevant studies which were not identified through the search.

The search strategy was designed to reflect the inclusion and exclusion criteria and was peer-reviewed by an experienced information specialist (N.S.). As we expected to identify extensive evidence related to the search terms, the search was restricted to titles and abstracts, which helped to reduce the hits returned. No restrictions were set as to time of publication or publication type.

4.2.5 Search

Example of search strategy via Ovid MEDLINE (Literature search performed: July 10 2018).

1 exp Skin Ulcer/
2 (pressure adj (ulcer* or sore* or injur*)).ab,ti.
3 (decubitus adj (ulcer* or sore*)).ab,ti.
4 (bedsore* or bed sore*).ab,ti.
5 (varicose ulcer* or venous ulcer* or leg ulcer* or stasis ulcer* or crural ulcer* or ulcus cruris or ulcer cruris).ab,ti.
6 ((arterial or ischemic or ischaemic) adj3 (ulcer* or wound*)).ab,ti.
7 (diabet* adj3 (ulcer* or foot or feet or wound*)).ab,ti.
8 (rheumatoid adj3 (ulcer* or wound*)).ab,ti.
9 (connective adj3 (ulcer* or wound*)).ab,ti.
10 (malignant adj3 (wound* or ulcer*)).ab,ti.
11 (fungat* adj3 (wound* or tumor* or tumour* or ulcer*)).ab,ti.
12 ((smelly or malodorous) adj3 (wound* or ulcer* or tumor* or tumour*)).ab,ti
13 exp Surgical Wound/

14 exp Surgical Wound Dehiscence/
15 ((surg* adj5 wound*) or (surg* adj5 dehisc*)).ab,ti.
16 ((unpleasant or pain or painful or malodo?r or odo?r or smell* or itch* or pruritus or leakage or exudate*) adj3 (wound* or ulcer*)).ab,ti.
17 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18 exp "Quality of Life"/
19 exp Adaptation, Psychological/
20 exp Attitude to Health/
21 exp "Activities of Daily Living"/
22 (quality of life or QoL or wellbeing or well-being).ab,ti.
23 ((patient* or people*) adj3 (experience* or perspective* or perception* or view?)).ab,ti.
24 18 or 19 or 20 or 21 or 22 or 23
25 exp qualitative research/
26 exp Grounded Theory/
27 exp Interviews as Topic/
28 Focus Groups/
29 exp Narration/
30 (qualitative or focus group* or interview* or discourse analysis or content analysis or thematic analysis or narrativ* or ethnograph* or ethnolog* or ethnonurs* or field stud* or phenomenolog* or hermeneutic* or grounded theory or life experience or lived experience or data synthesis or metasynthesis or meta-synthesis or synthesis).ab,ti.
31 25 or 26 or 27 or 28 or 29 or 30
32 17 and 24 and 31

4.2.6 Selection of sources of evidence

All citations from all sources were combined into one file (using Microsoft Excel) and the references were de-duplicated. Firstly, all retrieved search hits were independently screened by two reviewers (L.P. and research assistant E.B.) for eligibility against the inclusion criteria. All irrelevant references were rejected immediately, while if one met or appeared to meet the inclusion criteria it was considered for further assessment. In the second phase, attempts were made to obtain full text copies of potentially relevant studies through electronic databases, through the University of Manchester Library, British Library or directly (journal publishers). In cases where a full copy of the study could not be obtained, the citation was excluded from further assessment. All retrieved full text copies of publications were then assessed by one reviewer (L.P.). Two other reviewers (J.G., N.C.) undertook a verification check on 10% of included studies.

4.2.7 Data charting process

A data extraction form was developed in advance and used to chart the data, with adherence to the research question and the objectives of the study. Two reviewers (L.P., J.G.) independently tested a draft of the data extraction form on five studies, as recommended by Levac et al. (2010). The data extraction form was later revised by consensus between all three reviewers (L.P., J.G., N.C.). Only one reviewer (L.P.) extracted the data from studies; the other two reviewers (J.G.; N.C.) checked the accuracy of data extraction for 10% of included studies. Authors were contacted to confirm if multiple reports (articles) were drawn from one study (i.e. same participants).

4.2.8 Data items

For data charting from studies we extracted the items listed in table 1.

Table 4.1: Items extracted in data charting.

	Reviews and synthesis of qualitative studies	Primary qualitative studies
1	Authors' details; year of publication and source of reference	Author; title; year of publication and source of reference
2	Review objectives	Aims of the study
3	Search strategies	Study setting
4	Study inclusion and exclusion criteria	Study design (including approach to data collection and data analysis)
5	Included settings	Recruitment and sample size
6	Included populations (age of participants, gender of participants, sample size)	Inclusion/exclusion criteria
7	Included wound types (definition)	Age of participants and gender of participants
8	The number of included qualitative studies or mixed method studies	Wound type (definition)
9	Whether any funding declared and nature of funding	Whether any funding declared and nature of funding

4.2.9 Synthesis of results

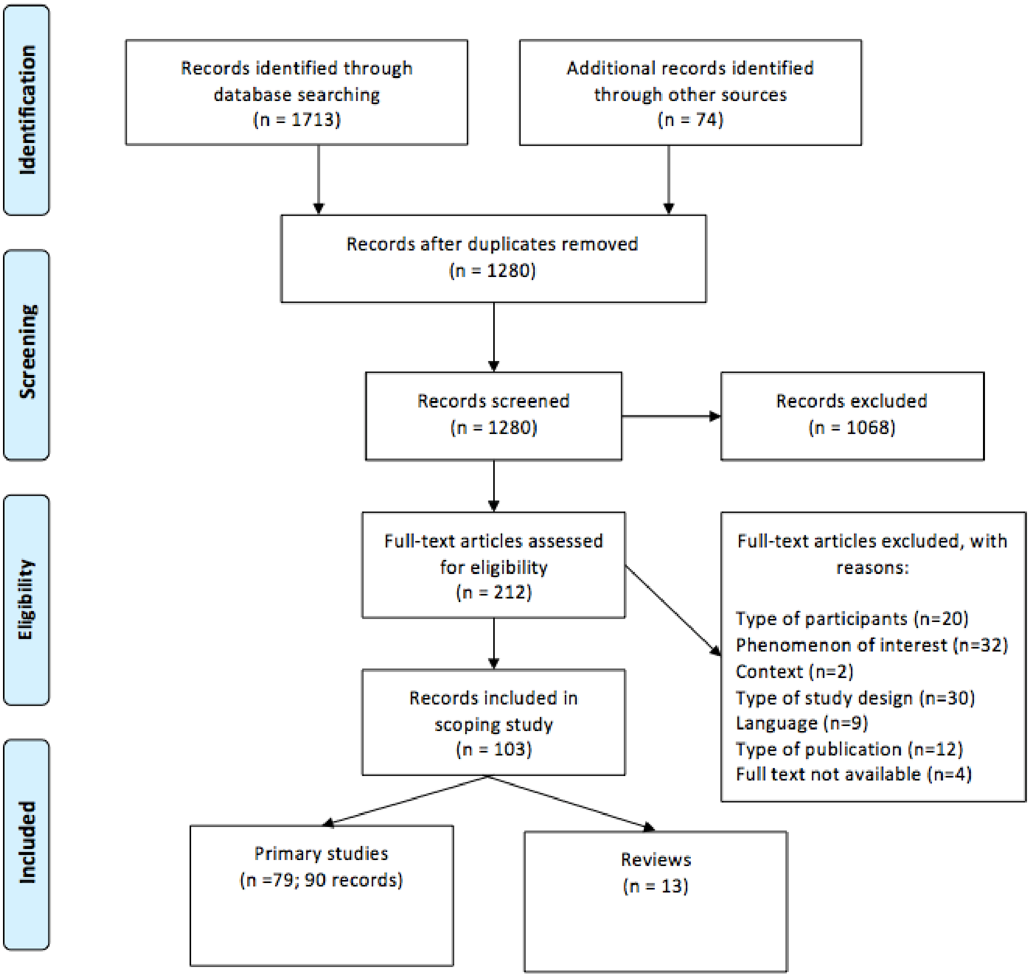
The results are presented in narrative format, and in tables, charts and figures. We have summarised studies based on the types of publication (primary or reviews/synthesis studies) and grouped them by wound type. A summary of the characteristics of included studies and reviews/synthesis studies is presented in table format. Some of the data, such as the numbers of screened and included studies, are presented in a flowchart and line charts. The geographical locations of included primary studies are presented as a map. Epidemiological data with numbers and characteristics of included studies are compared in table format.

4.3 RESULTS

4.3.1 Selection of sources of evidence

The search yielded a total of 1,787 relevant records, which were de-duplicated and screened for potential inclusion in this scoping review. Of these, 216 records were obtained in full text for detailed assessment. The total of 103 records; 90 records of 79 primary studies (Abbotts, 2010; Andersson et al., 2010; Ashford et al., 2000; Bale et al., 2007; Barg et al., 2017; Bolas & Holloway, 2012; Bradbury & Price, 2011a; Bradbury & Price, 2011b; Brod, 1998; Brown, 2005a, 2005b, 2010; Byrne & Kelly, 2010; Cezar da Silva et al., 2015; Chadwick, 2002; Charles, 1995; Chase et al., 1997; De Vera, 2003; Douglas, 2001; Dudley et al., 2017; Ebbeskog & Ekman, 2001; Ebbeskog & Emami, 2005; Edwards, 2003; Fagerdahl, 2014; Fagerdahl et al., 2013; Firth et al., 2011, 2013; Fox, 2005; Fox, 2002; Gorecki et al., 2012; Green et al., 2013; Green et al., 2018; Haram & Dagfinn, 2003; Hopkins, 2004; Hopkins et al., 2006; Husband, 2001; Hyde et al., 1999; Jackson et al., 2017; Jackson et al., 2018; Jones et al., 2008; Kapp & Annells, 2010; Kinmond et al., 2003; Kirupa, 2014; Krasner, 1998; Langemo et al., 2000; Lewis, 2007; Lindahl et al., 2007; Lo et al., 2008; Lund-Nielsen et al., 2005a, 2005b; Lund-Nielsen et al., 2011; McCaughan et al., 2015, 2018; McGinnis et al., 2015; McPherson & Binning, 2002; Monsen et al., 2017; Morgan & Moffatt, 2008; Mudge et al., 2006; Mudge et al., 2008; Neal, 2015; O’Brien et al., 2014; Ottosen & Pedersen, 2013; Pagliaro Borges Soares et al., 2013; Palfreyman et al., 2007; Parry et al., 1996; Piggin & Jones, 2007; Probst et al., 2013a; Probst et al., 2013b; Ribu & Wahl, 2004; Rich & McLachlan, 2003; Searle et al., 2005; Skavberg Roaldsen et al., 2011; Stevens, 2006; Tanner et al., 2012; Tanner et al., 2013; Taverner et al., 2014; Umeh et al., 2017; Van Hecke et al., 2013; Walburn et al., 2012; Walshe, 1995; Watson-Miller, 2006; Zhu & Kath, 2017; Flanagan et al., 2006; Gorecki et al., 2010; Cipolletta & Amicucci, 2017; Wellborn & Moceri, 2014; Lernevall et al., 2017; Delea et al., 2015; Madden, 2015; Alexander, 2010) and 13 review or synthesis studies (Briggs & Flemming, 2007; Fearns et al., 2017; Franks & Morgan, 2003; González-Consuegra & Verdú, 2011; Goodridge et al., 2005; Gorecki et al., 2009; Gorecki et al., 2011; Green et al., 2014; Green & Jester, 2009; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018; Taverner et al., 2011) which met the inclusion criteria are included in this scoping review (Figure 1).

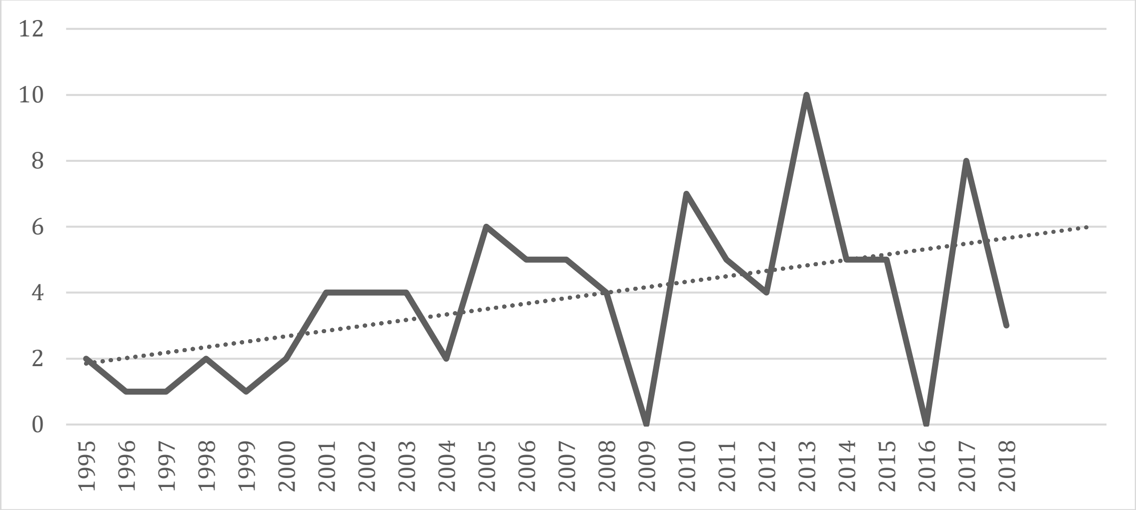
Figure 4.1: Process of study identification. Adapted from Moher et al., (2009).



4.3.2 Size and geographical distribution of evidence base

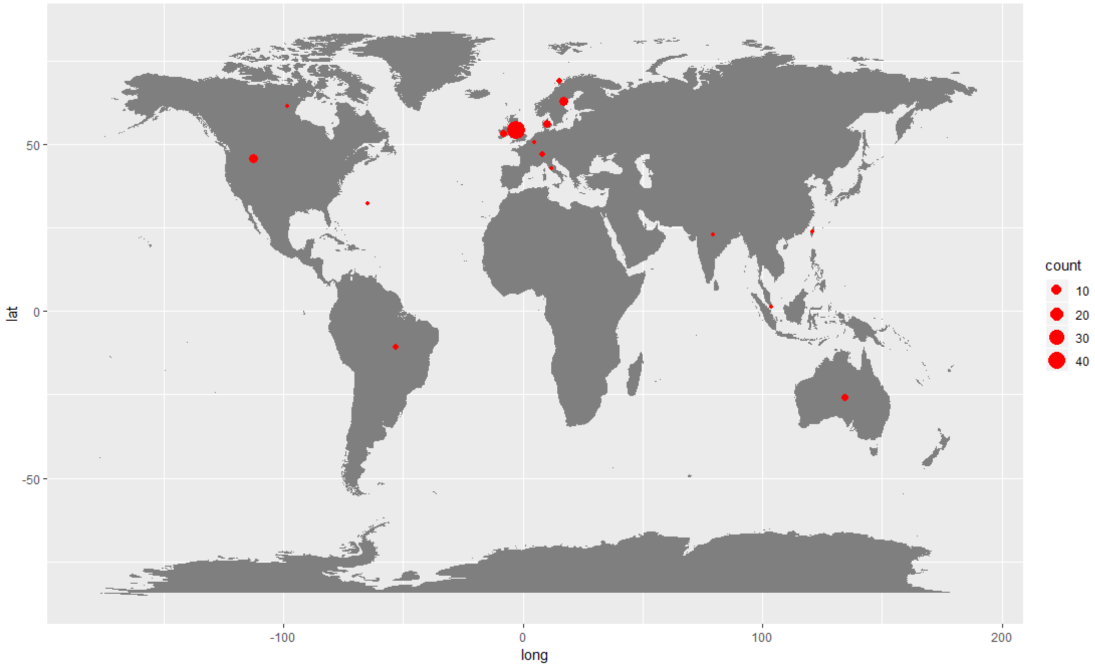
We included 103 records published between January 1995 and June 2018. There was a small amount of research published between 1995 and 2000, while after 2000 the number of papers increased, peaking in 2013. We did not identify any eligible papers published in 2009 or 2016 (Figure 2).

Figure 4.2: Numbers of eligible papers published per year between 1995 and 2018.



The majority of records reported primary studies, which were conducted in high income countries; specifically 47 (52%) reported that the study was carried out in the United Kingdom (Ashford et al., 2000; Bradbury & Price, 2011a, 2011b; Brod, 1998; Brown, 2005a, 2005b, 2010; Chadwick, 2002; Charles, 1995; Douglas, 2001; Dudley et al., 2017; Edwards, 2003; Firth et al., 2011, 2013; Fox, 2002; Gorecki et al., 2012; Green et al., 2013; Green et al., 2018; Hopkins, 2004; Husband, 2001; Jackson et al., 2017; Jackson et al., 2018; Jones et al., 2008; Kinmond et al., 2003; Lewis, 2007; Madden, 2015; McCaughan et al., 2015; McGinnis et al., 2015; McPherson & Binning, 2002; Morgan & Moffatt, 2008; Mudge et al., 2006, 2008; Neal, 2015; Ottosen & Pedersen, 2013; Palfreyman et al., 2007; Piggin & Jones, 2007; Rich & McLachlan, 2003; Searle et al., 2005; Stevens, 2006; Tanner et al., 2012; Tanner et al., 2013; Taverner et al., 2014; Walburn et al., 2012; Walshe, 1995; Gorecki et al., 2010; McCaughan et al., 2018; Abbotts, 2010), eight in Sweden (Andersson et al., 2010; Ebbeskog & Ekman, 2001; Ebbeskog & Emami, 2005; Fagerdahl, 2014; Fagerdahl et al., 2013; Lindahl et al., 2007; Monsen et al., 2017; Skavberg Roaldsen et al., 2011) eight in USA (Barg et al., 2017; Chase et al., 1997; De Vera, 2003; Krasner, 1998; Langemo et al., 2000; Parry et al., 1996; Umeh et al., 2017; Wellborn & Moceri, 2014), five in Denmark (Flanagan et al., 2006; Lernevall et al., 2017; Lund-Nielsen et al., 2005a, 2005a; Lund-Nielsen et al., 2011), four in Australia (Alexander, 2010; Hyde et al., 1999; Kapp & Annells, 2010; O’Brien et al., 2014), three in Ireland (Bolas & Holloway, 2012; Byrne & Kelly, 2010; Delea et al., 2015), two in each of Norway (Haram & Dagfinn, 2003; Ribu & Wahl, 2004) and Switzerland (Probst et al., 2013a; Probst et al., 2013b), and one in each of Taiwan (Lo et al., 2008), Belgium (Van Hecke et al., 2013), Islands of Bermuda (Watson-Miller, 2006), Canada (Fox, 2005), Italy (Cipolletta & Amicucci, 2017) and Singapore (Zhu & Kath, 2017). Two papers reported a single research study carried out in two countries, namely United Kingdom and Belgium (Bale et al., 2007; Hopkins et al., 2006). Two studies were conducted in Brazil (Cezar da Silva et al., 2015; Pagliaro Borges Soares et al., 2013), a middle income country, and one only one study was carried out in a lower-middle-income country, namely India (Kirupa, 2014) (Figure 3).

Figure 4.3: Geographical distribution of primary study settings.



4.3.3 Nature and characteristics of included studies

<u>Studies by wound type</u>

Most studies (29 studies from 32 records, 35.6%) reported findings about people with venous leg ulcers (Brown, 2005a, 2005b, 2010; Byrne & Kelly, 2010; Cezar da Silva et al., 2015; Chase et al., 1997; Douglas, 2001; Ebbeskog & Ekman, 2001; Ebbeskog & Emami, 2005; Edwards, 2003; Green et al., 2013; Green et al., 2018; Hopkins, 2004; Husband, 2001; Jones et al., 2008; Krasner, 1998; McCaughan et al., 2015; Mudge et al., 2006; O'Brien et al., 2014; Palfreyman et al., 2007; Rich & McLachlan, 2003; Skavberg Roaldsen et al., 2011; Stevens, 2006; Van Hecke et al., 2013; Walburn et al., 2012; Walshe, 1995; Wellborn & Moceri, 2014; Zhu & Kath, 2017; Flanagan et al., 2006; Mudge et al., 2008; Cipolletta & Amicucci, 2017; Charles, 1995); 14 studies (15 records, 16.7%) concerned people with foot ulcers associated with diabetes (Ashford et al., 2000; Barg et al., 2017; Bradbury & Price, 2011a; Bradbury & Price, 2011b; Chadwick, 2002; De Vera, 2003; Delea et al., 2015; Fox, 2005; Kinmond et al., 2003; Kirupa, 2014; McPherson & Binning, 2002; Parry et al., 1996; Ribu & Wahl, 2004; Searle et al., 2005; Watson-Miller, 2006); ten studies (11 records, 12.2%) related to a mixed sample of people with different types of leg ulcers, i.e. leg ulcers of venous, arterial, mixed or have included people with leg ulcers of other aetiology (Firth et al., 2011, 2013; Haram & Dagfinn, 2003; Lernevall et al., 2017; Lewis, 2007; Madden, 2015; Taverner et al., 2014; Hyde et al., 1999; Morgan & Moffatt, 2008;

Umeh et al., 2017; Brod, 1998), seven studies (10 records, 11.1%) related to pressure ulcers/injuries (Bale et al., 2007; Fox, 2002; Gorecki et al., 2010; Gorecki et al., 2012; Hopkins et al., 2006; Jackson et al., 2017; Jackson et al., 2018; Kapp & Annells, 2010; Langemo et al., 2000; McGinnis et al., 2015), six studies (8 records, 8.9%) related to malignant wounds (Alexander, 2010; Lo et al., 2008; Lund-Nielsen et al., 2005a, 2005b; Lund-Nielsen et al., 2011; Piggin & Jones, 2007; Probst et al., 2013a; Probst et al., 2013b), and six studies (7 records; 7.8%) related to open surgical wounds (Andersson et al., 2010; Dudley et al., 2017; McCaughan et al., 2018; Monsen et al., 2017; Neal, 2015; Tanner et al., 2012; Tanner et al., 2013). Six studies (6 records; 6.7%) (Abbotts, 2010; Bolas & Holloway, 2012; Fagerdahl, 2014; Fagerdahl et al., 2013; Lindahl et al., 2007; Ottosen & Pedersen, 2013) included participants with various types of wounds (open surgical wounds, ulcers of various aetiology, and others). One study included participants with leg ulcers of arterial aetiology (Pagliaro Borges Soares et al., 2013).

When looking at types of complex wounds in reviews or synthesis studies, we found that eleven reviews predominantly included studies of participants with lower extremity ulcers of venous, arterial and mixed or diabetic aetiology (Briggs & Flemming, 2007; Fearns et al., 2017; Franks & Morgan, 2003; González-Consuegra & Verdú, 2011; Goodridge et al., 2005; Green et al., 2014; Green & Jester, 2009; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018; Taverner et al., 2011). Only two reviews (Gorecki et al., 2009; Gorecki et al., 2011) included primary studies of patients with pressure ulcers.

In Table 2, the numbers of records identified are compared according to prevalence by subtype of complex wounds. There is a general congruence between prevalence of wound subtypes and the frequency with which subtypes have been studied; however, open surgical wounds are addressed by only a small number of studies despite their relatively high prevalence. Six studies (Abbotts, 2010; Bolas & Holloway, 2012; Fagerdahl, 2014; Fagerdahl et al., 2013; Lindahl et al., 2007; Ottosen & Pedersen, 2013) which included a sample of mixed types of complex wounds are not included.

Table 4.2: Comparing epidemiological data with number of records identified.

Prevalence data from epidemiological studies		Number of records identified	
Wound type	Prevalence per 1,000 of population	Records of reviews or synthesis studies	Records of primary studies
Leg ulcers (Venous, Arterial, Mixed)	0.44[1]	11	11
Venous leg ulcers	0.29[1]	0	32
Arterial leg ulcers	0.05[1]	0	1
Pressure ulcers/injuries	0.33[1]	2	10
Foot ulcers related to diabetes	0.13[1]	0	15
Malignant fungating wounds	0.02[1]	0	8
Open surgical wounds	0.38[2]-41[3]	0	7

Data source: [1]Hall et al., 2014; [2]Pađen et al., 2019; [3]Chetter et al., 2017.

Nature and variety of included review/synthesis studies

We identified a total of thirteen review/synthesis studies, five were classified as systematic literature reviews with or without synthesis of qualitative studies (Gorecki et al., 2009; Green et al., 2014; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018). Three out of thirteen were classified as meta-synthesis or qualitative evidence synthesis (Briggs & Flemming, 2007; Fearns et al., 2017; Taverner et al., 2011), one as mixed-method systematic review (Gorecki et al., 2011) and one as an integrative review (González-Consuegra & Verdú, 2011). Three of the included papers (Franks & Morgan, 2003; Goodridge et al., 2005; Green & Jester, 2009) were classified as review articles with no specific details. Eight reviews included qualitative and quantitative evidence (Franks & Morgan, 2003; González-Consuegra & Verdú, 2011; Goodridge et al., 2005; Gorecki et al., 2009a; Gorecki et al., 2011; Green et al., 2014; Herber et al., 2007; Persoon et al., 2004). The number of included primary studies varied from two to twenty qualitative studies in various geographical locations and populations. Further details on objectives, information sources, settings and populations of the studies included in the reviews and findings are in Table 3.

Table 4.3: Characteristics of included review/synthesis studies.

Author details; year of publication	Review type and objectives	Information sources	Included settings	Included populations (sample size)	Included wound type (definition)	The number of included qualitative studies or mix method studies	Funding
Briggs et al., 2007,	Synthesis of qualitative research Review and synthesis of qualitative studies which have focused on living experience of having open leg ulcer	MEDLINE (r) (1995-2005), CINAHL (1982-2005), EMBASE (1980-2005), ASSIA (1985-2005), Social Science Citation Index (1985-2005), British Nursing Index (1985-2005), PsychINFO (1985-2005)	Not reported	Not reported	Leg ulcer (venous, arterial, mixed)	12 qualitative studies were included into review.	not reported
Person et al., 2003	Systematic literature review To gather information about the impact of leg ulcers on patient's daily life as described in quantitative and qualitative studies.	From 1985 to 2002 MEDLINE, CINAHL Reference lists from obtained studies	Qualitative studies: UK (n=4), New Zealand (n=1), Australia (n=1), USA (n=2).	Sample 4-37	Venous (n=4) or not clear (n=4)	Synthesis of 14 surveys, 6 longitudinal studies, 9 experimental studied and 8 qualitative studies.	not reported
Gorecki et al., 2009	Systematic literature review and meta synthesis To identify the impact of pressure ulcers and	From inception to 2008 AMED, British Nursing Index, MEDLINE, Embase, PsycINFO, CINAHL, Cochrane Library, Proquest, Networked Digital Library of Theses	Across Europe, United States, Asia, Australia (number of each is not reported	Sample of 5-468	Pressure ulcer of grade 1 or higher (EPUAP, 1999)	10 qualitative studies and 21 quantitative study	

Author details; year of publication	Review type and objectives	Information sources	Included settings	Included populations (sample size)	Included wound type (definition)	The number of included qualitative studies or mix method studies	Funding
	pressure ulcer intervention on health-related quality of life.	and Dissertations, International Theses in Progress, Theses Canada Portal, Australian Digital Theses Program, and Index to Theses. Specialist journals and relevant conference proceedings were hand searched, 15 experts were contacted, the UK National Research Register was searched, the Internet was searched for PU self-help Web sites, and a citation search was performed on all included studies and systematic reviews identified in the search					
Herber et al., 2007	Systematic review To analyse journal articles that describe or measure the impact of leg ulceration on patient's quality of life in order to improve the content of an educational programme that aims to enhance self-	From 1982 (1990) to January 2006 MEDLINE, CINAHL Hand search of journals: Journal of wound care Journal of Clinical Nursing Advances in Skin and Wound Care Reference lists	Qualitative studies: New Zealand (n=1), UK (n=7), USA (n=2), Sweden (n=1), Australia (n=1), Germany (n=1)	Sample 4-55 patients	Leg ulcers (venous ulcers (n=7), various stages of chronic venous insufficiency (n=1), different leg ulcer aetiologies (n=4), not reported (n=1)	13 qualitative studies, 13 quantitative studies	Not reported

Author details; year of publication	Review type and objectives	Information sources	Included settings	Included populations (sample size)	Included wound type (definition)	The number of included qualitative studies or mix method studies	Funding
	care agency in leg-ulcer patients	Authors contacted field experts					
Taverner et al., 2011	Meta-synthesis of qualitative studies Investigate the experience of chronic painful leg ulceration	From 1990 to 2011. Medline, EMBASE, CINAHL, PsychINFO	UK (n=9), Sweden (n=1), Australia (n=1), USA (n=2)	sample of 6-39 patients	Venous leg ulcers (n=9), leg ulcers - aetiology not reported (n=4)	13 qualitative studies	Not reported
Green et al., 2009	Research review - not clear To identify the studies that investigated HRQoL and venous leg ulceration.	Not reported	Not clearly reported - Sweden (n=1), Australia (n=1), others not clear	not clearly reported - 5-37 patients	not clearly reported: venous leg ulcers (n=7), leg ulcer - aetiology not clear (n=1)	8 qualitative studies	Not reported
Green et al., 2014	Systematic review To explore the factors that impact on the quality of life of patients with chronic venous leg ulceration.	From 1990 -to 2013. MEDLINE, CINAHL, BNI, EMBASE; PsychINFO, AMED and HMIC. Cochrane Collaboration database and Google Scholar.	UK (n=6), NZ (n=1), Sweden (n=1), USA (n=1), Australia (n=1), Ireland (n=1)	Sample of 4-15 patients	Venous leg ulcer (n=9), aetiology not clear (n=2)	11 qualitative studies, 12 quantitative studies	Study was funded by West Midlands Strategic Health Authority
Fearns et al., 2017	Qualitative evidence synthesis	From 1990 to 2014, MEDLINE, MEDLINE in Process,	UK (n=11), USA (n=4), Norway (n=2), Sweden	Not reported.	Leg ulcers (n=12), pressure ulcers (n=5), diabetic foot	20 qualitative studies	Funded by Scottish Government

Author details; year of publication	Review type and objectives	Information sources	Included settings	Included populations (sample size)	Included wound type (definition)	The number of included qualitative studies or mix method studies	Funding
	To explore patient's experiences of chronic wounds and determine improvements for clinical practice	EMBASE, CINAHL, PsychINFO. Review of reference lists.	(n=1), Australia (n=1), multiple sites in UK and Belgium (n=1)		ulcers (n=2), multiple types of chronic wound (n=1)		.
Franks et al., 2003	Review To review the existing evidence on the evaluation of health-related quality of life for patients suffering from chronic leg ulceration.	Time frame of search is not reported. CINAHL, MEDLINE, EMBASE.	UK (n=6), USA (n=3), Sweden (n=1), New Zealand (n=1), Australia (n=1)	Sample of 8-39 patients	Leg ulcers - aetiology not reported or clear (n=4), venous leg ulcers (n=6), Chronic wound - type not defined (n=1)	12 qualitative studies, 8 studies which reported on disease-specific tool development, 5 cross-sectional studies, 8 longitudinal and outcome studies.	Not reported
Goodridge et al., 2005	Literature review (not clear what type To review the available studies of HRQoL in diabetic patients with foot ulcers.	From August 1980 to August 2004. CINAHL, MEDLINE	UK (n=3), Norway (n=1), Sweden (n=1)	Sample 7-21 patients	Lower extremity ulcers (leg or foot) - aetiology not reported or clear (n=2), diabetic foot ulcer (n=3)	5 qualitative studies, 3 quantitative studies	Not reported
Gorecki et al., 2011	Mix-Methods Systematic Review To identify and	From inception to 2010. AMED, British Nursing Index, MEDLINE, Embase, PsycINFO, CINAHL and Cochrane Library	not reported, data were sourced from primary studies: UK (n=1), multiple	not reported, data were sourced from primary	Pressure ulcers of II-IV category (n=6)	6 qualitative studies, 4 quantitative studies	Financial support was provided by the National

Author details; year of publication	Review type and objectives	Information sources	Included settings	Included populations (sample size)	Included wound type (definition)	The number of included qualitative studies or mix method studies	Funding
	synthesize all research that obtained verbal patient reports of pressure ulcer pain.	(including the Central Register of Controlled Trials) In addition, the Web of Knowledge database was searched. A hand search of relevant conference proceedings and specialist journals was undertaken. In addition, dissertation abstracts were searched in: ProQuest Dissertations & Theses, Networked Digital Library of Theses and Dissertations, International Theses in Progress, Theses Canada Portal, Australian Digital Theses Program, Index to Theses, and Russian Academy of Sciences Bibliographies. Finally, a citation search was performed.	sites in UK and Belgium (n=1), USA (n=2), Canada (n=1)	studies: Sample of 8-35 patients			Institute for Health Research (NIHR) under its Programme Grants for Applied Research funding scheme (RP-PG-0407-10056).
Phillips et al, 2018	Systematic review of qualitative research To systematically identify, evaluate and synthesize qualitative research that examined the symptoms and health-related quality of life themes that are	From inception to November 2015. CINAHL, Embase, Medline, PsycINFO, Science Citation Index, Social Science Citation Index and ProQuest dissertations and theses, Additionally, reference lists of included studies and related reviews were examined and citation searches were	UK (n=8), USA (n=3), South Africa (n=1), Ireland (n=1)	Sample of 4-38 patients	Venous leg ulcer	13 qualitative studies in 16 papers	Funded by the National Institute for Health Research NIHR under the Programme Grants for

Author details; year of publication	Review type and objectives	Information sources	Included settings	Included populations (sample size)	Included wound type (definition)	The number of included qualitative studies or mix method studies	Funding
	important from the perspective of patients with venous leg ulceration	conducted.					Applied Research programme (RPPG-1210-12009).
González-Consuegra et al., 2011	Integrative review To explore the impact of venous leg ulcers on health-related quality of life and analyse the quality of life instruments that have been used for this topic	From 2003 to 2008. MEDLINE (through PubMed and Webspirs), PsycINFO, COCHRANE, CINAHL, LILACS (Latin-American and Caribbean Information Centre for Health Sciences), FECYT (Fundacio´n Espan˜ ola para la Ciencia y la Tecnologı´a), EMBASE (Excerpta Medica Database) and CUIDEN	UK (n=3)	Sample of 8 - 38	Venous leg ulcer	2 qualitative, 1 mixed method, 19 quantitative	No specific funding

Nature and variety of included primary studies

The majority of study designs were qualitative (85 records, 94.4%), five of studies were mixed method (qualitative and quantitative) studies (Bradbury & Price, 2011; Jackson et al., 2017; Jackson et al., 2018; Flanagan et al., 2006; Lund-Nielsen et al., 2005b). The philosophical background or theoretical approach of the studies was described in various ways. Hermeneutic was the most frequent description (18 records, 20%) (Alexander, 2010; Bale et al., 2007; Byrne & Kelly, 2010; Ebbeskog & Ekman, 2001; Edwards, 2003; Hopkins, 2004; Hopkins et al., 2006; Jones et al., 2008; Kapp & Annells, 2010; Kirupa, 2014; Krasner, 1998; Lernevall et al., 2017; Lindahl et al., 2007; Ottosen & Pedersen, 2013; Piggin & Jones, 2007; Probst et al., 2013a; Watson-Miller, 2006; Wellborn & Moceri, 2014), followed by phenomenology (14 records, 15.6%) (Ashford et al., 2000; Bolas & Holloway, 2012; Brown, 2005a, 2005b; Charles, 1995; Chase et al., 1997; Dudley et al., 2017; Fox, 2002; Green et al., 2013; Kinmond et al., 2003; Langemo et al., 2000; Lund-Nielsen et al., 2011; Rich & McLachlan, 2003; Walshe, 1995), grounded theory (8 records, 8.9%) (Barg et al., 2017; Brown, 2010; Douglas, 2001; Husband, 2001; Lo et al., 2008; Taverner et al., 2014; Van Hecke et al., 2013; Cipolletta & Amicucci, 2017), descriptive approach (5 records, 5.6%) (Andersson et al., 2010; Hyde et al., 1999; McCaughan et al., 2018; Pagliaro Borges Soares et al., 2013; Zhu & Kath, 2017), ethnography (4 records; 4.4%) (De Vera, 2003; Lewis, 2007; Neal, 2015; Parry et al., 1996), interpretative phenomenological analysis (2 records; 2.2%) (Probst et al., 2013b; Wellborn & Moceri, 2014), phenomenography (2 records; 2.2%) (Fagerdahl, 2014; Skavberg Roaldsen et al., 2011), a pragmatic approach (1 record; 1%) (Morgan & Moffatt, 2008), and thematic framework (1 record; 1%) (McGinnis et al., 2015). A large number of the studies did not state their specific approach (33 records, 36.7%). Eight studies (9 records; 10%) were designed as longitudinal (Brod, 1998; Chase et al., 1997; De Vera, 2003; Fagerdahl et al., 2013; Hopkins, 2004; Hyde et al., 1999; Lernevall et al., 2017; Lund-Nielsen et al., 2005a, 2005b). Tables 4-11 describes further specifics of included studies, namely: aims, study location, data collection technique, data analysis approach, sampling strategy, participants and sample size.

Table 4.4: Studies included a sample of people with foot ulcers related to diabetes.

	Author, Year, Location	**Aim of the study**	**Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
1	**Ashford et al., 2000, UK**	To uncover the quality of life issues patients have regarding their diabetic foot ulcer.	Phenomenology/ semi structured, conversational interviews/ not clear	Not clear	21	49-75; F: 6, M: 15
2	**Barg et al., 2017, USA**	To explore perceptions among people with type 2 diabetes about foot ulcers and lower extremity amputations.	Integrated approach using grounded theory/ open-ended semi-structured interview/ integrated approach for data analysis	Purposive	39	Average 60.9 years (SD 13.9), F:15, M:24
3	**Bradbury et al., 2011a*, UK**	To explore the effect of specific diabetic foot ulcer pain on life quality from the patient's perspective.	Qualitative study/ semi-structured interviews/thematic content analysis	Purposive	3	71-86, F:1, M:2
4	**Bradbury et al., 2011b*, UK**	To explore effects of diabetic foot ulcer pain on everyday life.	2 phases, 1 phase quantitative, 2nd phase qualitative/ Semi structured interviews/ Thematic content analysis (Burnad, 1991),	Purposive	3	71-86, F: 1, M:2
5	**Kinmond et al., 2002, UK**	To address psychosocial health related quality of life issues for patients living with diabetic foot ulceration.	Phenomenological approach/ semi-structured, conversational interviews/ interpretative phenomenological analysis	Not clear	21	mean age for men (58.4), mean age for female (59.4), M:15, F:6
6	**Kirupa, 2014, India**	To explore the experiences of patient living with a chronic leg ulcer and describe the patient experiences related to care of chronic leg and foot ulcer.	Interpretive phenomenology/interview with open-ended questions/data analysis by using Moustakas (1994) method.	Purposive	6	not reported, F:5, M:1
7	**Watson-Miller, 2006, UK**	To explore participants' experience with diabetic foot ulceration in Bermuda	Hermeneutic phenomenology/unstructured interviews/ Data analysis was inspired by Burnard (1991) and thematic content analysis	Purposive	6	28-66, F:3, M:3
8	**Fox, 2005,**	To explore the experiences of people living with diabetic	Qualitative study/In-depth semi-structured open-	Not reported	10	40-70, F:4, M:6

	Author, Year, Location	Aim of the study	Design, Data collection technique, Data analysis approach	Sampling strategy	Sample size	Age (years) and gender (F-female, M-male) of participants
	Canada	foot ulcer, in order to better understand the day-to-day challenges, they face, and to develop recommendations for improving support.	ended interviews/Data was analysed thematically			
9	**Searle et al., 2005, UK**	To explore the experience of foot ulceration and treatment from the perspective of both patients and podiatrists.	Qualitative study/Interview/Constant Comparison Analysis	Non-theoretical	13	45-66, F:4, M:9
10	**Chadwick, 2002, UK**	To explore the health knowledge, beliefs, behaviours and decisions of people with Type 2 diabetes who ulcerate for the first time.	Qualitative study/semi-structured interviews/Data were analysed for themes and content.	Convenience	8	not reported, not reported
11	**McPherson et al., 2002, UK**	To examine the perceptions of patients with diabetes regarding their chronic foot ulcer.	Qualitative study/Focus group interview/Thematic analysis	Not clear	4	not reported, F:0, M:4
12	**Parry et al., 1996, USA**	To investigate health beliefs related to diabetes and care of ulcers in an African American population with Type 2 diabetes.	Ethnography/interview/Data analysis followed two strategies of coding	Not clear	20	2 subjects under 40, 4 subjects between 40-50, 7 subjects between 50-60 and 7 subjects between 60-70 years, F:13, M: 7
13	**Ribu et al., 2004, Norway**	To illuminate the significance of patient's experiences with regard to living with lower extremity ulcers and diabetes.	Qualitative study/In-depth interviews/Thematic and meaning analysis (Kvale, 1997).	Not reported	7	21-83, F:3, M:4
14	**De Vera, 2003, USA**	To describe the perspectives of Yaqui Native Americans with diabetes regarding biomedical and traditional methods for healing foot ulcers.	Ethnographic approach/Participant observation, in-depth interviews, field notes/Ethnographic data analysis	Purposive	4	58-76, F:3, M:1
15	**Delea et al., 2015,**	To explore the attitudes and experiences of foot care services in Ireland among people with diabetes and	Qualitative study/Semi-structured interviews/ Inductive Thematic Analysis	Purposive	10	40-72, F:0, M:10

	Author, Year, Location	Aim of the study	Design, Data collection technique, Data analysis approach	Sampling strategy	Sample size	Age (years) and gender (F-female, M-male) of participants
	Ireland	active foot disease or lower limb amputations.				

*Same study, more reports. Confirmed by author.

Table 4.5: Studies included a sample of people with malignant fungating wounds.

	Author, Year, Location	Aim of the study	Type, Design, Data collection technique, Data analysis approach	Sampling strategy	Sample size	Age (years) and gender (F-female, M-male) of participants
1	**Alexander, 2010, Australia**	To present the totality of the experience from the perspective of those living it.	Hermeneutic phenomenology/ Unstructured open-ended interviews/ Thematic analysis	Purposive	3	56-87, F: 2, M: 1
2	**Lo et al., 2008, Taiwan**	To explore the experience of cancer patients living with a malignant fungating wound.	Grounded theory - pragmatic approach/Semi structured interviews/Thematic analysis	Purposive	10	42-72, F:6, M:4
3	**Lund-Nielsen et al. 2011, Denmark**	To describe the experience of health care avoidance in women with advanced breast cancer who have developed malignant wounds.	Descriptive phenomenological approach/ semi-structured in-depth interviews/ 4-step analysis by Giorgi and modification of Malterud approach	Purposive	17	47-90, F: 17, M:6
4	**Lund-Nielsen et al., 2005a*, Denmark**	To investigate the way malignant fungating wounds affect femininity, sexuality and daily life in women with progressive breast cancer.	Qualitative study/semi-structured interviews/thematic analysis	Part of larger study	12	57–85, F:12

5	**Lund-Nielsen et al., 2005b*, Denmark**	To investigate the experience of women with advanced breast cancer who have a malignant fungating wound and to test the benefits of a structured, evidence-based, management regimen, combined with psychosocial support.	Qualitative and quantitative study/Semi-structured interviews/Theme analysis	Part of larger study	12	57–85, F:12
6	**Piggin et al, 2007, UK**	To illuminate the meaning and experience of living with a malignant fungating wound.	Heideggerian hermeneutic phenomenology/Unstructured interviews/ Content hermeneutic analysis	Purposive	5	not reported, F:5
7	**Probst et al., 2013a*, Switzerland**	To understand the lived experiences of patients with malignant breast wound and their informal carers.	Interpretative phenomenological analysis/ Semi-structured interviews/Van Manen approach (1990)	Purposive	9	40-76, F:9
8	**Probst et al., 2013b*, Switzerland**	To explore how women with a malignant fungating wounds on the breast cope at home.	Heidegger's hermeneutic phenomenology/ Semi-structured interviews/ interpretative approach	Purposive	9	40-76, F=9

*Same study, more reports. Confirmed by author.

Table 4.6: Studies included a sample of people with open surgical wounds.

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
1	**Andersson et al., 2010, Sweden**	To elicit and evaluate patient's experiences associated with acquiring a deep surgical site infection.	Descriptive design/ Open ended interviews/Content analysis	Not clear	14	Not clear - <40, >65, F:5, M:9
2	**Dudley et al., 2017, UK**	To explore women's lived experiences of a dehisced perineal wound following childbirth and how they felt participating in a pilot and feasibility randomised controlled trial.	Husserls Phenomenology/ semi structured interviews/Giorgi framework	Purposive	6	20-38, F:6

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
3	**McCaughan et al., 2018, UK**	To explore patients' views and experiences of living with a surgical wound healing by secondary intention.	Descriptive approach/semi-structured interviews/thematical analysis using framework approach	Purposive	20	19-76, F:11, M:9
4	**Monsen et al., 2017, Sweden**	To explore experiences of negative pressure wound therapy at home, in patients with deep perivascular groin infection after vascular surgery and management in daily life.	Explorative qualitative interview study/semi structured interview/Conventional content analysis	Purposive	15	62-84, F:6, M:9
5	**Tanner et al., 2013*, UK**	To obtain information from patients' experiences of surgical site infections to improve clinical practice.	Qualitative study/Narrative-based interviews/Thematic content analysis	Not clear	17	30-79, F:8, M:9
6	**Tanner et al., 2012*, UK**	To provide an in-depth understanding of the lived experience of suffering an surgical site infections.	Qualitative study/Unstructured interviews/Thematic analysis	Not clear	17	30-79, F:8, M:9 confirmed by author
7	**Neal, 2015, UK**	To establish the effect that wound had on the rehabilitation of traumatic amputees from military patient perspective.	Ethnography/Semi-structured interviews/ Coding framework (Miles and Huberman, 1994) and using 3-phase methods (Strauss and Corbin, 1988)	Not clear	10	23-30, M:10

*Same study, more reports. Confirmed by author.

Table 4.7: Studies included a sample of people with pressure ulcers.

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
1	**Fox, 2002, UK**	To examine patients' experiences of pressure ulcers.	Descriptive phenomenological/ semi-structured interviews/content analysis (Burnard, 1991)	Purposive	5	30-64, F:1, M:4
2	**Gorecki et al., 2010*, UK**	To develop a conceptual framework of health-related quality of life in pressure ulcers, based on patients' views about the impact of pressure ulcers and interventions on health-related quality of life to inform the development of a new patient-reported outcome measure.	Qualitative study/Semi structured interviews/ Ongoing analysis and thematic analysis	Purposive	30	22-94, F:12, M:18
3	**Gorecki et al., 2012*, UK**	To identify and define contributory factors that affect PU-related health related quality of life and explore patterns of association between health related quality of life and contributory factors.	Qualitative study/ Semi structured interview/ Five stage framework analysis	Purposive	30	22-94, F:12, M:18
4	**Hopkins et al., 2006**, UK and Belgium**	To explore lived experience of older patients with pressure ulcers.	Heideggerian phenomenology/Unstructured interviews/ Interpretative phenomenological analysis	Purposive	8	67-101, F:5, M:3
5	**Bale et al., 2007**, UK and Belgium**	To explore the older persons experience of having grade 3 or 4 pressure ulcer that had been present for longer than a month and to test the methodology and study design.	Heideggarian phenomenology /Unstructured interviews/Interpretative phenomenological analysis	Not clear	8	68-101, not clearly reported (F:5, M:3)
6	**Kapp et al., 2010, Australia**	To discern both commonalities and uniqueness of human experience.	Hermeneutic phenomenology (Van Manen aproach)/Unstructured in-depth interviews/Thematic analysis	Purposive	7	aged 65 years and older (mean = 73 years), F: 3, M: 4

	Author, Year, Location	Aim of the study	Type, Design, Data collection technique, Data analysis approach	Sampling strategy	Sample size	Age (years) and gender (F-female, M-male) of participants
7	**McGinnis et al., 2015, UK**	To explore the views and opinions of patients with multiple sclerosis who have a pressure ulcer and compare these to the general pressure ulcer population	Thematic framework/Semi-structured interviews/Thematic framework	Purposive	6	48-61, F:5, M:1
8	**Jackson et al., 2018*, UK**	To report findings on patient's experiences and perceptions of loss associated with pressure injury.	Mix-methods study/Interviews/Thematic content analysis	Convenience	12	31-92, F:9, M:3
9	**Jackson et al., 2017*, UK**	To provide rich, narrative accounts of pain associated with pressure injury, derived from in-depth qualitative interviews from people with experience of living with pressure injury in their own homes.	Mix-methods study/Interviews/Thematic content analysis	Convenience	12	31-92, F:9, M:3
10	**Langemo et al., 2000, USA**	To identify themes related to the experience of having a pressure ulcer.	Phenomenology (Spiegelberg 1975)/Unstructured interview/Content analysis (Colaizzi method)	Nonprobability purposive	8	27-52, F:1, M:7

*Same study, more reports. Confirmed by author in report. ** Same study, more reports, confirmed in report.

Table 4.8: Studies included a sample of people with venous leg ulcers.

	Author, Year, Location	Aim of the study	Type, Design, Data collection technique, Data analysis approach	Sampling strategy	Sample size	Age (years) and gender (F-female, M-male) of participants
1	**Ebbeskog et al., 2001*, Sweden**	To illuminate elderly persons experiences of living with venous leg ulcer.	Phenomenological-Hermeneutics (Ricoeur)/interview/Qualitative content analysis	Purposive	15	74-89, F:12, M:3

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
2	**Ebbeskog et al., 2005*, Sweden**	To describe the lived experiences of older patients with venous leg ulcers, during dressing changes as out patients with a focus of their concerns about care interventions.	Qualitative study/ research interviews/Interpretative phenomenological analysis	Purposive	15	74-89, F:12, M:3
3	**Skavberg Roaldsen et al., 2011, Sweden**	To identify and describe how physical activity is perceived and understood by individuals with current or previous venous leg ulcer.	Phenomenography/Semi-structured interviews/ Phenomenographic analysis procedure described by Dahlgren and Fallsberg	Not clear	22	60-85, F:13, M:9
4	**Van Hecke et al., 2013, Belgium**	To explore knowledge/ information deficits and underlying processes in (information) seeking behaviour in patients with venous leg ulcers..	Grounded theory/Semi-structured interview/Analysis guided with grounded theory	Not clear	15	40-59: 5 patients, 60-79: 5 patients 80 or more 5 patients, F:10, M:5
5	**Brown, 2010, UK**	To the findings of the qualitative phase and make recommendations for practice.	Grounded theory/Focus groups/Cyclical data analysis process of grounded theory	Purposive	28	60 and over, not clear
6, 7	**Brown, 2005a,b, UK**	To explore whether the presence of a chronic venous leg ulcer impacts negatively on a patient’s social life, and to determine whether the ‘Knitting Needle syndrome ‘actually exists.	Phenomenology (Husserl)/Semi-structured in-depth interviews/Common themes were described	Purposive	8	65 and over, not clear
8	**Chase et al., 1997, USA**	To determine the lived experience of healing a venous ulcer for patients treated in an ambulatory surgical clinic.	Phenomenology/ Interviews and field notes/ Van Manen approach	Not clear	7	not clear, not clear
9	**Douglas, 2001, UK**	To explore and describe patients’ feelings about and their experiences of venous leg ulceration.	Grounded theory/Unstructured and semi-structured interviews and recording non-verbal behaviour and personal and intuitive feelings in diary/Grounded theory	Purposeful homogeneous	8	65-94, F:6. M2

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
10	**O'Brien et al., 2014, Australia**	To gain an understanding of the perspectives of adults with venous leg ulcer, in relation to exercise.	Qualitative study/Semi-structured discussions with groups and individual interviews/Thematic content analysis	Purposive convenience	10	66-87, F:5, M:5
11	**Edwards, 2003, UK**	To explore the perceptions of patients presenting with venous leg ulceration who were labelled as 'non-compliant' with compression bandaging by district nurses.	Heidiggerian Hermeneutics/Non-directive - open Interviews/Structured analysis (Dielkelmann et al's (1989))	Purposive	14	50-96, F: 13, M:1
12	**Green et al., 2013*, UK**	To explore the impact on the daily lives of people with chronic venous leg ulcers.	Phenomenology/Unstructured interviews/ Thematic analysis	Purposive	9	39-99, F:5, M:4
13	**Green et al., 2018*, UK**	To explore the lived experiences of patients with leg ulcers and the impact of this condition on their quality of life.	Qualitative study/Unstructured interviews/ Thematic analysis (Braun and Clark, 2006)	Two-stage approach	9	39-99, F:5, M:4
14	**Hopkins, 2004, UK**	To investigate how people with non-healing venous leg ulcers live and cope with this chronic condition.	Hermeneutic phenomenology/ Unstructured interviews and diary/ Interpretative phenomenological analysis	Purposive	5	47-78, F:1, M:4
15	**Husband et al., 2001, UK**	To explore the patient's experience of venous ulceration and how it is shaped within primary care.	Grounded theory/in-depth interview/constant comparative process of data analysis	Purposive	39	not clear (average of men = 67, women =74), F:35, M:4
16	**Jones et al., 2008, UK**	To elicit stories of the individuals' experiences of living with chronic venous ulceration, and to 'generate' meaningful descriptions.	Hermeneutic phenomenology/Unstructured interviews/Data analysis using Colaizzi (1978) and Van Manen (1990)	Purposive	20	52-86, F:12, M:8
17	**McCaughan et al., 2013 (2015), UK**	To explore patients' experiences of venous leg ulceration and of the acceptability of larval therapy as a treatment.	Qualitative study/In-depth interviews/Framework approach to analysis	Purposive,	18	29-93, F:6, M:12
18	**Mudge et al., 2006, UK**	To explore patients' understanding of adherence in terms of their experiences of compression bandage systems for the	Focus group study/Focus group semi structured format/content analysis (Stemler,	Purposive, part of larger study	6	64-86, F:4, M:2

	Author, Year, Location	Aim of the study	Type, Design, Data collection technique, Data analysis approach	Sampling strategy	Sample size	Age (years) and gender (F-female, M-male) of participants
		treatment of chronic venous leg ulceration.	2001)			
19	**Palfreyman et al., 2007, UK**	To examine, from the perspective of patients, the impact of venous leg ulcers on health-related quality of life and to explore differences in impact between current and former intravenous drug users and the general population.	Qualitative study/Semi-structured interviews/ Framework analysis	Purposive	19	27-79, F:5, M:14
20	**Rich et al., 2003, UK**	To explore patients' perceptions of living with leg ulcers.	Phenomenology/semi-structured interviews/analysis approach is not clear	Purposive	4	55-89, F:1, M:3
21	**Stevens, 2006, UK**	To explore the psychosocial effects of pain that a person living with compromised tissue viability and their family may experience.	Qualitative study/In-depth interview/not clear	Not clear	1	not clear, F:1
22	**Walshe, 1995, UK**	To explore and describe the experience of living with venous leg ulcer from patient perspective.	Phenomenology/unstructured interviews/ Phenomenology approach (Swanson-Kaufmann & Schonwald Aproach)	Purposive	13	Elderly, half of participants aged over 85 years, F:12, M:1
23	**Wellborn et al., 2014, USA**	To describe the lived experience of chronic venous insuffiency sufferers and to explore how this chronic disease affected their health-related quality of life.	Interpretive phenomenological analysis/ one on one interviews or focus group/ Interpretive phenomenological analysis	Convenience	10	mean age was 66, F:6, M:4
24	**Zhu et al., 2017, Singapore**	To gain deep insight into the experiences of patients living with chronic leg ulcer from their perspective.	Exploratory descriptive design employing thematic analysis/ semi-structured interviews/data was analysed thematically using constant comparison.	Purposive maximum variation	8	38-86, F:4, M:4
25	**Cezar da Silva et al, 2015, Brazil**	To identify the experiences constructed by people with venous ulcers, in the process of living with this chronic condition	Qualitative study/Semi-structured interview/Content analysis technique.	Not clear	14	47-79, F:9, M:5

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
26	**Flanagan et al., 2006, Denmark**	To profile the characteristics and experience of individuals suffering from painful venous leg ulceration. To describe the experience of having a painful chronic venous leg ulcer treated with a foam dressing releasing ibuprofen.	Quantitative and Qualitative study/Case series/Semi-structured interviews/Data analysis based on principles of reduction and interpretation	Purposive	10	45-86, F:5, M:5
27	**Byrne et al., 2010, Ireland**	Not clear (Lived experience of venous leg ulcer and its effect on patients' lives).	Phenomenology (Heidegarian hermeneutic)/Unstructured interview/Giorgi thematic analysis framework for data analysis	Not reported	not reported	not reported, not reported
28	**Krasner, 1998, USA**	To describe and explore the meaning of the experience of living with painful venous ulcers.	Heideggerian hermeneutic phenomenology/In-depth interviews/ Phenomenological analysis (Dikelmann 1996)	Purposive	14	30-86, F:7, M:7
29	**Walburn et al., 2012, UK**	To explore the negative emotions associated with living with an ulcer and investigated the factors that underpinned this distress.	Qualitative study/In-depth semi-structured interviews/Thematic analysis (Framework analysis)	Part of prospective quantitative study	14	not reported, not reported
30	**Mudge et al., 2008, UK**	To collect data from the patients to inform the development of questionnaire that could be used to collect data on patients wound-related pain experience globally.	Focus group study/Focus group semi structured format/content analysis (Stemler, 2001)	Purposive (Systematic, non-probabilistic	6	not clear, not clear
31	**Charles, 1995, UK**	To ascertain the physical, psychological and social effects of living with a leg ulcer.	Phenomenology/Interview/Data analysis using Giorgi approach (1985)	Not reported	4	not reported, F:1, M:3
32	**Cipolletta et al, 2017, Italy**	To differentiate among patients' experiences, by analysing personal, social and relational dimensions related to leg ulcer onset and to the care process.	Grounded theory (Glaser and Strauss, 1967; Strauss and Corbin, 1998)/Semi-structured interviews/Analysis guided by grounded theory	Purposive	21	27-78, F:12, M:9

Table 4.9: Studies included a mixed sample of people with leg ulcers of venous, arterial, mixed aetiology or sample of people with leg ulcers of other aetiology.

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
1	**Lewis, 2007, UK**	To examine the lived experience and cultural illness explanations of a sample of British- Indian patients living with leg and foot ulceration.	Ethnography/ Semi-structured interviews/ Green's (1999) framework	Not clear	16	25-84, F:4, M:12
2	**Taverner et al., 2014, UK**	To develop a grounded theory to describe and explain the experience of pain and its impact, as reported by individuals who had pain associated with chronic leg ulceration.	Grounded theory - Strauss and Crobin (1990)/Semi structured interviews/grounded theory approach	Purposive	11	68-100, F:9, M:2
3	**Haram et al., 2003, Norway**	To investigate patients' experience of wound care, with the premise that taking into account the patient perspective can improve treatment and adherence.	Qualitative study/Open-ended interviews/ Martinsen's theoretical framework	Not clear	9	60-96, F:5, M:4
4	**Lernevall et al., 2017, Denmark**	To investigate how patients suffering from arterial or mixed leg ulcers experience their everyday.	Hermeneutic phenomenology/ Semi structured interviews and focus groups/ Dreyer's Ricoeur inspired method of analysis	Purposive	6	61-72, F:2, M:4
5	**Firth et al., 2013*, UK**	To explore participants' experiences of healthcare provision relating to ulcer management.	Qualitative study/ In-depth interviews/Framework - matrix based analytic method (Ritchie et al., 2003)	Purposive	23	45-88, F: 17, M:6
6	**Firth et al., 2011*, UK**	To explore the added impact of foot ulceration on health-related quality of life in non-diabetic patients with rheumatoid arthritis.	Qualitative study/In-depth interviews/Framework - matrix based analytic method (Ritchie et al., 2003)	Purposive	23	45-88, F: 17, M:6

7	**Madden, 2015, UK**	To explore the impact of footwear, bandaging and hosiery interventions in the everyday lives of women and men undergoing treatment for chronic, complex wounds	Qualitative study/Semi-structured interviews/ Inductive Thematic Content Analysis	Iterative sampling	19	21-97; F:11, M:8
8	**Hyde et al., 1999, Australia**	To focus on the experience of living with leg ulcers and to explore women's views by talking to them about their experiences	Descriptive approach/In-depth semi-structured interviews with 1 follow up interview/ Analysis followed Diekelmann et al. approach.	Not clear,	12	70-93, F:12
9	**Morgan et al., 2008, UK**	To explore the relationship between patients with non-healing leg ulceration and the nurses providing their care in a community setting.	Pragmatic approach/Semi-structured interviews/ Thematic analysis	Purposive	5	32-74, F:3, M:2
10	**Umeh et al., 2017, USA**	To provide a qualitative investigation into the impact leg ulcers have on the quality of life of individuals with sickle cell disease.	Qualitative study/Semi-structured interviews/ Analysis was done with coding the data and hierarchical coding	Not clear -	20	29-63, F:11, M:9
11	**Brod, 1998, UK**	To examine the impact of lower extremity ulcers on the quality of life of patients with diabetes and their care givers	Focus group study/Focus group/Data analysis approach is not clear.	Not clear	14	39-83, F:6. M:8

Table 4.10: Studies included a sample of people with leg ulcers of arterial aetiology.

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
1	**Pagliaro Borges Soares et al., 2013, Brazil**	To understand the meaning of quality of life from the perspective of patients and identify the impact of arterial ulcers on quality of life in the patients' perception.	Descriptive approach/ interview- semi structured interview/ content analysis (Bardin, 2010)	Not clear	10	30-81, F:4, M:6

Table 4.11: Studies included a mixed sample of people with different types of complex wounds.

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
1	**Fagerdahl, 2014, Sweden**	To describe the patient's conceptions of wound treatment with negative pressure wound therapy.	Phenomenographic approach/Non-structured interview/Phenomenographic approach	Purposive	8	20-73, F:2, M:6
2	**Fagerdahl et al., 2013, Sweden**	To describe the experience of patients with wounds treated with advanced moist wound therapy and negative pressure wound therapy.	Qualitative study/diary/Qualitative content analysis (Graneheim and Lundman)	Purposive sampling (part of RCT)	15	41-91, not clear
3	**Abbotts, 2010, UK**	To understand patient's perceptions and experiences of topical negative pressure.	Subtle realism/Focus group and individual interviews/Thematic analysis	Purposive	12	34-79, F: 7, M: 5

	Author, Year, Location	**Aim of the study**	**Type, Design, Data collection technique, Data analysis approach**	**Sampling strategy**	**Sample size**	**Age (years) and gender (F-female, M-male) of participants**
4	**Bolas et al., 2012, Ireland**	To understand patient experience and perceptions of using negative pressure therapy.	Phenomenology/Semi structured interviews/ Interpretative phenomenological analysis	Purposive	6	57-99, F: 4, M: 2
5	**Lindahl et al., 2007, Sweden**	To illuminate the meaning of living with malodorous, exuding ulcers	Hermeneutics - Ricoeur/Individual interview/ Ricoeur inspired method	Not clear	9	41-95, F:7, M:2
6	**Ottosen et al., 2013, UK**	To study patients' experiences of negative pressure wound therapy used for wounds of various aetiologies in the outpatient setting and the influences on daily life.	Phenomenological-hermeneutic framework/semi-structured interviews/Ricoeur inspired method	Purposive	10	29-71, F:5, M:5

4.3.4 Study funding

There was no funding source explicitly reported (or the funding was not clear) for 49 (54.4%) of the total of 90 records. Thirty-two out of 90 records stated funding from non-commercial sources, such as institutes for research, hospital funds, university grants and charity (Abbotts, 2010; Bale et al., 2007; Barg et al., 2017; Brown, 2010; Chase et al., 1997; Dudley et al., 2017; Ebbeskog & Ekman, 2001; Fagerdahl, 2014; Firth et al., 2011; Fox, 2005; Gorecki et al., 2010; Gorecki et al., 2012; Green et al., 2013; Haram & Dagfinn, 2003; Hopkins et al., 2006; Jackson et al., 2017; Jackson et al., 2018; Lindahl et al., 2007; Lo et al., 2008; Madden, 2015; McCaughan et al., 2015, 2018; Mudge et al., 2008; Mudge et al., 2006; Palfreyman et al., 2007; Ribu & Wahl, 2004; Rich & McLachlan, 2003; Searle et al., 2005; Skavberg Roaldsen et al., 2011; Tanner et al., 2012; Tanner et al., 2013; Umeh et al., 2017). Five records referred to funding wholly or partially from industry (Flanagan et al., 2006; Langemo et al., 2000; Lund-Nielsen et al., 2005a, 2005b; Taverner et al., 2014). The authors of three records explicitly declared that the study was not funded externally (Cipolletta & Amicucci, 2017; Ottosen & Pedersen, 2013; Probst et al., 2013a). Only four (Fearns et al., 2017; Gorecki et al., 2011; Green et al., 2014; Phillips et al., 2018) out of 13 reviews were reported to be funded, in particular, non-commercially, while others did not specifically explain their funding, or it was unclear.

4.4 DISCUSSION

4.4.1 Main findings

This scoping review aimed to explore and scope the published qualitative research about peoples' experiences of living with complex wounds, and to investigate, describe and map the extent, nature and variety of the evidence. We identified 90 records of 79 primary studies and 13 reviews or synthesis studies addressing people's perspectives of different types of complex wounds or wound-related symptoms in various contexts, e.g. users of different services and people in different geographical locations.

Size and geographical distribution of studies

Our findings indicate that the number of qualitative studies about complex wounds is increasing annually. One explanation might be that people perspectives and health-related quality of life have been recognised as a priority for further research (Cowman et al., 2012), or it may be a consequence of patient-need led research (Mader et al., 2018). Our study has also shown that the studies identified are mostly distributed across high-income countries, whereas there are only two studies from middle- and one lower-middle-income countries

(Brazil and India respectively) and none from lower-income countries. Exploring people's perspective of living with wounds in other countries might provide valuable information for health care professionals, as the accessibility of health services and care pathways and the potential barriers in treatments might have different impacts on people's well-being.

Studies by wound type

There is congruence between wound prevalence and the number of studies reflecting how much we understand the experience. On one hand, most of the studies were about the most frequent wound types, namely leg ulcers (Hall et al., 2014; Cullum et al., 2016; Gray et al., 2018). On the other hand, some types of complex wound, such as arterial leg ulcers and malignant wounds, are less researched, possibly due to their lower prevalence (Hall et al., 2014) and consequent lower research priority. Another reason for the unequal distribution of studies might reflect the fact that the prevalence and natural history of some types wounds have been studied in more depth only in very recent years, such as, for example, open surgical wounds, which are common (Hall et al., 2014; Chetter et al., 2017), yet people's perspective of living with them is under-researched.

Nature and characteristics of studies found

The primary studies and reviews/synthesis used a variety of methodological approaches, which can bring different understandings of a phenomenon. A large proportion of the primary studies used phenomenology and hermeneutics as their philosophical background, which matches the aims of the scoping review i.e. exploring what is like to live with complex wounds. Phenomenology and hermeneutics can provide substantial and comprehensive understanding of people's experiences of the phenomena (Nelms, 2015; van Manen, 1990). Furthermore, health care professionals can become more familiar with and aware of the complexity of phenomena and provide individually planned care. Grounded theory has also been used, albeit less often. Grounded theory provides the opposite understanding to phenomenology or hermeneutics. It is used to develop a theory through exploring the relationships between concepts and allows further hypothesising (Glaser, 1999, 2001, 2003). Although most studies stated that they used phenomenology, hermeneutics or grounded theory, slightly more than a third of the included studies did not state their philosophical approach. The reason for this might be that they employed a more pragmatic approach, using various methods of, for example, data collection (exploring “lived experience” and “process”), or, for data analysis, using approaches which are typically associated with certain philosophical approaches – but which, pragmatically, might be used complementarily (Johnson et al., 2001).

The review/synthesis studies identified had varied aims and objectives, which required the use of different approaches to identification, selection, assessment of risks related to the design of included primary studies, and reporting of findings. The majority of the review/synthesis studies were reported as systematic reviews, which are characterised by a systematic, complex and reproducible methodological process aiming to minimise bias when answering a study question (Cullum & Dumville, 2015). However, other methods, such as integrative reviews or meta-synthesis, were also used. An integrative review is a flexible method which integrates empirical evidence and theoretical literature and allows a comprehensive understanding of phenomenon (Whittemore & Knafl, 2005); however, it has been critiqued for low methodological rigour (Hopia et al., 2016). On the other hand, meta-synthesis studies usually include only individual qualitative studies, with the aim of generating a theory, reconceptualising an abstract phenomenon or carrying out an in-depth and over-arching analysis of a phenomenon (Atkins et al., 2008; Barnett-Page & Thomas, 2009; Toye et al., 2014; Walsh & Downe, 2005). Methodological considerations related to meta-synthesis studies have been the subject of ongoing debate, mainly concerning lack of clarity and rigour related to the method itself (France et al., 2014, 2019; Herber & Barroso, 2020; Thorne, 2017).

We also looked at some key features related to participant selection criteria, in particular the phenomenon of interest. The phenomenon of interest was most commonly reported by the studies; however the type of wound eligible for inclusion often lacked clear definition: for example, studies reported including people with leg or foot ulcers, without further explanation of aetiology (arterial, venous, mixed, related to diabetes, connective tissue disorders, etc.). Providing clear definitions might improve the credibility and transferability of the findings, as studies have suggested that the experience of having lower limb ulcers might differ based on aetiology; for example, wounds related to diabetes (Bengtsson et al., 2008; Bradbury & Price, 2011a; Ribu et al., 2006) are considered to be more painful than venous leg ulcers (Persoon et al., 2004). Furthermore, it might improve and ease the conducting of future synthesis studies, as reviews might want to answer more specific and narrower questions (related to specific phenomena or populations).

Variation was also noted in the number, age and gender of participants. The majority of studies included males and females aged from 19 to 101 (the outliers for all studies, regardless of type). However, a recent prevalence study by Hall et al. (2014) found that children and adolescents also seem to be affected by complex wounds (0.03 per 1,000 of population for age groups between 0 and 9, and 0.22 per 1,000 of population for age groups from 10-19). This could indicate the need to address the phenomenon in younger people as well.

Given that complex wounds are long-term conditions, we also looked at studies which employed a longitudinal design. Five approaches to data collection were reported as being used in these studies, namely: sequential focus groups (Brod, 1998), a focus group followed by an individual interview (Lernevall et al., 2017), an interview and written patient diary (Fagerdahl et al., 2013; Hopkins, 2004), an interview and observations (Chase et al., 1997; De Vera, 2003) and sequential interviews (Hyde et al., 1999; Lund-Nielsen et al., 2005a, 2005b). Using longitudinal approaches to explore people's experience of living with wounds might bring in-depth understanding of chronological narrative, as the findings could illustrate the trajectory and transition during the course of living with wounds (Calman et al., 2013; Murray et al., 2009; Vogl et al., 2018).

Study funding

We found that few of the studies declared any external funding sources, although the amount of funding for biomedical research is increasing overall (Hoffman et al., 2020; *UK Health Research Analysis 2018*, 2020). There are some possible explanations for this; some of the studies were small scale studies undertaken as part of a post graduate qualification in research, such as a Masters or PhD, and did not receive external funding. In the past, researchers did not always declare funding, as peer-reviewed journals did not have policies related to disclosure of funding and conflict of interest, which has changed only in the past decade (Rowan-Legg et al., 2009). Another explanation might be that, traditionally, qualitative studies were set as low priority for public funding (Cartier et al., 2018), as the findings might not be generalisable (Polit & Beck, 2010) and instead studies seeking to study treatment effect were prioritised.

Another aspect to be considered is redundancy of research. This scoping review has identified clusters of research areas which have been addressed by a number of primary studies and reviews. For example, if we look specifically at studies related to leg ulcers, we find that many primary studies and systematic reviews or evidence synthesis studies have been published even in the last few years, which had similar aims and used similar research methods (Briggs & Flemming, 2007; Charles, 1995; Chase et al., 1997; Green et al., 2013; Green & Jester, 2009; Green et al., 2018; Jones et al., 2008; Phillips et al., 2018; Rich & McLachlan, 2003; Taverner et al., 2011; Walshe, 1995), while it seems that there are populations such as people with arterial leg ulcers, malignant fungating wounds or open surgical wounds which are scarcely researched. Therefore it is important to avoid research duplication or even research waste (Chalmers et al., 2014) by targeting research gaps, and thereby avoiding the overuse of available research resources.

4.4.2 Implications for future research

There is a need to understand the perspectives of people with under-researched types of complex wound, namely: open surgical wounds, arterial ulcers and malignant, fungating wounds. Future studies should also consider using different traditions of study design (phenomenology, hermeneutics, ethnography, grounded theory or pragmatic approaches, mix-method approaches) and methods of data collection by using a longitudinal approach when exploring people’s perspectives. By doing so, the phenomenon can be explored comprehensively and in depth. The geographical distribution of the studies indicates that people’s perspectives of having complex wounds are generally under-researched in middle- and low-income countries; therefore future research should address this. The perspectives and quality of life of children and adolescents are also under-researched. Empirical data suggest that complex wounds occur in children and adolescents, but no relevant qualitative study has been carried out yet. Special attention must be drawn to improving study reporting. Studies should be reported according to international standards, allowing and increasing the transferability potential of research findings.

Although our scoping review aimed to explore the extent and nature of research related to people’s perspective of living with complex wounds, we suggest that researchers should consider a shift from researching the phenomenon, where the peoples’ perspective has already been researched in depth, to developing and researching beneficial interventions, which would address the problems and challenges raised by peoples and improve their quality of life.

4.5 STRENGTHS AND LIMITATIONS

This study has a number of strengths. Firstly, it provides a comprehensive insight into the extent and nature of the research into people’s perspectives of living with most types of complex wound. Furthermore, it makes a particular contribution in outlining the populations and types of complex wounds which have and have not been researched.

The study also has a few limitations. Firstly, we selected only studies published in English, which might have resulted in a risk of publication bias. Unfortunately, there is a lack of empirical evidence which would quantify the extent to which language (dissemination/publication) bias affect results in qualitative reviews (Booth et al., 2018; Toews et al., 2017). The geographical distribution of the included studies reassured us that we had identified studies from various countries. Furthermore, when checking the full texts for eligibility we excluded only nine studies published in other languages (Fig. 1). Therefore we believe that we missed only a small number of studies published in other (local) languages.

Secondly, it is possible that we also missed some studies, as we did not seek studies in the grey literature. There is extremely limited empirical evidence related to patterns of publishing qualitative research compared with quantitative research (Dwan et al., 2008, 2014; Toews et al., 2016, 2017). Petticrew et al. (2008) have suggested that only 44.2% of qualitative studies presented at conferences were later published. The reason for this is related to studies' low trustworthiness or poor reporting: for example, only 50% of abstracts included details on context/setting, whereas 57.9% gave details on the sample or sampling procedures, and 55.3% contained details related to study findings. As the objective of the scoping review was to explore the extent and nature of evidence (in particular the tradition, methods, phenomenon of interest, study participants, study context), it seemed that excluding grey literature would not affect the trustworthiness of the findings. Another reason for excluding grey literature was pragmatic, namely, we had limited research resources and were not able to fund the translation of studies.

A third limitation of this study is the possibility of errors in the data charting process, although as we used primarily single data extraction (with double confirmation for 10% of studies) we think that this would not have greatly affected the estimates or conclusions of this scoping review.

We did not undertake critical appraisal of the included studies, despite some writings suggesting this should be part of scoping reviews (Arksey & O'Malley, 2005; Levac et al., 2010; Tricco et al., 2018; Whittemore et al., 2014). Our primary objectives were specifically exploratory in nature, and associated with three main concepts – the extent, nature and mapping of evidence – and did not aim to produce a meta-synthesis of findings (i.e. content analysis of themes); therefore we believed that critical appraisal would exceed our aim.

4.6 CONCLUSION

This scoping review has explored qualitative research on peoples' perspectives of living with complex wounds and has comprehensively illustrated the nature and extent of the current evidence base. We identified a large number of primary studies and reviews or qualitative evidence syntheses. These studies overlap in specific types of complex wounds, such as venous leg ulcers, while some types are particularly under-researched, namely arterial leg ulcers, open surgical wounds and malignant fungating wounds. No qualitative study involving children or adolescents with complex wounds was identified; therefore future studies might want to target all affected populations. This study also identified a few shortcomings related to the reporting of studies, so future studies should improve reporting to allow and improve the transferability of findings. The findings from this study could be useful for researchers in particular as they inform them about research gaps and targets related to exploring people's perspectives of living with complex wounds.

Funding statement

No specific funding was obtained to conduct this scoping review.

Acknowledgments

The authors would like to thank and acknowledge the contribution of Naomi Shaw, information specialist, for reviewing the search strategies, and Ellen Broderick for her contribution in independently screening the search results for eligible studies.

CHAPTER 5: A CROSS-SECTIONAL SURVEY OF PATIENTS WITH OPEN SURGICAL WOUNDS IN SLOVENIA

Ljubiša Pađen [a], Jane Griffiths [a], Nicky Cullum [ac]

[a] Division of Nursing, Midwifery and Social Work
The University of Manchester
Oxford Road
Manchester, M13 9PL, UK
E-mail: ljubisa.paden@postgrad.manchester.ac.uk

[b] Department of Nursing, Faculty of Health Sciences
University of Ljubljana
Zdravstvena pot 5
1000 Ljubljana, Slovenia

[c] Research & Innovation Division, Manchester University NHS Foundation Trust Research Office
1st Floor, Nowgen Building
29 Grafton Street
Manchester, M13 9WU, UK

The Chapter 5 has been published as journal article:

Pađen, L., Griffiths, J., & Cullum, N. (2019). A cross-sectional survey of patients with open surgical wounds in Slovenia. *Health & Social Care in the Community*, 27(4), e213–e222. https://doi.org/10.1111/hsc.12700

ABSTRACT

Most surgical wounds heal by primary intention, i.e. the wound is closed with sutures, clips or glue. However some surgical wounds are either left open to heal from the bottom up ("healing by secondary intention") or break open partially or fully after primary closure. There is little basic knowledge about the occurrence and natural history of surgical wounds healing by secondary intention (SWHSI); therefore the aim of this survey was to estimate the number of people with SWHSI in Slovenia, the nature of these wounds, and to investigate how they are managed. A multi-service, cross-sectional survey was carried out over a two-week period in the city of Ljubljana, Slovenia (population 288,919). Health care professionals across health and social care settings completed one anonymised form for each patient with a SWHSI. Forms were completed for 110 patients. The point prevalence of SWHSI was 0.38 per 1,000 of the population (95% CI: 0.33 to 0.44). Patients' mean age was 50.5 years. The majority of SWHSI were planned to heal by secondary intention before surgery (76/110, 69%). 83% (92/110) of SWHSI were treated with wound dressings, and 6% were treated with negative pressure wound therapy. Data were missing for 11 cases. This survey is the first to provide essential information about the extent, nature and treatment of SWHSI in Slovenia. Furthermore, it is one of latest of a very small number of studies to have contributed to knowledge about SWHSI globally. The results from the survey can be used for planning future research, health resources management and policy development.

Key words: prevalence, surgical wound, healing by secondary intention, surgical wound dehiscence, wound care, unpleasant symptoms.

Bullet points

What is known about the topic:

- SWHSI appear to be a common type of complex wound in adults.
- Most people with SWHSI are treated in the community.

What this paper adds:

- Children and adolescent population are also affected by SWHSI.
- There is a large variation in treatments used for SWHSI.
- Patients with SWHSI experience common wound-related unpleasant symptoms.

5.1 INTRODUCTION

Complex wounds (superficial, partial or full thickness skin loss healing by secondary intention) have various underlying pathologies, such as vascular disorders, diabetes, cancer or other chronic diseases (Hall et al., 2014). They heal slowly and are complex to treat and care for (Cullum et al., 2016). Furthermore, previous research suggests the treatment of complex wounds is costly and impacts on the health care sector, as treatment is resource intensive (Guest et al., 2015; Sen et al., 2009).

Complex wounds are common and affect thousands of people every day. A review carried out by Cullum et al. (2016) showed that the prevalence of complex wounds ranges between 0.24% and 1.4%. It is well documented that complex wounds have a negative impact on patients' quality of life (QoL) and are often perceived as 'horrible', 'smelly' and 'painful' (Girouard et al., 2008; Herber et al., 2007; McCaughan et al., 2018; Persoon et al., 2004).

In the past two decades wound care has received a lot of attention from researchers. Many studies have aimed to investigate which interventions might be effective in promoting wound healing or preventing wounds (Dumville et al., 2015; Atkinson & Cullum, 2018; Lavallée et al., 2017; Westby et al., 2016; Norman et al., 2017). However, less has been written about the basic nature of wounds and their prevalence (Cullum et al., 2016). Whilst there has been a great deal of research on the prevalence of leg ulcers, diabetic foot ulcers and pressure ulcers, surgical wounds are under-researched regardless of the fact that a lot of conditions are treated with surgical procedures. Furthermore, it appears that surgical wounds healing by secondary intention (SWHSI) are particularly under-researched.

In a comprehensive review of the literature we identified only four studies which have been carried out that aimed to investigate the epidemiology of SWHSI, namely: two audits (Srinivasaiah et al., 2007; Vowden & Vowden, 2009a, 2009b) and two point prevalence surveys (Hall et al., 2014; Chetter et al., 2017). Both Srinivasaiah et al. (2007) and (Vowden & Vowden, 2009a, 2009b) carried out an audit in the United Kingdom and estimated that the proportion of all wounds that are SWHSI is approximately 28% (27.5% and 27.96% respectively). Hall et al. (2014) carried out a point prevalence study of all types of complex wound healing by secondary intention in Leeds (UK), a city with a population of 751,485. The estimated prevalence of SWHSI (including open surgical wounds, dehisced surgical wounds, abscesses and pilonidal sinuses) was 0.28 per 1,000 population. In the latest study in a defined geographical population of 455,842 in the north of England, the point prevalence of SWHSI was estimated to be 0.41 per 1,000 population (Chetter et al., 2017).

By looking at the available evidence on prevalence of SWHSI more closely, it can be seen that all studies come from the United Kingdom and that there is a lack of evidence from other parts of the world. Furthermore, the prevalence of SWHSI is potentially underestimated in these studies for several reasons, namely: not all health care providers were included in the survey (Srinivasaiah et al., 2007); secondly, it is often not clear whether hard-to-reach groups were included in the studies (Vowden & Vowden, 2009b, 2009a; Srinivasaiah et al., 2007; Chetter et al., 2017); furthermore people aged under 18 were excluded from one study (Chetter et al., 2017).

Previous studies mostly focused on estimating the number or cases of SWHSI, however there is also a lack of information on how these wounds are managed and what treatment strategies are used (Hall et al., 2014; Chetter et al., 2017). Providing information on the prevalence, nature and treatment of SWHSI is important for several reasons including: assessing the burden of this condition, care planning in acute settings and the community, health resources management, and informing future intervention studies and qualitative research on living with these wounds and associated symptoms.

The aim of this study was to explore the number and management of SWHSI in Ljubljana (Slovenia), with the following objectives:

a) Estimate the point prevalence of SWHSI in people of all ages.
b) Explore the natural history, characteristics and unpleasant symptoms of SWHSI.
c) Explore where and by whom people with SWHSI are treated.
d) Explore the wound management.

5.2 METHODS

5.2.1 Design

A multi-service, cross-sectional survey was carried out over a two-week period in the city of Ljubljana, Slovenia.

5.2.2 Setting

18 public health and social care providers across the city of Ljubljana (Slovenia) took part in the survey, namely:

- 1 Primary care service (Community Health Centre Ljubljana which included all services from pre-school to adulthood in clinics and the home),
- 4 Hospitals (University Medical Centre Ljubljana, Institute of Oncology Ljubljana, University Institute of Rehabilitation, University Psychiatric Clinic Ljubljana),
- 11 Social care providers (2 institutions for the care of people with intellectual disabilities and 9 nursing homes),

- 2 Other (1 free clinic, 1 clinic of the Administration of the Republic of Slovenia for Enforcement of Judicial Sanctions).

5.2.3 Participants

<u>Inclusion criteria:</u>

The studied diagnostic unit was a person with one or more surgical wounds healing by secondary intention, defined as: any wound following surgical intervention which has been intentionally left open to heal spontaneously or has been surgically closed (sutured) and has completely or partially broken open due to infection or other causes (i.e. a wound healing by secondary intention).

All people known to health and social care providers in the city of Ljubljana (Slovenia) were eligible for inclusion in the survey if they had at least one active surgical wound healing by secondary intention, the existence of which was clinically confirmed by a general practitioner (GP) or registered nurse (RN).

<u>Exclusion criteria:</u>

Patients with the following wounds were excluded from the survey:
- Wounds healing by primary intention.
- Surgical wounds, which were healing by secondary intention but had been surgically closed and remained closed.
- Stomas
- Surgery that did not involve an incision through the skin surface (e.g. tonsillectomy, dilation and curettage, dental extractions, procedures for prolapsed hemorrhoids).
- Wounds resulting from operations involving the eye (i.e. cataract surgery, removal of the eyeball).
- Non-surgical wounds healing by secondary intention including those that had been subject to sharp debridement (venous or arterial ulcers, diabetic foot ulcers, pressure ulcers).
- Fistulae (abnormal connection between internal organ and skin surface).

5.2.4 Data collection

A data collection form was designed to collect: anonymous demographic details about each patient with a SWHSI (gender, age, ethnicity), the characteristics of their wound (type of operation, location of wound, wound bed condition), and current wound management (how many consultations, treatment objectives and wound treatment given). Anonymous data were also collected about the health personnel who were filling in the forms, and the setting in which the patient was managed.

A pilot study with a sample size of 8 records of people with open surgical wounds was carried out in a 5 different settings to establish good communication and a rapport between the researcher, institutions and health personnel, to test whether the data collection instrument and guide for form completion were clear, readable and understandable, and to identify any barriers to completion of the data collection forms. After the pilot study, based on feedback received from health personnel, minor changes to the form and guide were made, namely additional explanation was added to one of the questions and one question was omitted.

The principal researcher conducted the survey and contacted all the principal/divisional nursing officers or medical directors of the included clinical settings. To increase the response rate, presentations were made to health personnel at their team meetings. A month before the start of the survey, the nominated contact persons were again informed by email or telephone of the exact date. A reminder was also sent by email on the day the survey started, and again on the day it ended. During the survey the principal researcher was available for questions and support by email or telephone.

Health personnel were asked to report whether they had patients with SWHSI in their current caseload (at a defined point in time) and, if so, to fill out one form per patient with a SWHSI. The health personnel completed the form after wound care was provided to patients, as part of the regular documentation of wound management procedures. Data collection in inpatient settings took place away from patients' bedsides so that the anonymity of the data was ensured.

The health personnel completed one form for each patient; however, as this was a multi-service survey it was possible that a patient with eligible wounds might be reported by multiple health care professionals from other clinical settings. This was overcome by instructing health personnel to decide amongst themselves who would complete the form, in order to avoid duplication. Furthermore, duplicate cases were identified afterwards based on other data, for example demography, location of wound, date of operation, date SWHSI occurred. In the case of an eligible patient having more than one SWHSI, health personnel were asked to complete the data for the wound that was the largest, as we assumed that it would usually be the wound which would take longest to heal and require the most care.

5.2.5 Data analysis

R statistical package and Microsoft Excel were used for the data analysis. Descriptive statistics (frequencies, proportions, means, mode, minimum [min] and maximum [max] values, standard deviations [SD] and interquartile range [IQR]) were used to present the prevalence and data on the natural history and treatment of the wounds. Confidence intervals (C.I.) were calculated using the Wilson score (Newcombe, 1998). Missing values are reported throughout the results. Because of the low number of missing values and the exploratory nature of the study, we did not use any formal statistics to deal with missing values. We analysed all cases in which the variable of interest was present.

The standard formula was used to calculate the overall prevalence: the number of people with wounds was divided by the population of the city of Ljubljana (288,919) (SI-STAT, 2018) and then multiplied by 100.

5.2.6 Ethical considerations

Ethical approval for the survey was obtained from the University of Manchester Research Ethics Committee 1 and Republic of Slovenia National Medical Ethics Committee.

5.3 RESULTS

During a two-week period, health care professionals reported 115 cases of SWHSI. After examining all forms and entering the data we excluded 5 completed forms as they did not meet the inclusion criteria (n=3) or were duplicates (n=2). In total, 110 reported cases were included in the survey analysis.

5.3.1 Characteristics of the study population

54% (59/110) of the survey population were men. The mean age was 50.5 years (SD: 24.31 years, IQR between 25th and 75th percentile: 28.5-69.75 years), ranging from 3 months to 94 years. All patients were of white ethnic origin and were Slovenian residents (110/110).

5.3.2 Point prevalence estimate

The overall point prevalence of people with SWHSI was estimated as 0.38 per 1,000 of the population (95% C.I.: 0.33 to 0.44). Table 1 shows the distribution of the prevalence of

SWHSI by 10-year age categories. It appears that SWHSI are more common in age groups from 60 to 69, 70 to 79 and 80+ (Figure 1).

Table 5.1: Point prevalence estimates by 10-year age categories.

Age (years)	Number of cases of SWHSI	Size of population	Point prevalence per 1,000 of population	95% Confidence interval
0-9	8	29,730	0.27	0.14 to 0.45
10-19	9	24,688	0.36	0.21 to 0.56
20-29	12	38,274	0.31	0.19 to 0.47
30-39	8	43,898	0.18	0.10 to 0.32
40-49	10	40,580	0.25	0.14 to 0.40
50-59	15	38,639	0.39	0.25 to 0.55
60-69	20	35,422	0.56	0.40 to 0.71
70-79	15	22,148	0.68	0.47 to 0.83
80-89	11	13,033	0.84	0.58 to 0.96
90-99	2	2,452	0.82	0.26 to 0.98
100+	0	55	-	-

Figure 5.1: Point prevalence estimates by age.

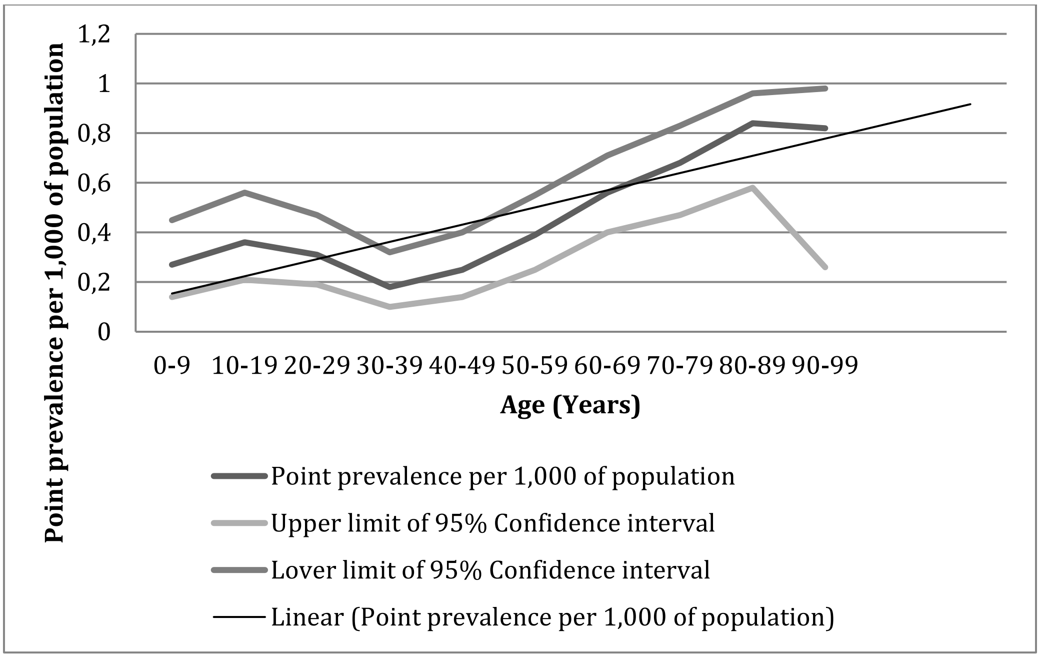


Table 2 displays an overview of point prevalence estimates for males and females. The prevalence of SWHSI is higher in males than females.

Table 5.2: Point prevalence estimates by gender.

Gender	Number of cases of SWHSI	Size of population	Point prevalence per 1,000 of population	95% Confidence interval
Male (M)	59	139,264	0.42	0.34 to 0.51
Female (F)	51	149,655	0.34	0.27 to 0.42

5.3.3 Nature of SWHSI

Most of the patients had one SWHSI (104/110, 95%), three people had two, and three had three SWHSI. As shown in Table 3, SWHSI were mostly related to surgical specialties of skin and soft tissue surgery (61/108, 55%), followed by abdominal (20/108, 18%) and vascular (10/108, 9%) surgery. A smaller proportion of SWHSI were associated with other types of surgical specialty. The most frequent surgical procedures that preceded the SWHSI were incision, drainage excision and debridement of skin, or soft skin lesions or abscesses (47/110, 43%), nail avulsion (15/110, 14%), laparotomy with or without bowel resection and lavage (10/110, 9%). Other abdominal operations preceding the SWHSI were on the gall bladder, stomach, appendix and bowel (7/110, 6%), lower limb amputations (7/110, 6%), pilonidal sinus excision (7/110, 6%) and vascular by-pass (3/110, 3%). 14 cases (13%) were reported to have had other surgical procedures. The majority of the SWHSI were related to emergency procedures (81/110, 74%) and 69% (76/110) were planned to heal by secondary intention before surgery. Wounds which were surgically closed and then spontaneously dehisced were more prevalent in males than females (M: 16/24, F: 8/24).

Table 5.3: Wound categories according to type of surgical specialty.

	Wound category				
Surgical specialty	Planned healing by secondary intention	Broken down surgically closed wound	Surgically closed wound intentionally re-opened	Missing	Total (n)
Orthopaedic	-	2	-	-	2
Trauma	2	1	-	-	3
Vascular	4	6	-	-	10
Colorectal	-	1	-	-	1
Plastic-reconstructive	3	1	-	-	4
Urology	-	3	-	-	3
Thoracic	-	-	1	-	1

Cardio	-	1	-	-	1
Abdominal	8	7	5	-	20
Neurosurgery	-	1	-	-	1
Oral or maxillofacial surgery	-	-	-	-	0
Obstetrics/gynecological	1	-	1	-	2
Operations of soft tissues, skin or nails	57	1	2	-	60
Aesthetic (Cosmetic)	-	-	-	-	0
Missing	-	-	-	2	2
Total	75	24	9	2	110

The overall mean duration of SWHSI at the point of survey was 10.1 days (110/110, 100%). In 33 out of 110 reported cases, closed surgical wounds had dehisced spontaneously or were intentionally re-opened in a median time frame of 9.5 days from surgery (SD: 11.4 days; IQR between 25th and 75th percentile: 4.25-15.5 days). Most of the dehisced wounds had broken down or were re-opened in an acute health care setting (25/33), and only a few of them had broken down in the community, including residential homes (4/33).

We asked health care professionals to record whether patients experienced wound-related unpleasant symptoms such as pain (92/110, 84%), malodour (34/110, 32%), exudate (82/110, 75%) or pruritis (11/110, 10%).

5.3.4 Management of SWHSI

Most of the treatments were provided in the community at GP surgeries (58/110, 53%) and a smaller proportion of patients were treated by community nurses at patients’ homes (4/110, 4%). Others were treated in acute care (37/110, 34%), or wound care clinics (10/110, 9%), and one case was reported to have been treated at a non-acute nursing department. Irrespective of setting, registered nurses most frequently completed the form (61/110, 55%), followed by nursing assistants (47/110, 43%), while a general practitioner and a medical student filled out one form each (Table 4).

Table 5.4: Treatment location and job title of health professional who completed form.

	Acute Setting - Hospital	Wound Care Clinic	General Practitioner Surgery	Community Health Care Services	Other services	Total
Registered Nurse	37 (61%)	9 (15%)	10 (16%)	4 (7%)	1 (2%)	61 (100%)
Nursing Assistant	-	1 (2%)	46 (98%)	-	-	47 (100%)
General Practitioner	-	-	1 (100%)	-	-	1 (100%)
Medical student	-	-	1 (100%)	-	-	1 (100%)
Total	37 (34%)	10 (9%)	58 (53%)	4 (4%)	1 (1%)	110 (100%)

Health care professionals recorded treatment objectives for SWHSI for each patient. The form allowed them to record more than one objective. The most frequently recorded objectives were: absorption of exudate (98/108, 91%), protection of wound bed and surrounding skin (79/108, 73%), bacterial load management (59/108, 55%), hydration of wound bed (59/108, 55%), encouragement of granulation (46/108, 43%), odour management (42/108, 39%) and debridement (16/108, 15%). For two patients the healthcare professionals did not record any treatment objectives, while for another two patients, the healthcare professionals chose the option “other treatment objectives”; however they failed to provide further details.

83.6 % (92/110) of SWHSI were treated with dressings whilst 6.3% (7/110) received negative pressure wound therapy (NPWT) (data were missing for 11 cases). Furthermore, NPWT was reported to be used only in hospital settings, and no cases were identified elsewhere. 42% (46/108) of patients received antibiotic therapy for their SWHSI. Health care professionals reported that for five patients they did not know whether they were receiving antibiotics, and data were missing for a further two patients.

Health care professionals reported different patterns of dressing change (table 5). The mean frequency was 4 times per week (SD: 4.05 per week, IQR between 25th and 75th percentile: 2.75-4 per week). Dressings were changed most commonly every 2-3 days (70/98, 71%).

Table 5.5: Frequency of dressing change.

Dressing type	Average frequency of dressing change per week	Min. frequency of dressing change per week	Max. frequency of dressing change per week
Non-woven swabs with ringer solution	14.0	7	21
Gauze with Wound Irrigation Solution	14.0	14	14
Irrigation with tap water	14.0	14	14
Irrigation with 0.9% Sodium Chloride	10.5	7	14
Activated charcoal dressing with silver	7.0	0	14
Alginate dressing with medicinal honey	7.0	7	7
Non-woven swabs	7.0	0	14
Non-woven swabs with 0.9% Sodium Chloride	7.0	7	7
Ringer solution pre-activated wound dressing	7.0	7	7
Sodium carboxymethylcellulose (NaCMC) containing 1.2% silver	3.7	2	7
Island dressing	3.3	0	7
Alginate	3.3	0	7
Polyamide net coated with soft silicone	3.2	2	14
Gauze	3.0	3	3
Soft silicone faced polyurethane foam dressing	2.8	2	3
Polyurethane foam	2.7	2	3
Hydrogel	2.5	2	3
Knitted viscose fabric impregnated with a polyethylene glycol (PEG) base containing 10% povidone-iodine	2.0	0	3
Skin Closures	2.0	2	2

When comparing data on primary dressings for each treatment objective, it seems that a variety of dressings were used for a variety of treatment objectives (table 6).

Table 5.6: Treatment objectives and used primary dressings.

Treatment objectives	Primary dressing type
Absorption	Alginate (n=26), Polyamide net coated with soft silicone (n=22), Non-woven swabs with 0.9% Sodium Chloride (n=6), Sodium carboxymethylcellulose (NaCMC) containing 1.2% silver (n=5), Soft silicone faced polyurethane foam dressing (n=4), Knitted viscose fabric impregnated with a polyethylene glycol (PEG) base containing 10% povidone-iodine (n=4), Non-woven swabs (n=4), Non-woven swabs with ringer solution (n=4), Island dressing (n=3), Polyurethane foam (n=3), Activated charcoal dressing with silver (n=2), Alginate dressing with medicinal honey (n=1), Gauze (n=1), Gauze with wound irrigation solution (n=1).
Bacterial load management	Alginate (n=26), Polyamide net coated with soft silicone (n=6), Non-woven swabs with 0.9% Sodium Chloride (n=1), Sodium carboxymethylcellulose (NaCMC) containing 1.2% silver (n=5), Soft silicone faced polyurethane foam dressing (n=1), Knitted viscose fabric impregnated with a polyethylene glycol (PEG) base containing 10% povidone-iodine (n=1), Non-woven swabs (n=1), Non-woven swabs with ringer solution (n=1), Polyurethane foam (n=2), Activated charcoal dressing with silver (n=2), Alginate dressing with medicinal honey (n=1), Hydrogel (n=2), Irrigation with 0.9% Sodium Chloride (n=2), Irrigation with tap water (n=2), Ringer solution pre-activated wound dressing (n=1).
Encouraging granulation	Polyamide net coated with soft silicone (n=19), Alginate (n=9), Hydrogel (n=2), Polyurethane foam (n=2), Soft silicone faced polyurethane foam dressing (n=2), Sodium carboxymethylcellulose (NaCMC) containing 1.2% silver (n=2), Knitted viscose fabric impregnated with a polyethylene glycol (PEG) base containing 10% povidone-iodine (n=1), Non-woven swabs (n=1), Non-woven swabs with ringer solution (n=1), Non-woven swabs with 0.9% Sodium Chloride (n=1).
Hydration	Alginate (n=22), Polyamide net coated with soft silicone (n=7), Non-woven swabs with 0.9% Sodium Chloride (n=5), Non-woven swabs with ringer solution (n=4), Soft silicone faced polyurethane foam dressing (n=3), Hydrogel (n=2), Irrigation with 0.9% Sodium Chloride (n=2), Knitted viscose fabric impregnated with a polyethylene glycol (PEG) base containing 10% povidone-iodine (n=2), Non-woven swabs (n=2), Sodium carboxymethylcellulose (NaCMC) containing 1.2% silver (n=2), Gauze with wound irrigation solution (n=1), Irrigation with tap water (n=1), Polyurethane foam (n=1), Ringer solution pre-activated wound dressing (n=1).

Treatment objectives	Primary dressing type
Odour management	Alginate (n=16), Polyamide net coated with soft silicone (n=3), Non-woven swabs with ringer solution (n=3), Hydrogel (n=2), Irrigation with 0.9% Sodium Chloride (n=2), Irrigation with tap water (n=2), Polyurethane foam (n=2), Non-woven swabs (n=2), Sodium carboxymethylcellulose (NaCMC) containing 1.2% silver (n=2), Activated charcoal dressing with silver (n=1), Gauze (n=1), Ringer solution pre-activated wound dressing (n=1), Soft silicone faced polyurethane foam dressing (n=1), Knitted viscose fabric impregnated with a polyethylene glycol (PEG) base containing 10% povidone-iodine (n=1), Non-woven swabs with 0.9% Sodium Chloride (n=1).
Overgranulation	Non-woven swabs with 0.9% Sodium Chloride (n=1).
Protection	Alginate (n=25), Polyamide net coated with soft silicone (n=25), Non-woven swabs (n=4), Non-woven swabs with 0.9% Sodium Chloride (n=5), Soft silicone faced polyurethane foam dressing (n=3), Island dressing (n=2), Knitted viscose fabric impregnated with a polyethylene glycol (PEG) base containing 10% povidone-iodine (n=2), Activated charcoal dressing with silver (n=1), Alginate dressing with medicinal honey (n=1), Polyurethane foam (n=1), Sodium carboxymethylcellulose (NaCMC) containing 1.2% silver (n=1), Non-woven swabs with ringer solution (n=1), skin closure (n=1).
Other objectives	Activated charcoal dressing with silver (n=1), Island dressing (n=1).

Health care professionals were asked how long the wound care consultation had taken for each patient; the mean duration of consultation was 12.7 minutes (106/110, SD: 11.87 min, IQR between 25th and 75th percentile: 5-15 min). The minimum time spent was 1 minute (swab applied on excised pilonidal sinus), and the maximum was 60 minutes for wounds treated with NPWT.

5.4 DISCUSSION

This survey is one of the first to provide insight into the prevalence, natural history and management of SWHSI. It is the first study to be carried out in Slovenia, and adds to knowledge about SWHSI globally.

5.4.1 Prevalence of SWHSI

The estimated point prevalence of SWHSI in Ljubljana, Slovenia is 0.38 per 1,000 of the population (110 reported cases in a defined population of 288,919). The estimated point prevalence in this study is within the range of prevalence rates reported in previous studies i.e. 0.28 to 0.41 (Hall et al., 2014; Chetter et al., 2017). Explanation for these slight differences across studies might be a reflection of the natural fluctuation of prevalence over time.

This study is to our knowledge the first to also provide deeper insight into the point prevalence of SWHSI in children and the adolescent population. We estimated the point prevalence in children and young people aged 19 years and younger to be 0.31 per 1,000 of population (95% C.I.: 0.21-0.44); most of these were nail avulsions, abscess excisions and pilonidal sinus operations rather than dehisced wounds. Future intervention studies might want to address the post-surgical management of toenail avulsion, skin and soft tissue infection and pilonidal sinus as they are high volume areas of care that lack research evidence (Eekhof et al., 2012; Smith et al., 2016; Fahimi et al., 2015; Al-Khamis et al., 2010; Lund et al., 2017). In common with Hall et al. (2014) we also found that the prevalence of SWHSI increases with age and that they are more common in men (Vowden & Vowden, 2009a, 2009b; Chetter et al., 2017).

5.4.2 Nature of SWHSI

More than two thirds of all SWHSI in this survey had been planned to heal by secondary intention at the point of surgery; higher than the 47.6% reported by Chetter et al. (2017). The likely explanation for this difference might be the larger proportion of skin and soft tissue infections and nail avulsions in our survey.

We defined wound duration as the period between surgery and data collection. The median duration (in days) of SWHSI was lower than that reported by Chetter et al. (2017). One possible explanation for the shorter duration in Slovenia is that of the type of surgery was different.

In our study, wound breakdown occurred in a median time frame of 9.5 days after surgery, which is in similar to the findings of Chetter et al. (2017), where the median time was 9.0 days (95% C.I.: 7-9 days), Van Ramshorst et al. (2010), where the mean was 9 days (range between 3-32 days) and Kenig et al. (2014) where wound dehiscence occurred on average at 9.8 days (range between 3.3-16.3 days). Furthermore as most of the patients are treated in the community (Hall et al., 2014; Chetter et al., 2017), data on when wound breakdown occurred might be useful for care planning i.e. nurses could visit more frequently to detect any complications early on that could lead to wound breakdown (for example wound infection).

5.4.3 Management of SWHSI

More than half of the patients with SWHSI were treated in primary care settings, which is similar to results from previous studies (Vowden & Vowden, 2009a, 2009b; Hall et al., 2014; Chetter et al., 2017). Within the primary care settings, only a few cases were reported to have been treated at the patients' homes by community care nurses, while other patients received care from GP surgeries. This could lead to speculation that the majority of patients with SWHSI are probably mobile, which is also consistent with Vowden and Vowden's (2009a, 2009b) findings.

Previous studies of SWHSI have touched on treatments used but did not report detail (Chetter et al., 2017; Hall et al., 2014). We have shown a variety of primary and secondary dressings in use and some concerns about practice. For example, dry swabs were used as a primary dressing for SWHSI even though it is documented that their use is associated with more pain (Vermeulen et al., 2004) and wound bed trauma (Treatment of Pressure Ulcers: Quick Reference Guide, 2009). Furthermore, there was frequently a contradiction between the stated treatment objectives and the properties of the selected dressing (e.g. gauze for reducing odour or non-woven swabs for encouraging granulation). Moreover, a variation in dressing change time was identified: frequencies of change ranged from three times per day to twice per week. This could indicate that some wounds need more frequent dressings, or might be a sign of uncertainty among healthcare personnel about treatment selection and wound care regime; there is a lack of good evidence on the clinical effectiveness of wound dressings or other topical agents for healing SWHSI (Norman et al., 2016; Vermeulen et al., 2004, 2007). Another explanation for such variety in treatment might be insufficient knowledge about wound management in community care; in Slovenia there are no specialised wound care services in the community, unlike the UK for example, and no specialist wound care courses for nurses or nursing assistants.

This survey identified that SWHSI were less frequently treated (6%) with NPWT than with wound dressings, which is similar to Chetter et al. (2017). Use of NPWT is largely increasing (von Beckerath et al., 2017; Apelqvist et al., 2017), however it seems that is less frequently used in Slovenia, as it is anecdotally associated with the use of more resources (staff resources, more frequent follow-ups, costs, etc.). Another explanation might be that there is no robust evidence on the clinical effectiveness of NPWT or any economic evaluations (Dumville et al., 2015).

Wounds are at risk of developing infection and various different antimicrobial treatments are used for prevention or treatment of infection (Norman et al., 2016). Although systemic antibiotic use in Slovenia is lower than in the UK (*Antimicrobial Consumption*, 2018), we found that 42% of patients were treated with antibiotic therapy for their SWHSI, which differs from Chetter et al's (2017) study where the number of patients was lower (27.8%). A possible explanation for this might be the fact that our study identified more people whose wounds were left open at the time of surgery, potentially because of high risk of infection (abdominal and colorectal surgeries) or with clinical presentations of infection such as abscesses.

We asked health care professionals to report how much time was spent on wound management. The mean time spent on wound management in our study is shorter (mean 12.6 minutes with minimum of 1 minute) than in Vowden and Vowden (2009b), where the mean time was 18.1 min for all acute wounds. One possible explanation of such a difference might be people's understanding of the phrase "wound management". Although in our pilot study healthcare professionals understood wound management as a wider concept than dressing change, it could be that not everyone who completed the forms understood it in this way. Another explanation might be that nurses reported only 'their' time, whereas a large proportion of wounds were treated in GP surgeries, where care is shared between GPs, RNs or nursing assistants, which is different to the UK. On the whole, we still think that this rough estimate of consultation time illuminates the time spent on providing wound care, even though it could be an underestimate.

5.4.4 Unpleasant symptoms

McCaughan et al. (2018) have carried out a qualitative study, where they have explored the lived experience of SWHSI, however, we believe ours is the first large scale study to look specifically into the burden of unpleasant symptoms experienced by people with SWHSI. It seems that symptoms such as pain, exudate, malodour and pruritus are common in SWHSI. It is well documented that unpleasant symptoms of other types of wounds interfere with patients' QoL, however there is a variation of the severity and impact across different types of wounds (Girouard et al., 2008; Gorecki et al., 2009; Gorecki et al., 2011; Herber et al., 2007; Persoon et al., 2004; Probst et al., 2013b). Future studies might want to look at the burden of unpleasant symptoms in SWHSI in more in depth. Furthermore evidence on the impact of SWHSI on patients' quality of life and their experiences is needed so that practitioners can provide optimal care for patients.

5.4.5 Strengths and limitations

This study has a number of strengths. Firstly it provides insight into the prevalence of SWHSI, including the 0-19 age group, in Slovenia. This paper makes a particular contribution in outlining the types of dressings and treatments used for SWHSI. Furthermore this study is the first to provide data about the extent of wound related unpleasant symptoms experienced by patients with SWHSI. Moreover this study also highlights the need for future studies on wound management uncertainties, assessing patients' quality of life and wound related symptom burden.

The study's limitations are mostly associated with the data collection technique. Because the survey was designed for multiple health care professionals to collect data we could not validate responses and non-responses. We had to rely on nursing assistants to report some of the data. In Slovenia nursing assistants are part of the wound treatment team but do not undergo specialist training and are therefore not necessarily able to accurately report wound treatment objectives (they follow general practitioner directions for wound treatment). Furthermore, it is also possible that not all cases were reported. However we are confident that we secured a good response rate through careful preparation, provision of guidance about form completion and the simplicity of the data collection form. Secondly, two health care institutions did not participate in the survey, namely Health Care Centre for Students and Slovenian Railway Health Care Centre, however community health care nurses who work independently from those institutions did participate, so we expect that there were very few missing cases. Thirdly, it is possible that we missed patients who live in Ljubljana and seek treatment outside Ljubljana or were self-treating, however we think that there will be only few of those. The above might have resulted in an underestimation of prevalence however the fact that our prevalence is similar to that reported in the UK is reassuring. This study has drawn attention to wound related symptom burden, however because of the nature of data collection in this study, healthcare professionals were only recording symptoms if they were reported by the patients themselves, so their prevalence might be under- or overestimated. Another challenge of this study is a risk to external validity as the sample consisted only of white Slovenians; therefore, caution is needed with interpretation. We attempted to compare our sample with Ljubljana's population but there are no official data on ethnicity in Slovenia.

5.5 CONCLUSION

This survey is the first to provide essential information about the extent, nature and treatment of SWHSI in Slovenia. Furthermore, it is one of the latest studies to have contributed to knowledge about SWHSI globally. The prevalence data from this survey is similar to results from previous studies; it seems that SWHSI are a common type of complex wound. Most people with SWHSI are treated in primary care settings with a variety of wound dressings and other topical treatments. The results from the survey can be used for planning future research and health resources and in improving wound care.

CHAPTER 6: A QUALITATIVE EXPLORATION OF THE MEANING OF LIVING WITH AN OPEN SURGICAL WOUND

Manuscript prepared for submission.

Ljubiša Pađen [a], Jane Griffiths [a], Nicky Cullum [ac]

[a] Division of Nursing, Midwifery and Social Work
The University of Manchester
Oxford Road
Manchester, M13 9PL, UK
E-mail: ljubisa.paden@postgrad.manchester.ac.uk

[b] Department of Nursing, Faculty of Health Sciences
University of Ljubljana
Zdravstvena pot 5
1000 Ljubljana, Slovenia

[c] Research & Innovation Division, Manchester University NHS Foundation Trust Research Office
1st Floor, Nowgen Building
29 Grafton Street
Manchester, M13 9WU, UK

Correspondence:
Ljubiša Pađen (Ljubisa Paden)
Division of Nursing, Midwifery and Social Work
The University of Manchester
Oxford Road
Manchester, M13 9PL, UK
E-mail: ljubisa.paden@postgrad.manchester.ac.uk
Phone: +38640187949

ABSTRACT

Little is known about the experiences of people living with open surgical wounds. These wounds are relatively common and predominantly affect young and actively working people. Open surgical wounds are very unpleasant to live with as they are deep, and during the process of healing they may produce exudate which can be malodourous and they can also be painful. The aim of this qualitative study was to explore the meaning of living with open surgical wounds. We collected data using two individual interviews with each of ten people who had open surgical wounds. Our analytical approach was based on qualitative content analysis. We found that meaning of living with open surgical wounds is shaped by five subthemes: “enduring healing”, “life disruption”, “adapting to a new reality”, “striving for healing” and “returning to normal life;” all under an overarching theme of “negotiating a new normality”. Findings from this study emphasise that open surgical wounds are a chronic condition with a typical ‘chronicity’ trajectory. Furthermore, attention should be given to providing support interventions for people with open surgical wounds who deal with complex challenges in their everyday lives.

6.1 BACKGROUND

Complex wounds (also known as chronic wounds or hard to heal wounds) are wounds with superficial, partial or full thickness skin loss left open to heal by the growth of granulation tissue (referred to as healing by secondary intention) (Cullum et al., 2016). There are different subgroups of complex wounds, which differ in aetiology or underlying pathology (Hall et al., 2014; Cullum et al., 2016; Martinengo et al., 2019), namely: arterial and venous ulcers, wounds related to diabetes, pressure injuries/ulcers, malignant wounds, and open surgical wounds (OSWs).

Some complex wounds, such as arterial and venous ulcers, wounds related to diabetes and pressure injuries/ulcers have been extensively studied from the point of view of epidemiology (Cullum et al., 2016; Martinengo et al., 2019), interventions (Cochrane Wounds, n.d.) and impact on quality of life (Persoon et al., 2004; Herber et al., 2007; Briggs & Flemming, 2007; Phillips et al., 2018; Coffey et al., 2019; Gorecki et al., 2009), whilst OSWs have been less studied and only recently received research attention (Chetter et al., 2017, 2019; Liu et al., 2018; McCaughan et al., 2018; Norman et al., 2020; Pađen et al., 2019; Seidel et al., 2020; Shiroky et al., 2020; Thom et al., 2020).

Surgical wounds are usually sutured or clipped and heal by primary intention without complications (Harper et al., 2014; Young & McNaught, 2011; Walter et al., 2012). However some surgical wounds are open and heal by secondary intention, for a variety of reasons. Surgical wounds may be deliberately left open to heal because of a high risk of infection: open healing allows easy drainage (Chetter et al., 2017, 2019). Alternatively, surgical wounds may be left open to heal because of a large tissue deficit, after excision, where wound edges cannot be surgically approximated, or when a delayed primary closure technique is used (Siribumrungwong et al., 2014). OSW can also result from wound dehiscence e.g. partial or full separation of surgically closed wound with or without the exposure of underlying tissue or even organs (World Union of Wound Healing Societies, 2018). Surgical wound dehiscence occurs due to various reasons, such as: disruption in healing (impact of local and systemic factors, including patient comorbidities), or surgical technique, and can even occur due to excessive tension on wound edges, for example when the patient is coughing (Casha et al., 2014; Listewnik et al., 2019; Sandy-Hodgetts et al., 2015).

Little is known about *living with* OSWs, despite their prevalence and potential for causing unpleasant symptoms and negative impact on well-being, compared to an ever-growing body of literature on living with other types of complex wounds (Alexander, 2010; Briggs & Flemming, 2007; Coffey et al., 2019; Gorecki et al., 2009; Herber et al., 2007; Lindahl et al., 2007; Lo et al., 2008, 2012; Persoon et al., 2004; Phillips et al., 2018; Probst et al., 2013a;

2013b). Findings from studies of other types of complex wounds have illustrated the negative effects they have on people's physical, psychological and social well-being (Briggs & Flemming, 2007; Coffey et al., 2019; Gorecki et al., 2009; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018). For example, the wound itself is associated with negative emotions such as fear, frustration, anxiety and depression. Researchers reported that people with wounds often had restricted social lives, reduced social contact and experienced social isolation (Kinmond et al., 2003; Lindahl et al., 2007; Lo et al., 2008). Complex wounds also affect mobility and produce a cascade of even deeper impacts on people's wellbeing (Briggs & Flemming, 2007; Coffey et al., 2019; Gorecki et al., 2009; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018).

While there is likely to be some overlap of the impact of open surgical wounds with other types of complex wounds, there may be important differences as yet unexplored. For example, people with open surgical wounds are more likely to be younger compared to people with other types of complex wounds (Chetter et al., 2017; Hall et al., 2014). Complex wounds such as leg ulcers or foot ulcers are often shallow, affecting skin and subcutaneous tissue, while surgical wounds can be deep and affect deep tissue and organs (Chetter et al., 2019). Furthermore, complex wound related symptoms are diverse in their intensity; some studies have suggested that people with pressure injuries/ulcers (Girouard et al., 2008) or wounds related to diabetes (Ribu et al., 2006) experience pain more frequently compared with people with leg ulcers (Persoon et al., 2004), while people with leg ulcers are reported to experience more frequent wound related pruritus (Paul, 2013) than people with open surgical wounds (Pađen et al., 2019).

A recent UK study by McCaughan et al. (2018) illustrated the experiences of people living with OSWs. This qualitative interview study found that people suffer greatly due to their deep, odorous and moist wounds, with all domains of daily life being greatly impacted, especially for those who were young and still working. Importantly, the study by McCaughan et al. (2018) was cross-sectional and a longitudinal approach would capture people's experiences and the impact over time (Chetter et al., 2019; Murray et al., 2009).

Apart from the qualitative study by McCaughan et al (2018), the only study to our knowledge that has looked at unpleasant symptoms of OSWs was carried out by us as a part of an epidemiological survey across health and social care services in Ljubljana (Slovenia). One of the aims of that study was to explore the burden of unpleasant symptoms experienced by people with OSWs. We identified 110 patients with OSWs and found that they frequently experienced symptoms, such as pain and exudate (84% and 75% respectively), while malodour (32%) and pruritus were experienced less frequently (10%) (Pađen et al., 2019). The impact of these unpleasant symptoms which were prevalent in the OSWs population were explored in this subsequent study.

A relative lack of understanding of the impact of OSWs directed us towards the need for further exploration of how patients are affected by them. Furthermore, as existing quantitative data on OSW have suggested that impacts on quality of life change over time, and considering the possible limitation of the findings in the context of condition evolution in McCaughan et al.'s (2018) study, we designed a longitudinal, qualitative study, with the aim of understanding in depth the meaning of living with OSWs.

6.2 METHOD

A qualitative, interview-based study sought to explore the meaning of living with open surgical wounds over time.

6.2.1 Procedures

After obtaining approval from the University of Manchester Research Ethics Committee 1 (Ref. 16301) and the Republic of Slovenia National Medical Ethics Committee (0120-451/2016-2 KME 32/09/16), and gaining the permission of the local primary services provider, we commenced our participant recruitment procedures.

Participants with OSW were sampled from Primary Care Services in Ljubljana (Slovenia), where adult patients generally have their own general practitioner (some of the patients under 26 years old might still use school health services – medical doctors specialising in paediatric or school medicine). Patients with major surgical wound complications would generally be referred to a surgeon and then, according to the treatment plan, wound management would be provided by primary care teams (General practitioner and Registered nurse or Nursing assistant). Minor complications such as wound dehiscence would be managed by primary care teams.

Inclusion criteria were: people with open surgical wounds, defined as "superficial-, partial-, or full-thickness skin loss wounds healing by secondary intention", which had been clinically confirmed by an medical doctor or registered nurse; at least 18 years old; living at home and being treated in the community; able to understand and communicate in Slovene and able to give informed consent. Participants were excluded if they had impaired cognitive capacity (such as dementia) or had pre-existing, documented severe mental illness or had any other complex wounds besides a surgical wound healing by secondary intention, as this might influence people's experiences of the observed phenomena. Participants who had terminal illness or were in emergency situations were also excluded.

Recruitment was carried out in two phases. First, the health professionals who were providing healthcare services to eligible participants approached the potential participants and briefly informed them about the study. All eligible participants were given a Participant Information Sheet and asked if they were prepared to participate. In the second phase, i.e. 24 hours later, the researcher contacted each eligible participant who had signalled their willingness to participate, providing them with additional explanations about the study, and answering any questions, and then the participant was asked to sign the consent form for participating in the study.

6.2.2 Participants

Ten people (five women, five men) with OSWs were recruited with a median age of 41.5 years (18-73 years). All were white and Slovenian. Participants represent a range of sociodemographic backgrounds: three participants had completed lower level secondary school, two upper level secondary school, three a Bachelor degree and two a master's degree. Three participants were married and four lived in partner unity. The majority of people were employed (n=7).

People underwent different types of surgery (dupuytren contracture, pilonidal sinus excision, different abdominal surgeries, amputations, excision of abscesses, C-section) which resulted in open surgical wounds involving different body locations (finger/hand, gluteus, abdomen, leg, foot, armpits/upper extremities). Four people had an open wound at the time of surgery and six had wound which was closed and then dehisced.

6.2.3 Data collection

Data were collected between April 2017 and March 2018, through semi-structured interviews using a topic guide. Researcher (L.P) asked open-ended questions with follow-up questions to elicit participants' experiences, for example: "Please describe your journey of having the wound". Each participant took part in two interviews, one when the patient was identified as eligible to participate (usually at the beginning of their condition) and the second when the wound had healed completely or had almost healed (between 4 and 16 weeks after first interview). The interview recordings lasted between 17 and 59 minutes. The researcher (L.P.) transcribed each interview immediately afterwards. After the first interview participants were asked to answer a short demographic questionnaire.

6.2.4 Data analysis

Data were analysed using a qualitative content analysis (QCA) approach (Graneheim and Lundman (2004) and Graneheim et al. (2017). During the analysis process, all the interviews were read as a whole to obtain a sense of them. The first reading helped the researcher (L.P.) to understand the ideas for further data analysis. In the next process in the analysis the transcribed text was divided into units of meaning (words, sentences or phrases associated with the context). Each meaning unit was then condensed (text and words which were not related to the context were removed from the meaning unit). The condensed meaning unit was abstracted and labelled with a code. Due to the rich nature of the data, the codes were merged, based on similarity, into subthemes which reflected the manifest content, and one overall theme which reflected the latent content (Graneheim & Lundman, 2004; Graneheim et al., 2017). The data analysis was discussed and codes and subthemes agreed among all three researchers (L.P., J.G., N.C.).

6.2.5 Language consideration

The first two phases of analysis (categorisation into meaning units and condensing) were carried out in the Slovene language. This decision was taken due to limited resources being available for translating complete interviews. The data were then coded directly in English and the analysis process was completed in English.

6.2.6 Confidentiality and ethical considerations

A strategy to ensure participants' privacy and confidentiality was developed in advance. Ethical considerations such as emotional distress, safety or even identification of poor or less than optimal practice during the interviews were taken into consideration and were specifically addressed in the ethics review application (protocols available upon request).

6.3 RESULTS

The meaning of living with open surgical wounds is about “negotiating a new normality” which is reflected in the complex disruption of life, perceived as long and emotionally harrowing. Helping people to live with OSWs involves supporting them to be active and cope with their wound related difficulties. The journey through the experience of having an open surgical wound is then resolved on returning to normal, though a reconstructed life which reflects new challenges related to past experiences. The analysis resulted in five sub-themes: “Enduring healing”, “Life disruption”, “Adapting to a new reality”, “Striving for healing” and “Returning to normal life”. The sub-themes are presented in the sections that follow.

6.3.1 Enduring healing

People with open surgical wounds were enduring healing. The experience of living with a chronic, slow-healing wound was unexpected and unpleasant. People who experienced wound dehiscence were surprised by it and usually not aware of dehiscence as a possibility; the situation they found themselves in was previously unimaginable for them. On the other hand, for people who were aware that their wound would be left open to heal during surgery, the "surprise" was associated with the time healing took to occur; for them it was unimaginable that they would be able to live with an open wound for such a long time. People often used rich descriptors for their wound, such as: *nasty, smelly, ugly, horrible, disgusting, awful, dirty, unsightly and dreadful*, which reflected how unpleasant having a wound could be. Experiencing open surgical wounds and open healing provoked various reactions and feelings, including fears, worries and anger. The fears and worries were very much involved with the wound itself, wound-related symptoms, and the overall experience itself.

> *The wound was horrible – everything was, all the smell and pain. I was afraid of how it was going to end. At some point I was even scared that everything would fall out of my stomach. I didn't imagine this could happen.* (P8)

The majority of people had fears and worries connected with the unpleasant symptoms associated with their wounds, such as pain, odour and exudate. They were worried that the symptom might be a sign of complications, perceiving exudate and odour as signs of a deterioration in healing. Often the symptoms increased their level of general uncertainty. People often reported fear of physical pain. It seemed that the experience of pain was initially more extreme, from their descriptions of their experience of open wounds, but later was accepted as part of the experience and people moved their focus away from it, or it seemed less important.

> *The wound is really painful; it's burning. It is unpleasant, and it really bothers me, also because everything is bandaged, and it really burns me inside. It's horrible, really horrible.* (P1)

> *At the beginning it hurt a lot, but now it doesn't any more. My skin has become "deaf", which is logical, you know, if you have an open wound for weeks*. (P3)

The worries, fears and uncertainty were closely associated with their overall experience of having a wound, or were due to the length of the healing. People also talked about their experience at a more abstract and holistic level, for example that it would affect their life "experience". Some of the people perceived their wound as a very intrusive body/life experience.

> *Well, I always wanted a life, to make it nice, joyful, make something positive out of it, but now, I am losing it. I can't go to the mountains, I can't run, people are staring, and you either care about this or you don't. The "joy" has become ordinary life. The wound is now a barrier to the joy. (P5)*

6.3.2 Life disruption

Open surgical wounds interfered with most aspects of people's daily living, namely physical daily activities, work and their general social life. Open surgical wounds impacted on relationships with partners and provoked various reactions from loved ones. The wounds also impacted on people's physical appearance; they evoked concerns about appearance and attractiveness in those affected and could cause embarrassment and shame.
Mobility was one of the activities most frequently referred to as being affected: the ability to move around in the home environment and in the outside environment. People described how their mobility was significantly reduced due to wounds and that they often needed assistance. The anatomical location of a wound influenced its impact on mobility. Sometimes treatment strategies and people's beliefs and fears caused reduced mobility, for example a treatment such as negative pressure wound therapy, which can be bulky and requires electrical power.

> *You always have to take a care of those ropes* [cable and drainage system] *from the machine* [NPWT]*. You have to take care so you don't get stuck in the chair or on the door hook. You can't shower; you just use a cloth to wash yourself. You always have to look at that* [NPWT]*. I've started to cook a bit, now, but you have to take care.* (P3)

Reduced mobility due to the wound often affected daily activities such as participation in family and leisure activities, shopping and buying food. The wounds interfered with people's ability to take care of their personal hygiene whilst simultaneously heightening the need for hygiene as they induced feelings of being dirty and smelly due to odour and exudate. People often noticed reduced appetite due to wound-associated symptoms such as pain or odour. Furthermore, participants often had physical limitations, which often prevented them preparing meals or left them unable to lift heavy things due to the wound.

> *Firstly, you have to take care of the wound, change your dressings. It starts to impact you; I can't hang clothes up to dry… I can't lift heavy things… which bothers me as I can't bring groceries from the shop. It also bothers me as I can't take care of my child* [new-born]*, it's hard to lift him. It is so unpleasant* (P8).

People described disruption of work life due to the wounds, as they had to stay home on sick leave. Long periods of sick leave decreased financial stability and people were often in need of support from others. Furthermore, people often perceived work in a wider context of satisfying their needs, both social and professional. People were often pushed to make hard decisions which could affect them in later life; for example, one male patient said:

> *I had to leave school. I felt a lot of pressure; I was getting more and more F(s)* [School grade]. *It didn't work as I was missing too much. My parents supported this choice and I felt relieved*. (P2).

Wounds and related symptoms also challenged people's social lives. People often considered whether they would have social interaction, or were worried that others would notice the wound. In general they reduced physical social contact with others or started to avoid them despite their expressed need to meet them.

People with open surgical wounds reported the impact on their relationships with their partners, and their reactions. Younger people described how their relationships were affected by reduced sexuality due to their changed physical appearance. Thoughts and feelings of being dirty (i.e. having wounds and wound symptoms) and fear of rejection produced feelings of low self-esteem, and people lost interest in sexuality or close physical contact. On the other hand they sought signs of acceptance from their partners, which evoked feelings of being still desired.

> *I am quite emotional, my partner is an important part of my life - a special part, I would say; and this was additional pressure on me. All this smell and exudate, you don't really have sex. … It felt good, when she kissed me, and that she was there for me.* (P9)

Female participants more frequently reported the reactions of their loved ones. Male partners' initial responses to the wounds were described as practical and solution-focused.

> *I can't describe how scared I was; my brains didn't work. I talked with my husband, he was also scared, but he just said, we need to go to doctor. For him it felt natural what to do, but I was completely lost.* (P8)

It seems that partners and significant ones (parents, children) suffered along with the people with wounds. Like the people with wounds, partners also experienced fear and worries, and felt an imbalance in the harmony of their family and relationship. This created an emotional spin-off for the people with wounds, as they were worried for their life partners' and important ones' feelings. People with wounds greatly appreciated their partners' support. Acceptance, non-judgment and not holding back boosted their morale.

> *She accepted the wound. You know she has a "stubborn cancer", and when she is ill, she doesn't have any energy, but she is very supportive of me, she pushes me onward and motivates me to continue.* (P5)

Physical appearance and concerns related to attractiveness featured in some of the (mostly younger, female and male) people's descriptions. Bodily disfigurement was an important factor for people. They were concerned about their body image; they were often afraid of exposing their bodies in front of others. They were worried about their attractiveness and felt undesirable. A person's perceived personal attractiveness and physique were often attributed to society-wide interaction related to physical appearance. Women described feeling less feminine.

Wounds, wound-associated symptoms and scarring produced feelings of embarrassment and shame. Most of the descriptions concentrated on people's beliefs about themselves (for example, being dirty or smelly) and perceived societal prejudices. People often described issues with the visibility of their condition, i.e., they were worried about how they were or would be perceived by others due to the malodour and extensive leaking from the wound. Although in reality most of the people's wounds were hidden under clothes, they were still concerned about stigma. Some were worried about others noticing their condition, due to wound odour:

> *I am always scared that someone might smell the wound odour. Maybe this is my issue, I don't know, but I am worried. The majority of people only see my child anyway and I didn't tell everyone about the wound. They can't see it, but I know that I have it.* (P10)

Furthermore, a major issue for people was future scars after healing, which for them could be seen as marks which could provoke "labelling".

> *People look at scars and just see a "scar-face. How should I describe… let's say that people are looking at you with some scorn…* (P9)

6.3. 3 Adapting to a new reality

In the process of adaptation, people became aware of the negative impacts of the wound, and their personal frailty, and started to accept a new reality. Acceptance was related to changed thoughts and rationalisation. Participants reported that they had to accept the situation, as it was expected that it would take great amount of time to achieve complete healing. People started to understand that they would have to live with the wound and they would have to adapt to a new way of living for some time.

> *When I looked at it, I understood that this is a part of me, that this looks as it looks; and then you start to think, to process it in your head; and I don't mean from a medical perspective – where is the infection and is there redness – but in your subconcious, this is on you, this is yours, this is you... You start to be aware that this is really on you and that it will stay for some time, and that you have to accept it. This is how it is.* (P6)

Acceptance and setting new priorities were later resolved in actions such as seeking information about the wound, causes of the wound, treatments, and instructions for care. People with wounds often sought information on the Internet – various forums and online patient support groups – and information from nurses and physicians. However, information from different sources was often contradictory or wrong, which caused concern and uncertainty. The actions of seeking information and instructions for care often illustrated that people were aware that they lacked information or that they had poor information about their treatment or their condition.

> *I looked at the Internet, as I needed information about this "condition". I am not a professional like you… When you hear the word "gangrene" you are scared, and then you seek information.* (P7)

> *I was reading information on the Internet about the condition. But then, when you start to read you can find almost anything. There are a lot of stupid things written which can even lead to harm.* (P9)

A sense of empowerment encouraged people to adopt new behaviour. Actions related to taking care of the wound were described at an abstract level, such as being aware of and alert to the need for action, or were described more specifically, for example, physical actions such as changing dressings, or providing time for care, and taking control of the wound and themselves. Changes in the physical performing of daily activities were noted and constructed patterns of protective behaviour. People reported that they protected their wounds with long periods of rest, reducing physical forces on the wound and being careful with it.

People with open surgical wounds also narrated a range of intersected coping strategies related to themselves and their state of the mind. There was a need to boost optimism and morale in order to live with a wound in everyday life. People described encouraging themselves to live, by staying positive and insisting on continuing with everything. They were self-motivating to cope with a life which was different for them. People also comforted themselves by minimising their experience or by comparing their condition to something far worse:

> *It is just a period of time which has to be got through, with surgery and antibiotics, and then I hope that everything will be ok. It is not like I have only three months of life left.* (P9)

Seeking and accepting outside support, especially at the beginning of the journey, was often perceived as needed; people were content, and felt pleasant, relieved and encouraged. People sought support and gave importance to having support. On the other hand, support became a burden to them. Later, support was perceived as an intrusion into their life; people felt controlled, and under pressure due to questions and expectations.

> *It was all about the finger: my wound was the most important topic of each encounter. No one was interested in me, and I was fed up with people. It is nice to have people around you, but enough is enough. I said, "You have your life, leave me; I will manage; my finger is ok."* (P1)

People also developed maladaptive coping strategies, such as self-isolation and withholding information. They withdrew and started to avoid the people supporting them, often due to the perceived invasiveness of the support.

> *I needed my time. There were always calls asking how I felt and if I needed something. I started to turn them down, as I needed my peace. I remember, later, once my brother said that I am making it too complicated.* (P10)

Furthermore, people started to withhold information about their condition. The reasons for information reticence were related to the nature of condition, perceived self-image, rumours, keeping their privacy and not raising concerns.

> *People are, by their nature very interested in other people's business. Everyone wants to know what, how and why. One even asked me if I had stepped on a bomb, and this* [comments from others] *became unpleasant. All those questions and advice – I started to tell them that it was getting better so they would leave me alone.* (P7)

6.3.4 Striving for healing

People with wounds strove for healing. They exerted themselves to recover and were willing to do or try anything to achieve it. Some people were willing to accept invasive treatments regardless of potential complications, side-effects or risks associated with treatment, as treatments were often perceived as a hope to end the suffering.

> *I had seven operations. The wound didn't heal and they* [surgeons] *proposed plastic surgery. I was willing to undergo it regardless of whether I would suffer from long lasting aesthetic deformation – my buttocks would be deformed. I was not happy about it, but I would go for it, so the wound would heal better.* (P2)

People made an effort to go through this experience. They struggled, often perceiving their actions as a "fight", and hope for healing.

Striving for healing was related to people's treatment adherence, treatment experiences and relationship with the nurse or physician. The majority of people said that they adhered to the advice and simple treatment interventions by following nurses'/physicians' orders; however when they felt that the treatment was not working as they expected, some patients took matters into their own hands, and others did not follow advice.

> *Well, I have to have those dressings every day, and I shower twice a day as instructed. But these dressings don't work, so I started to use dressings with silver instead. I read that silver kills bacteria, so wounds heal more quickly*. (P2)
>
> *I knew that I had to rest, but I went to the birthday celebration. Later I bled from the wound… A nurse came to change the dressing, but I had to go to the toilet, and probably I put too much weight on my foot and it started to bleed even more*. (P5)

In their willingness to do anything, people accepted various treatments which were offered to them, namely wound dressings, negative pressure wound treatment (NPWT), hyperbaric oxygen treatment (HBOT), light therapy, orthosis, various medicines such as antibiotics, anti-inflammatory drugs, biological treatment and analgesics, and surgical debridement and additional surgery. People were often uncertain about their treatment plans; they were scared, had unanswered questions and were worried about or even unaware of potential side effects or complications. They often felt frustrated by their experience; often the treatment interventions raised concerns for them because they felt disempowered.

> *They propose different things to you and you try different things. I tried various dressings, including with silver to reduce the smell, and I got an allergic reaction. No one told me about this… I also tried laser light therapy, which helped a bit, I think, but then the healing didn't make progress… I was on antibiotics, and then at least*

> *the smell reduced a bit. …I used pain medication to control the pain; I took one pill every two hours.* (P6)

Over the weeks or months of treatment, people with wounds and their health professionals built a relationship. According to the narratives, a good and trusting relationship was a requirement for treatment success. People experienced a variety of behaviour from nurses/physicians, which was mostly positive. They said that they had often been reassured and comforted, and that they trusted and believed in the health professionals, which helped them to get through the experience. However on their journey they also had negative experiences, where, due to a lack of information, lack of empathy, or perceived incompetence, they reacted with mistrust and fear, and sought information and treatment elsewhere.

> *The worst thing is that nurses and doctors don't know a lot about this. I lost trust in the local GP and emergency services: they didn't know anything and I didn't want to go back there. When I first had surgery I had a hole 10 cm wide and 3 cm deep in my foot. I only trust the surgeon. She is really professional and I also go to the department* [surgical department] *to get my dressing changed.* (P7)

People were patient and persistent in using health care services. Waiting times were of concern, however, they were willing to wait for additional check-ups, consultations with physicians from other specialties, and for other treatment to be provided.

People expected healing. Their expectations at the beginning were often not realistic and they were also burdened with healing-related uncertainty; however, their expectations changed over time. Healing was of particular interest for them; they were very glad when any progress was observed. People cherished feedback from healthcare professionals, and often asked them to take a photo, especially those people who could not see the wound due to its location. Photographs and feedback lifted their morale.

> *I look at my wound. I don't know a lot about the treatments, but I look when she* [community nurse] *changes the dressings and nicely washes the wound, and I look to see the progress in healing. This means a lot to me, and I do observe progress.* (P5)

6.3.5 Returning to normal life

Finally, once healing occurred people started to slowly return to their normal lives, and many said that their life was back in balance. People experienced positive emotions and their self-esteem began to improve; they felt free again, were able to move freely and enjoyed life again. They started to perform daily activities in their old routine, and feel content with the normality of their lives. Their physical and mental performance started to improve greatly; they socialised with others again and were happy that attention had shifted away from them and their condition.

> *It was really hard experience. I can't really describe how it was. I was in fear, scared until the wound started to heal. I was scared that I would lose my leg. But when the healing occurred I almost immediately felt well, and the community nurse was also happy; we all were. And now that the wound is almost healed I feel great. I was really down, but now I feel completely different, really!* (P4)

Participants who were still working were happy to return to work, felt positive, changed their daily routine, were accepted at work, improved the social-professional domain of life, and improved their finances. People started to make plans for the future again.

> *When you are at home so much, you say to yourself that it's time to go to work. You also get tired of being at home all the time. I am doing well at work and I am quite happy. My routine has changed, and now that I am back, I can see how I was under pressure due to the wound.* (P6)

People said however that the experience was stressful and unpleasant and had marked them for life. They kept remembering the experience, and the memories, for them, triggered fears. They described how they developed subconscious fears about the potential recurrence of the wound and about possible future experiences.

> *The doctor said, that this could repeat in future. When I think about it I can just feel all the chills and being, I don't know… scared. It is not easy.* (P9)

Although they were content that the wound had healed, a scar was not perceived as the end of their experience. Scars evoked memories and thoughts about the experience. A scar was often perceived as an eternal mark of experience.

> *Well it may sound strange, but the scar will stay forever; it'll remind me every day of this experience. For example, when I take shower, I see it, or when I scratch my belly, I feel a hard scar and kind of everything returns.* (P10)

6.4 DISCUSSION

6.4.1 Main results

The aim of this study was to explore the meaning of living with open surgical wounds over time. By looking at the trajectory of meanings of living with OSW reflected in subthemes and the main theme, "*negotiating a new normality*", it became apparent that the findings mirror the discourse in the chronicity literature (Bury, 1982; Corbin & Strauss, 1991; Charmaz, 1997). Chronicity is the process of becoming chronically ill, going on the journey of living with chronic illness, where one's person (oneself) and one's life is affected and disrupted, and where a reconstruction of self (identity) and life through coping mechanisms is accomplished (Smith-Morris, 2010). The subthemes and overarching theme reflect that people went through a process (stages) when living with OSW. Although we did not aim to explore the process or understand the links between concepts in processes related to chronicity, the longitudinal nature of this study with time windows between interviews brought to the light the changes in the experience of OSWs that happened over time.

The subthemes "*enduring healing*" and "*life disruption*" describe in depth the phenomenon of having a wound, from the perspective of the patients' initial reactions to the descriptions of profound impacts on well-being. This is coherent with the work of McCaughan et al. (2018) on patient perspectives of OSW and findings from many studies of people with other types of complex wound (Persoon et al., 2004; Herber et al., 2007; Briggs & Flemming, 2007; Gorecki et al., 2009; Coffey et al., 2019; Phillips et al., 2018). Findings attributed to both sub-themes mirror Bury's (1982) concept of biographical disruption, described as the impact of a chronic condition on individuals' biographies (lives), where peoples' known lives change and social relationships with others are impacted or might change.

Apart from descriptions of radiating impact on people's wellbeing, attention must be given to the impact on relationships (including sexuality). Concerns over perceived appearance, including stigma, were more prominent in people's narratives in our study compared with that of McCaughan et al. (2018) and other complex wound research. Our study yielded that people's relationships with their loved ones (life partners) or other significant people were affected, especially in terms of sexuality and feelings of attractiveness. A possible reason for the extensive discussion of sexuality from both males and females is that our study sample consisted of young people with OSW (average 40.5 years), which is different from the overall population with complex wounds, who are typically older (Hall et al., 2014; Chetter et al., 2017) or the population in McCaughan et al.'s (2018) study, where the median age was 53 years. Intimate relationships can break down due to change of self-perceived identity (in our study, perceived feelings of attractiveness and physical appearance) during chronic illness (Charmaz, 1997; Bury, 1982). Furthermore, other social relationships can be impacted due to the strain, demands and expectations that a person with such a condition might place on another (Eriksson et al., 2019; Eriksson & Svedlund, 2006; Sautter et al., 2014).

People with OSWs have also expressed concerns with their physical appearance: they were often concerned about public stigma due to their wounds and wound-related symptoms, which confirms the findings from previous research (Lindahl et al., 2007; Taverner et al., 2011; Probst et al., 2013a; 2013b; McCaughan et al., 2018). Fears that wounds and symptoms such as malodour or exudate could be observed by others, are disgusting and have impacts on everyday living could be attributed to an underlying cause: to people internalising public stigma and developing self-stigma. Self-stigmatising behaviour has been substantially theorised in other areas of chronic disease research (Corrigan & Watson, 2002; Van Brakel, 2006; Scambler, 2009, 2006) and is related to social withdrawal, social isolation and social alienation, which lead to deterioration of mental health, and development of anxiety and depression (Leigh-Hunt et al., 2017).

The subtheme “*Adapting to a new reality*” reflects people’s reactions, which are similar to the psychological adjustments described in the healthcare and chronicity literature (Bury, 1982; Charmaz, 1995, 1997; de Ridder et al., 2008; Dekker & de Groot, 2018; Gagliardi et al., 2002; Stanton et al., 2007; Vann-Ward et al., 2017). Living a long time with a wound results in developing adaptation behaviour to the “new”, and can be interlaced with a high level of uncertainty. Charmaz (1997) describes how people learn how to live with chronic conditions by normalising their experience with adaptations that contain the unpleasant symptoms and make daily life ordinary. Furthermore, people react to new circumstances by seeking knowledge (Vann-Ward et al., 2017), and needing to be informed and empowered by information (Etkind et al., 2017). In our study, people with wounds have emphasised that they received conflicting information about their conditions and treatments. Conflicting information in healthcare is not a novelty; there have been many studies reporting that at some point up to 80% of patients receive conflicting information (often from various sources), which can affect their adherence to treatment and expected treatment outcomes (Carpenter et al., 2014, 2016; Elstad et al., 2012). Nurses and physicians should support people with information based on reliable and high quality evidence, and furthermore they should inform them about the credibility of health information sources, such as Google, and potential threats; however this could be challenging, as there are many existing uncertainties related to effective wound care interventions (Gray et al., 2017).

Coping strategies were also verbalised and noted in this study, which is similar to previous complex wound studies (Persoon et al., 2004; Herber et al., 2007; Briggs & Flemming, 2007; Coffey et al., 2019; Phillips et al., 2018); however, in this study we also observed maladaptive strategies such as the emotional over-involvement of loved ones; which has not been well reported in wound literature, in contrast to other chronic condition research, such as mental health (Butzlaff & Hooley, 1998; Izon et al., 2018). Some people, after having a wound for some time, withdrew from loved ones and often perceived their support as intrusive, implying that relatives were an overly intense source of support and often did not respect the patients' autonomy. Furthermore, people often concealed information from others; an issue that has also discussed in other chronicity literature, where it has been suggested that people withhold information due potentially negative perceptions of others and the need to appear healthy (Charmaz, 1997; Joachim & Acorn, 2000; Kaushansky et al., 2017; Munir et al., 2005).

In the subtheme "*striving for healing*", willingness to do anything to achieve complete healing was one of the central features. "Striving for" is similar to Charmaz's (1997) conceptualisation of the struggle for control in chronic illness. In their struggles, people aim to preserve their "self" (Vann-Ward et al., 2017). On the other hand, in the chronicity literature, the phenomenon of "surrendering" has also been described, which relates to a discontinuance of struggling against both unpleasant symptoms and the condition itself (Charmaz, 1995). The difference – why people in our study were motivated to seek resolution and were trying to achieve it – might be the fact that open surgical wounds, in contrast to chronic conditions, are expected to heal, or the fact that people's narratives related to their striving for healing were shaped by their age and their "old lives". Findings from our study also suggested that compliance and adherence, and trusting relationships with healthcare professionals, intersected with their "willingness". In some cases, people became non-adherent due to mistrust, based on their belief that the treatment was ineffective, or because they had received conflicting information or had mistrust in the nurse or GP-patient relationship (interaction); common reasons described in the chronic illness literature (Kyngäs, 2000; Kyngäs et al., 2000; Shahin et al., 2019; Ann Van Hecke et al., 2009, 2011). It is well documented that non-adherence can lead to negative outcomes for patients (Currie et al., 2012; Gosmanova et al., 2014; Guerci et al., 2019; Ho et al., 2006), and therefore nurses and physicians should build professional and trusting relationships with patients and deliver tailored interventions to enhance their adherence (Hallett et al., 2000; Kyngäs, 2000; Van Hecke et al., 2011; Weller et al., 2013). Some participants, in their striving for healing, were motivated to believe that treatments such as dressings containing silver would be effective, despite a lack of evidence that silver-containing dressings heal wounds more quickly (Vermeulen et al., 2007). Overall, there is a lack of reliable and valid evidence about the effectiveness of topical treatments on OSWs (Dumville et al., 2016; Jull et al., 2015; Norman et al., 2016; Smith et al., 2013; Smith et al., 2016; Vermeulen et al., 2004, 2007).

"*Returning to normal life*" is a sub-theme reflecting people's experience of achieving healing, which involves liberation, fears and memories. The sub-theme "*Returning to normal life"* departs from traditional chronicity descriptions of "resolution" (Bury, 1982; Charmaz, 1997), as the wounds had healed and people were able to continue with their "known" life, in contrast to other chronic conditions. However, findings from our study have shown that scars often became the vehicle for negative emotions. This phenomenon is often reported in patients with burns and other conditions (Ngaage & Agius, 2018). The possible explanation for this might be, as previously mentioned, that our study sample was younger in age and this was due to possible wider societal constructs on appearance. Another is that the interviews took place soon after the patients' wounds first healed and it was easy to be reminded of the event, or that people were traumatised by the experience of having wounds (Tedstone & Tarrier, 1997).

Conceptual similarities to the chronicity literature signal that experiencing OSW might be as devastating in terms of suffering as experiencing other chronic conditions which in lay understanding might be considered “more serious”. We were surprised to find such similarities with the chronicity literature, as the usual experience of OSWs is that it is expected to end (i.e. the OSW is expected to heal completely). Furthermore, complete healing is achieved in a shorter time frame (Chetter et al., 2019) compared with other complex wounds (Hall et al., 2014). Understanding and being aware that people with OSWs – a relatively short-term condition – respond in the same way as those with more typically long term conditions leads to the conclusion that people, regardless of the duration of their condition, might both suffer and find resolution in a similar ways (experiencing disruption and developing adaptations and coping mechanisms). Secondly, the findings signal health care professionals to be attentive when providing care: the care model for people with OSW should be adjusted in such a way as to promote addressing the whole range of their needs and suffering, which are related to the physical, psychological, social and vocational domains of people's well-being.

6.4.2 Trustworthiness

This study has a number of strengths. It is one of the first studies to provide in-depth insight into the meaning of living with open surgical wounds over time globally. A particular contribution of this study is that it has illuminated that the experience of having OSWs changes over time, which is probably a result of the longitudinal nature of this study. It has identified significant findings related to the impacts on people's wellbeing; furthermore it has revealed people's adapting and coping strategies, which enable them to normalise their lives. Another strength related to the findings is that the study has shed light on how experiences of OSWs are similar to those described in chronicity literature, which indicates the need to consider using a longitudinal design when exploring people's experiences with complex wounds.

There are also a few methodological considerations related to credibility, dependability and transferability. One limitation is that we recruited only ten participants for this study; however we believe that the variety in the sample and conducting two in-depth interviews have none the less contributed to variation in perspectives, depth and richness of findings, which promotes credibility. Though the analysis, up to the phase of development of sub-themes, was carried out by one researcher (L.P.), we believe that credibility is not affected, as we have described the approach in a logical and structured manner. Secondly, we have supported our findings (in terms of subthemes and a theme) with rich descriptions and quotes. Furthermore, all aspects of data collection and analysis were discussed with co-researchers (J.G. and N.C) in order to obtain the most plausible interpretation of findings. A possible critical issue in the data analysis is in fact that it was carried out partially in Slovene and was later continued in English; however we believe that this has not affected the credibility of findings to a great degree, as the primary researcher (L.P.) is proficient in both languages, and furthermore, the interviews (as a whole) and data analysis were discussed by all three researchers. Interviews as a data collecting technique can be seen as a possible threat to dependability (Graneheim & Lundman, 2004); however, due to the longitudinal nature of the study and through using a topic guide, we were able to return to the topics which were addressed only superficially (or were later revealed to be relevant in interviews with other participants) in the follow-up interviews. When considering transferability, we believe that findings from our study to be transferable to other people with OSWs as our sample reflects a similar population (in terms of gender and age) to those reported in epidemiological studies (Hall et al., 2014; Chetter et al., 2017, 2019; Pađen et al., 2019); however this population was homogeneous by race (all white Slovene). Users of this research must take into account the specific context related to this study.

6.5 CONCLUSIONS

The findings from this study have shown that people with open surgical wounds experience profound impacts on all domains of their well-being. Furthermore it highlights that the trajectory of having an open surgical wound is similar to that described in ‘chronicity’ literature. Regardless of the impacts and suffering, people cope, adapt and aim to achieve resolution. In the process of doing so, health care professionals should respond by providing effective treatments and support to people. However, this might be a challenge as there is an overall lack of relevant evidence for such interventions.

The results from this study could be used for clinicians to improve the competence and compassion in the care they provide. Furthermore, this study has also highlighted areas for further research, related to improving people’s experience of living with OSWs.

7 DISCUSSION

7.1 INTRODUCTION

In this chapter I summarise the three studies undertaken for this PhD in terms of the rationale for their conduct, their aims, methods, and key findings. Next I discuss the findings of the studies in the light of research published whilst this PhD was underway. I then identify the strengths and limitations of all three studies and consider key implications for research and clinical practice. The chapter ends with final conclusions.

7.2 OVERVIEW OF WORK UNDERTAKEN

I began this research by writing a literature review (now part of the Background chapter) which identified knowledge gaps in two key areas. Firstly, I found a general lack of epidemiological data about open surgical wounds. Secondly, while I identified numerous qualitative studies on people's perspectives of different types of complex wounds, I did not identify a comprehensive, high quality review of the types of people and wounds that have been studied.

To address this deficit in knowledge I conducted a scoping review (Study 1) which highlighted a lack of studies exploring people's perspectives of living with open surgical wounds. Although the purpose of the scoping review was to map research that had been done (rather than synthesise the findings), it became clear from both this review, and the narrative review in Chapter 2, that unpleasant symptoms associated with open surgical wounds had not been thoroughly explored.

The findings of the scoping review led me to undertake a cross-sectional survey, in Slovenia, of people with open surgical wounds (Study 2), which was designed to fulfil two related aims; to describe for the first time, the prevalence and treatments of open surgical wounds in Slovenia and secondly, to scope the unpleasant symptoms associated with open surgical wounds.

The cross-sectional study informed a subsequent, indepth qualitative study of the impact of open surgical wounds on the people who experience them. The qualitative study (Study 3) was designed to target the population identified in the cross-sectional survey. Importantly, this qualitative study was longitudinal in nature, aiming to explore, in depth, the meanings of living with open surgical wounds over time.

In the next section I will summarise the aims, methods and key findings of all three studies. Furthermore, I will discuss the findings in the light of recently published studies related to the aims of this thesis and conclude with my study's contributions.

7.2.1 People's perspectives of living with complex wounds – a scoping review (Study 1)

When I began my studies, I was aware that there were existing qualitative studies and reviews that had explored people's perspectives of living with wounds (Briggs & Flemming, 2007; Girouard et al., 2008; Gorecki et al., 2009; Gorecki et al., 2011; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018). There appeared to be evidence that complex wounds in general have negative impacts on people's well-being and quality of life. This research landscape appeared messy, however, in that different authors had looked at different wounds from a variety of different perspectives. From the existing studies it was hard to see which kinds of wounds had been studied from which perspective, and also whether there were areas where a systematic review or evidence synthesis might be required, or whether primary research in certain areas was what was needed. This motivated me to design a scoping review of qualitative research into people's experiences of living with complex wounds, with the objective of investigating and describing the nature, extent and variety of published research about patients' experiences of living with complex wounds, including the nature of the different wounds studied.

I carried out a comprehensive search of three electronic databases using a predefined search strategy to identify studies for potential inclusion. I included 103 records in this scoping review: 79 primary studies (90 records) and 13 reviews or syntheses published between January 1995 and June 2018.

The scoping review collated the research on living with complex wounds for the first time. I found a great deal of heterogeneity in the types of wounds studied and the ways in which they have been studied. Most studies (35.6%) focused on people with venous leg ulcers; the most common type of complex wounds with prevalence estimated at 0.44 per 1,000 population (Hall et al., 2014). In contrast, there is a relative lack of research about living with arterial leg ulcers, malignant fungating wounds and open surgical wounds, in spite of their relatively high prevalence. According to Hall et al. (2014) the prevalence of arterial leg ulcers is estimated to be 0.05 per 1,000 population, and that of malignant wounds 0.02 per 1,000 population. Meanwhile, the prevalence of open surgical wounds is estimated to be 0.41 per 1,000 (Chetter et al., 2017). Other under-represented groups include children and adolescents with complex wounds, about whom there are no studies despite their being affected, albeit less frequently (Hall et al., 2014; Pađen et al., 2019). Understanding the perspectives of younger people would allow wound care services to be adapted to address the specific needs of this group.

Most of the existing studies on living with a complex wound had been conducted in high-income countries, and only two studies conducted in middle and one in lower-middle income countries. This suggests that people's perspectives of life with a complex wound in low and middle income countries is under-researched. Understanding perspectives from those countries would be of value not only in their local context, but also for health professionals from western developed countries (Harrison & Daker-White, 2019). When considering global health challenges related to migration, these people might, for example, use other traditional forms of treatment for their wounds or have different perceptions and beliefs about health and illness (Degrie et al., 2017; Hultsjö & Hjelm, 2005; Saurina et al., 2010).

The scoping review identified that a variety of methodological approaches have been used in the primary studies of the experiences of people living with complex wounds. Most frequently, studies reported methodological approaches in the traditions of phenomenology and hermeneutics; grounded theory and other, more pragmatic approaches, were far less common. Meanwhile a considerable number of studies (almost a third) did not specify their approach. Each approach brings a different understanding of a phenomenon, as the onto-epistemological tradition and objectives of each differ. Phenomenology, for example, seeks to describe the essence of the lived experience (Husserl, 1997), while grounded theory aims to understand the process of experiences with the aim of generating theory (Glaser and Strauss, 1967, Charmaz, 2006).

I also identified the variety of approaches taken in the reviews or synthesis studies. The majority of the reviews/synthesis studies were described as systematic reviews, employing a systematic identification of studies, which reduces the risk of publication bias.

My scoping review identified only eight qualitative studies which took a longitudinal approach to understanding people's perspectives of living with wounds (Brod, 1998; Chase et al., 1997; De Vera, 2003; Fagerdahl et al., 2013; Hopkins, 2004; Hyde et al., 1999; Lund-Nielsen et al., 2005a,b; Lernevall et al., 2017). Longitudinal qualitative approaches are useful for deep and detailed exploration of transition in the course of chronic conditions, including why and how people respond, negotiate and adapt to the process of living with conditions over time (Calman et al., 2013; Grossoehme & Lipstein, 2016; Murray et al., 2009) unlike those which are cross-sectional in nature.

The aim of my scoping review was to explore the nature of the existing studies and what had and had not been studied; it was not my intention to examine the findings of the qualitative studies or reviews but to "map the terrain" in order to identify the most logical "next step" (meta-synthesis of studies on a topic, if much evidence existed or new primary research if this was missing in an area).

People with open surgical wounds in particular were identified as underserved by qualitative research. My scoping study identified only six qualitative studies looking at open surgical wounds (the majority of which were published after the start of my PhD); of these only McCaughan et al. (2018) focused on people's perspectives of living with open surgical wounds. The other studies, focused on: surgical site infections (Andersson et al., 2010; Tanner et al., 2012, Tanner et al., 2013), and other wounds such as episiotomy, amputation or treatments (Dudley et al., 2017; Neal, 2015; Monsen et al., 2017). All six studies of open surgical wounds had a cross-sectional design; arguably less appropriate for open surgical wounds because their healing time lasts from weeks to years, and they frequently recur (Chetter et al., 2017; Chetter et al., 2019). Open surgical wounds are a long-term condition, and symptoms and coping strategies evolve over time. Furthermore, pre-existing prevalence data suggest that they are very common. Consequently I concluded that we do not know enough about life with an open surgical wound and this gap needed to be addressed. There was no point doing a meta-synthesis of people's perspectives of open surgical wounds because there was only small number of primary research studies. The findings from this scoping review identified the need for new primary research with the aim of exploring the meaning of living with an open surgical wound. Furthermore, it allowed me to tailor the research design of the subsequent qualitative study (Study 3), in the tradition of phenomenology and hermeneutics and employing a longitudinal study design.

7.2.2 A cross-sectional survey of open surgical wounds in Slovenia (Study 2)

I began my PhD in 2013. At that time there was a suggestion that open surgical wounds might be quite common (Hall et al., 2014); however, globally there was a lack of prevalence data about these wounds (Cullum et al., 2016). All previous prevalence studies or audits involving people with open surgical wounds referred to patients in the north of England (Hall et al., 2014; Sirnivasaiah et al., 2007; Vowden & Vowden, 2009 a,b), and there were no data on the prevalence, nature and treatment of these wounds in other countries, including Slovenia.

My scoping review also suggested that people with open surgical wounds were under-served by qualitative research, exploring experiences of living with these wounds. We do not understand much about the effects of open surgical wounds, including their symptoms and impact as there are no studies which have looked specifically at these. Such a knowledge gap might be an issue, as findings from synthesis studies of leg ulcers and pressure ulcers have shown that unpleasant symptoms are commonly experienced and are a vehicle for negative impacts on people's everyday living and quality of life.

To address the identified knowledge gaps I designed a cross-sectional survey with the aim of estimating the point prevalence in people of all ages in Ljubljana (Slovenia), exploring the natural history and characteristics of open surgical wounds, where people are treated and how they are managed. Furthermore I decided to explore the occurrence of wound-related unpleasant symptoms. This allowed me to explore, on a large scale, whether people with open surgical wounds experience frequent complex wound-related unpleasant symptoms, such as pain, exudate, malodour or pruritus.

I carried out a multi-service, cross-sectional survey over a two-week period in the city of Ljubljana, Slovenia (population 288,919). Health care professionals across 18 health and social care settings completed one anonymised form for each patient with an open surgical wound. Forms were completed for 110 patients.

The findings from this cross-sectional survey demonstrated that the point prevalence of open surgical wounds was 0.38 per 1,000 population (95% CI: 0.33 to 0.44), which is similar to estimates from the UK. My survey showed for the first time that open surgical wounds also affect children and adolescents, and that most of these were nail avulsions, abscess excisions and pilonidal sinus excisions. This concurs with the findings of Hall et al (2014), that while older people more frequently have wounds associated with underlying conditions, younger people seem to be affected predominantly by open surgical wounds. 54% of the sample in this cross-sectional study consisted of people who had had operations on soft tissue, and skin infections and nail avulsions. The majority of the wounds were planned, pre-operatively, to heal by secondary intention (76/110, 69%). Eighty three per cent (92/110) of open surgical wounds were treated with wound dressings, and 6% were treated with negative pressure wound therapy. There was wide variation in the treatments and wound dressings used, some of which were evidence based; others were outdated and potentially cause for concern. For example, dry swabs were still being used as primary dressings (in direct contact with the wound bed) although there is the evidence that removal is associated with wound bed trauma (Haesler, 2019). Furthermore, antimicrobial dressings with silver were also frequently used, for which we lack of good evidence on the clinical effectiveness (Vermeulen et al., 2007). The reason might lie in the organisation of services (no specialist wound services are available in the community in Slovenia) and possibly also a lack of education, as at the time of the study there were no specialist wound courses for nurses and nursing assistants in Slovenia.

Mine is the first large, cross sectional survey that shows that people with open surgical wounds do in fact experience wound related unpleasant symptoms, such as pain, exudate, malodour and pruritus, which are also experienced by people with other types of complex wound such as leg ulcers, pressure ulcers, malignant fungating wounds and wounds related to diabetes (Girouard et al., 2018; Persoon et al., 2004; Ribu et al., 2006; Bradbury and Price, 2011a,b; Bengtsson et al., 2008; Maida et al., 2009; Gorecki et al., 2009; Paul, 2013; Lo et al., 2008). A picture is now emerging of how unpleasant symptoms vary across different types of complex wound. I found that pain and exudate were commonly experienced by people with open surgical wounds (84% and 75% respectively), while malodour and pruritus seemed to be less common (32% and 10% respectively). This contrasts with leg ulcers, for example, where it is reported that up to 79% of people experience malodour and exudate (Persoon et al., 2004) and 45% of people experience pruritus. In the case of malignant fungating wounds it is reported that they are malodourous and exuding rather than itching: only 6% of people experience pruritus (Maida et al., 2009).

Understanding the manifestation and occurrence of wound related unpleasant symptoms could be also used to inform patients about what to expect when they have open surgical wounds, to prepare them for predictable aspects of the healing process and make them aware of potential risks.

When my PhD started in 2013, there was a global lack of epidemiological data related to open surgical wounds (addressed in the Background chapter, section 2.3.1). However, there have been studies published since my research began; particularly two primary studies undertaken in the north of England, by Chetter et al. (2017), and Gray et al. (2018). I will now discuss my research in the context of this other recent studies.

Chetter et al. (2017) carried out a survey of people with open surgical wounds in the north of England (UK) and estimated the prevalence at 0.41 per 1,000 population, which is very close to my estimate from Slovenia (0.38 per 1,000 population). Chetter et al. (2017) also found that the majority of open surgical wounds were treated in the community by nurses with wound dressings. These two prevalence studies (Chetter et al. and Pađen et al., 2019) were similar in some respects, but there were also distinctions. Both produced similar estimates of prevalence; however I believe that my study made a particular and original contribution to knowledge by showing that open surgical wounds also occur in children and adolescents (these age groups were excluded from the study by Chetter et al.). Furthermore my study was the first to look at the occurrence of unpleasant symptoms experienced by people with open surgical wounds.

Another study was recently conducted in Greater Manchester (study population of 1,560,195) by Gray et al. (2018). This study aimed to quantify the number, type and management of all complex wounds being treated across five NHS trusts. The prevalence of open surgical wounds in that study was estimated at 0.30 (95% CI 0.27-0.33) (N Cullum, personal communication, September 2020), which is slightly lower than the estimates from the other studies (Hall et al., 2014; Chetter et al., 2017, Pađen et al., 2019). This lower estimate is probably explained by inclusion of only community-based patients as up to 34% of people with these wounds are treated in acute hospital settings (Chetter et al., 2017; Pađen et al., 2019).

By looking at the point prevalence of open surgical wounds from today's perspective, it can be reliably concluded that the point prevalence in high-income countries is in a range between 0.28/1,000 and 0.41/1,000. All four studies identified (Hall et al., 2014; Chetter et al., 2017; Gray et al., 2018; Pađen et al., 2019) used similar designs to explore the point prevalence of wounds (point of time defined as a 14 day period), specified the denominator (three studies of defined populations in the UK, one from Slovenia) and defined the diagnostic unit (definition of wounds). The data were collected by health care professionals involved in patient care who also validated the cases. Differences in the prevalence estimates between the studies can be attributed to the fact that each study was looking at a slightly different population; specifically, Chetter et al. (2017) excluded children and adolescents from their study, while Gray et al. (2018) conducted their study in community settings only (however, this would not greatly affect the estimates as the majority of people are treated in the community (Hall et al., 2014; Chetter et al., 2017, Pađen et al., 2019)).

The key contributions of my cross-sectional survey are that it was the first to provide essential information about the extent, nature and treatment of open surgical wounds in Slovenia. Furthermore, it is one of the latest of a very small number of studies to have contributed to knowledge about these wounds globally. The findings from the study could be used for planning future research, health resources management and policy development. Implications are further discussed in Section 7.4.

7.2.3 A qualitative exploration of the meaning of living with an open surgical wound (Study 3)

The scoping review showed how little was known of people's perspectives of living with open surgical wounds. Furthermore, the scoping review suggested that given the nature of complex wounds, a longitudinal approach might be useful to explore people's perspective in subsequent qualitative studies.

The cross-sectional survey showed that the nature of open surgical wounds is diverse, involving wounds from soft tissue and skin operations such as abscesses and nail avulsions to those wounds which are the consequence of cancer operations and even amputation. In contrast to other types of complex wound, open surgical wounds also affect younger people. Study 2 also identified that people with open surgical wounds often experience common wound-related unpleasant symptoms, which suggests that there is likely to be some overlap of the impact of open surgical wounds with that of other types of complex wounds, but there may be important differences to be explored.

I designed a longitudinal qualitative study, with the aim to explore the meaning of living with open surgical wounds over time. I included 10 people (aged from 18 to 73 years) with different open surgical wounds (soft tissue operations, amputations, caesarean sections, abdominal operations, etc.), different locations of wound and type of healing at the time of surgery. I interviewed each person twice (at the beginning of their experience of having a wound and again when their wound had almost healed).

The findings show that the meaning of living with open surgical wounds is encompassed by five subthemes: “enduring healing”, “life disruption”, “adapting to a new reality”, “striving for healing” and “returning to normal life”, all under an overarching theme of “negotiating a new normality”. Living with wounds involves multi-layered, negative impacts on people’s well-being and profound suffering; however it also involves a positive shift to patterns of adapting to and coping with the wound. When wounds heal, people return to their previous life. However, scars are perceived as negative reminders of their experiences and induce fears about wound recurrence and future experiences.

An important finding from this study was that living with open surgical wounds has a typical ‘chronicity’ trajectory. While a description of the “chronicity” trajectory was conceptualised more than 30 years ago (Bury, 1982; Corbin & Strauss, 1991; Charmaz, 1997) and was explored in depth at that time in other chronic condition literature, it has not discussed in complex wound research where the focus has been concentrated on exploring the negative impacts of wounds on people.

I found that the trajectory of living with open surgical wounds (reflected in the overarching theme “negotiating a new normality”) is a helpful concept in wound research. It elucidates the meaning of living with open surgical wound, which is not only about suffering but also about coping, adapting and returning to normal life. Furthermore, the trajectory reflects a pattern of psychological, social and behavioural changes, which are to be expected when people are living with open surgical wounds for some time.

Comparing the results from this qualitative study with those from the few existing longitudinal studies of complex wounds and the theory of chronicity (Bury, 1982; Charmaz, 1995; Charmaz, 1997; Corbin, 1998; Corbin & Strauss, 1991) has also highlighted where my findings differ. “*Striving for healing”* (a theme also described in previous wound literature) encompassed people’s willingness and struggle to do anything to achieve complete healing, while Charmaz (1995) rather described the phenomenon of surrendering, which relates to ceasing to struggle against the illness. “*Returning to normal life*” is a subtheme which not only differs from the traditional chronicity trajectory but also from findings of other complex wound qualitative studies, and as such brings a unique contribution to knowledge. "*Returning to normal life"* reflects the time when wounds have healed and people are returning to their known routine, which also resolves in feelings of contentment, whereas the theory of chronicity trajectory describes the progression of the condition into the decreasing phase (where people's health declines) up to the point of death (deceasing phase) (Bury, 1982; Corbin & Strauss, 1991; Charmaz, 1995, Charmaz, 1997; Corbin, 1998). Furthermore, findings from other complex wounds studies have emphasised how people adapted and reconstructed their lives by going through a process of acceptance, and learned to live with their wounds rather then returning to normal life. This difference is probably because open surgical wounds are generally expected to heal (Chetter, 2019), whereas most other chronic conditions are lifelong. In spite of these differences, the findings highlight the importance of understanding the meaning of living with open surgical wounds in a new way: as a trajectory similar to that described in other chronic conditions.

Since I began my research, seven studies related to open surgical wounds have been published (identified in the scoping review), only one of which focused on people's experiences of living with these wounds (McCaughan et al., 2018). The other six studies looked at people's perspectives of surgical site infection (Andersson et al., 2010; Tanner et al., 2012, Tanner et al., 2013), experiences of treatment with negative pressure wound therapy (Monsen et al., 2017), women's perspectives of perineal dehiscence after childbirth (Dudley et al., 2017) or the impacts of wounds on the rehabilitation process of amputees (Neal, 2015).

McCaughan et al.'s (2018) study was the first to focus on people's perspectives of living with an open surgical wound. McCaughan et al. interviewed 20 people with different types of open surgical wounds and found that all domains of daily life were greatly impacted by open surgical wounds, especially among people who were young and still working. Living with wounds also impacted people's family members.

Despite the relatively recent publication of McCaughan's study, my study makes a complementary but distinct contribution. Both studies identified negative reactions to open surgical wounds: open surgical wounds impact people's well-being in all aspects of life and experiences with health care provision and treatments are an important part of that narrative. However, because I conceptualised this longitudinal qualitative study in the philosophical tradition of phenomenology and hermeneutics and used qualitative content analysis, I was able to not only describe but *interpret* people's experience of living with open surgical wounds. This was reflected in the overarching theme "*negotiating a new normality"*. My study showed that people were '*adapting to new reality',* that they were *'striving for healing'* and *'returning to normal life'*. This brings novel understanding of people's resilience and their behaviour – of seeking resolution – on their journey. My analysis goes further than the analysis in McCaughan et al.'s study that stopped at descriptions of people's experiences. Furthermore, my study also illuminated people's maladaptive strategies and behaviour during their life phase of living with wounds, which have not previously been described.

Secondly, the longitudinal, qualitative nature of my study brought a comprehensive understanding of transition during the course of living with wounds, which is reflected in the 'chronicity trajectory' in this study.

This study has contributed to the body of knowledge by in-depth description and interpretation of people's meanings of living with open surgical wounds over time. This qualitative study has highlighted areas for further research related to people's experiences, which are discussed in Section 7.4.

7.3 STRENGTHS AND LIMITATIONS

The research presented in this thesis has both strengths and limitations. Some of these have already been addressed within the methodology chapter (Chapter 3) and manuscripts (Chapters 4-6). In this section I will reflect on the most important strengths and limitations in relation to methodology and methods used in each study.

7.3.1 Scoping review

The scoping review aimed to explore the nature and extent of evidence related to people's perspectives of living with complex wounds. A scoping review (Arksey & O'Malley, 2005) was identified as the most suitable methodology to address the aim of this review, as opposed to systematic review or narrative review methods, as scoping reviews allow questions related to the extent and nature of evidence to be addressed. The limitations of Study 1 are related to the risk of publication bias, as I included only studies published in English; however the geographical distribution of the included studies, and the fact that only nine studies were excluded on language criteria, reassured me that there are probably only few relevant studies which were ineligible. It is also possible that I missed some eligible studies because I only searched three databases; CINAHL, MEDLINE, and EMBASE, however these are the major health databases so it is unlikely that many studies were missied.

I have not included grey literature which could introduce the risk of publication bias; however, there is a lack of evidence related to publication patterns in qualitative studies and therefore it is hard to estimate whether including grey literature would have significantly affected the validity of findings. Petticrew et al. (2008) have suggested that only 44.2% of qualitative studies presented at conferences were later published. The reason for this is related to studies' low trustworthiness or poor reporting: for example, only 50% of abstracts included details on context/setting, whereas 57.9% gave details on the sample or sampling procedures, and 55.3% contained details related to study findings. As the objective of the scoping review was rather to explore the extent and nature of evidence than contrasting research by definite findings, it seemed that excluding grey literature would not affect the trustworthiness of the findings. Another reason for excluding grey literature was pragmatic, namely, we had limited research resources and were not able to fund the translation of studies.

The scoping review also has methodological strengths. I developed a protocol, in advance of looking at the literature or making any decisions about how to analyse it and this protocol was peer-reviewed by my supervisors. The protocol enabled me to make important methodological decision in advance of seeing any studies and follow defined steps when conducting the scoping review. Furthermore, it gave clarity which helped me in selecting studies and extracting data, as well as both of my supervisors and our hired research assistant. An important strength of this scoping review is also that the titles and abstracts of studies for inclusion were screened by two people, working independently. Another strength of the review was that the search strategy was peer-reviewed by a Cochrane information specialist, upon whose suggestions the strategy was adapted so as to maximise the sensitivity and specificity of the search.

7.3.2 A cross-sectional survey

The cross-sectional survey of people with open surgical wounds aimed to explore the prevalence, nature and treatment of open surgical wounds in Ljubljana (Slovenia). To address this aim I considered two ways of collecting data, namely using routinely available data and designing and employing bespoke data collection. I discovered that there are no routinely available data about any type of complex wound in Slovenia (in common with the UK situation), so I opted for bespoke data collection. I designed a cross-sectional survey and developed a strategy to avoid the common pitfalls identified in previous systematic reviews of complex wound prevalence (i.e. Cullum et al., 2016, Graham et al., 2003; Briggs & Closs, 2003). This is one of the important strengths, as I was able to design a study which would produce results that would be comparable with other high qualty prevalence studies (i.e. Hall et al., 2014; Chetter et al., 2017; Gray et al., 2018).

The limitations of this cross-sectional survey are associated with the data collection method. This study was designed in such a way that multiple health care professionals (i.e. medical doctors, registered nurses or nursing assistants) collected the data, and therefore I was not able to validate responses and non-responses. However I believe that a good response rate was achieved by careful preparation, the provision of guidance about form completion and the simplicity of the data collection form. It is possible that some people with open surgical wounds have been missed in this survey. The reason for this might be that some might have sought help outside Ljubljana, sought help in the private care sector or were self-treating: however, I believe that I have probably missed only a few. Furthermore, two health care institutions did not participate in the survey, although community health care nurses from those institutions who worked independently did participate, so I expect that there were very few missing cases. The above might have resulted in an underestimation of prevalence; however the fact that the estimated prevalence from this study is similar to that reported in the previous studies carried out by Hall et al. (2014), Chetter et al. (2017) and Gray et al. (2018) is reassuring.

7.3.3 A qualitative study

This qualitative study aimed to explore the meaning of living with open surgical wounds over time. I considered different approaches to address this aim, namely: grounded theory, phenomenology, hermeneutics and qualitative content analysis. I argued about and discussed in depth each approach and the respective procedures for undertaking this study. Based on the merits of each I used qualitative content analysis as it is a systematic and flexible method which is useful for the analysis of large volumes of data (Bengtsson, 2016; Elo et al., 2014; Elo & Kyngäs, 2008; Graneheim et al., 2017; Graneheim & Lundman, 2004; Krippendorff, 2004). It involves the attribution of manifest and latent meaning to data (content), and then classifying the data to establish the degree of description and interpretation (Schreier, 2012).

The transferability of this research is limited by the sample which was recruited and the data analysis process. To address the first, this study recruited 10 people with open surgical wounds, which would at first sight be perceived as a relatively small number. However I must draw attention to the fact that there is a lack of empirical evidence related to sample size in studies using qualitative content analysis. From a theoretical perspective (Graneheim and Lundman, 2004) I sought rather the richness, depth and variation in narratives, which I achieved by conducting two interviews with each participant.

Another credibility issue is related to the data analysis which I carried out up to the phase of development of sub-themes. During analysis, I was aware that there were multiple realities in people’s narratives, however based on discussion with my supervisors I believe that I obtained the most plausible interpretation of findings. Secondly, I have supported the findings (in terms of subthemes and a theme) with rich descriptions and quotes, which allows the reader to judge the interpretation of the findings.

I carried out the analysis partially in Slovene and later continued in English; however, I believe that this has not affected the credibility of the findings to a great degree, as I am proficient in both languages, and furthermore, the interviews (as a whole) and data analysis were discussed with both of my supervisors.

There are a few important strengths of the interview study, namely, that with this study I have addressed a research gap identified in the scoping review and in doing so I used a longitudinal approach which provided in-depth description and interpretation of meaning of living with open surgical wounds over time. Furthermore, using a longitudinal approach increased dependability as in the follow-up interviews I was able to return to topics which were addressed only superficially (or were later revealed to be relevant in interviews with other participants). Another important strength of this research is that I was able to use a flexible method for data analysis, maintain focus, and stay within the tradition of Graneheim and Lundman's (2004) methodological approach, which was particularly helpful for me as novice qualitative researcher.

7.4 IMPLICATIONS FOR RESEARCH AND CLINICAL PRACTICE

7.4.1 Implications for future research

Findings from my scoping review of people's perspectives of living with complex wounds (Study 1) suggest that future qualitative studies should focus on exploring perspectives of living with leg ulcers from arterial aetiology and malignant fungating wounds, as this population is still under-researched despite the prevalence of these conditions. It is important to study these wounds as they might produce different impacts, due to the nature of the associated underlying condition. It is documented that arterial leg ulcers are caused by peripheral arterial disease (Mekkes et al., 2003) and people with peripheral arterial disease and ulcers are at a high risk of amputations (Humphries et al., 2016), whereas malignant fungating wounds are often a symptom of progressed cancer (Alexander, 2009), which can bring different perspectives of lived experience, in contrast to what has been studied before (for example pressure ulcers or open surgical wounds). By understanding in depth the differences in people's perspectives across types of complex wounds we can further develop health care responses in order to deliver beneficial interventions and achieve the best possible health outcomes.

The second area that was identified as under-researched is the perspective of children and adolescents living with complex wounds. Several prevalence studies (Hall et al., 2014; Gray et al., 2018 and mine – Pađen et al., 2019) have demonstrated that complex wounds affect children and young people, yet no studies have been identified which would include this population. Understanding children and young people's perspectives might provide important information for health care professionals, so they could tailor the way they provide care. It is documented from burns research that children have negative emotions related to procedural pain when a wound is debrided (Egberts et al., 2018) and also in other painful clinical procedures, such venepuncture, intravenous cannulation and radiology procedures (Bray et al., 2019; Rømsing et al., 2014; Shave et al., 2018). Although some of these findings might be transferable, there might also be important differences which need to be explored Including children and adolescents in research projects might be ethically challenging. However, there are many studies which have explored their perspectives of chronic conditions by using a qualitative study design (Carter et al., 2017; Parslow et al., 2017; Sligo et al., 2019) and various techniques for data collection, including children's drawings (Carter & Ford, 2013).

The scoping review (Study 1) also identified that the perspectives of people living with complex wounds in middle- and low-income countries are underserved by qualitative research. Findings from studies conducted in middle- and low-income countries focusing on atypical wounds resulting from infection with *mycobacterium ulcerans* suggest that people suffer greatly and seek help relatively late, which results in further health complications (Ackumey et al., 2012; Aujoulat et al., 2003; Effah et al., 2017). Understanding in depth the phenomenon of living with complex wounds in middle- and low-income countries would be beneficial as these countries are affected by poverty and people often have limited access to health care services, which might anticipate different health outcomes and perspectives (Driessens et al., 2020; Morris et al., 2005; Srivastava & McGuire, 2015; Woldemichael et al., 2019). Furthermore, it would allow tailoring the health services response to provide beneficial interventions for people with wounds.

Given the natural history of complex wounds, which heal slowly and are treated with various and also advanced treatment strategies (Hall et al., 2014; Chetter et al., 2017, 2019; Gray et al., 2018), and have documented negative impacts (Briggs & Flemming, 2007; Girouard et al., 2008; Gorecki et al., 2009; Gorecki et al., 2011; Herber et al., 2007; Persoon et al., 2004; Phillips et al., 2018), future qualitative studies might consider using a longitudinal approach, to data collection, similar to this study, as this might provide an in-depth and comprehensive understanding of perspectives and experiences of transition when living with wounds.

My cross-sectional survey of open surgical wounds (Study 2) also identified further areas of research. The study found that there is a large variety of wound dressings and other topical agents in use for open surgical wounds, which indicates that there might be uncertainty related to wound treatments among clinicians. Furthermore, it found that people were treated with interventions such as wound dressings and topical agents for which we do not have good evidence on their clinical effectiveness (Norman et al., 2016; Vermeulen et al., 2004, 2007). Investing research resources into producing evidence-based interventions for treatment of open surgical wounds would improve patient outcomes and would allow health systems to allocate resources effectively.

The symptom burden and quality of life of people with open surgical wounds is another area to be addressed in future research. The findings of the cross-sectional survey indicated that people with open surgical wounds experience common unpleasant symptoms, such as pain, exudate, malodour and pruritus. However in this study I addressed only the occurrence of symptoms, rather than exploring the severity of symptoms, due to the nature of the study design (people with wounds were not directly included in the survey). It is documented in other studies that the severity of unpleasant symptoms varies across different types of wounds (Girouard et al., 2008; Gorecki et al., 2009; Gorecki et al., 2011; Herber et al., 2007; Persoon et al., 2004; Probst et al., 2013b). Future studies might want to explore this in more depth by collecting quantitative data about unpleasant symptoms and quantifying the quality of life. This would be important as studies have shown that pressure ulcers are particularly painful (Girouard et al., 2008), while leg ulcers are rather malodorous (Herber et al., 2007), which suggests they have different impact on people’s well-being and that people could therefore have different needs. By further exploring unpleasant symptoms we might better understand and meet patients’ needs by providing specific interventions for wound management.

In my qualitative study (Study 3) I aimed to explore the meaning of living with open surgical wounds over time. Future studies might want to go a step further and explore the perspectives of patients’ loved ones and the impacts of living with someone who has open surgical wounds, as the findings from this study has shown that loved ones are closely involved in patients’ experience and care. This would be important, as understanding relatives’ perspectives can inform health care professionals how to support and empower them in living with – and caring for – people with open surgical wounds. A qualitative approach would suit this purpose, as it provides rich and in-depth understanding of people’s perspectives.

This qualitative study showed that people with open surgical wounds suffer and that all domains of quality of life are affected, which is consistent with findings from qualitative studies of other types of complex wounds. Future studies might want to design and further explore psychological, behavioural and social interventions for supporting people with wounds. Such complex interventions might be investigated with complementary approaches – suggesting a mixed-method study design (Moore et al., 2015).

The findings of this qualitative study are also consistent with the findings of the cross-sectional study, specifically regarding uncertainty related to treatment. The variety of treatments used and the mismatch between treatments and treatment objectives has led me to speculate that health professionals deal with a high level of uncertainty over treatment strategies. People interviewed for the qualitative study also reported that they had received conflicting information, that health professionals had opted for various treatment strategies, and that people were distrustful of some health professionals who – in their opinion – were incompetent. Further studies related to treatment effectiveness are needed.

7.4.2 Implications for clinical practice

The results from this study could be used by clinicians to improve competence and compassion in the care they provide.

As discussed above, the cross-sectional survey (Study 2) and qualitative study (Study 3) illustrated areas which can inform health care professionals to develop, tailor and describe care pathways (including specific care plans) for people with open surgical wounds. Furthermore both studies draw the conclusion that there is a need to provide competent care by using the available evidence on the clinical effectiveness of wound dressings, other topical agents and other interventions. Policy makers should consider directing health resources to primary services, developing clinical guidelines for care and educating health care professionals.

Another aspect to consider is the person-centred approach in care. The fact that impacts of complex wounds are common and the fact that most wounds were planned before surgery to be open, suggests that good preparation for surgery is important. Empowering people in advance might benefit their experience. By doing so, health care professionals could address the specific needs and uncertainties of people with open surgical wounds and support them with the available psychosocial interventions on their journey of living with these wounds. Furthermore, developing a relationship of trust between health care professionals and people with wounds is vital in the provision of care.

7.5 CONCLUSIONS

At the time when I began my PhD there was a lack of epidemiological data about open surgical wounds. A number of qualitative studies which I had read suggested that complex wounds and wound related unpleasant symptoms affect people's lives, however the evidence base was fragmented, had not been reviewed, and it was impossible to identify further study direction without employing a rigorous method for research mapping. To address both knowledge gaps I first conducted a scoping study, which directed me further to conduct a cross-sectional study, and later a qualitative study.

My scoping review identified that open surgical wounds were under-served by qualitative studies. Previous studies of people's perspectives of living with other types of complex wounds suggest that unpleasant symptoms are a significant factor in the gravity of the impact of wounds on people's lives; however no data were available for open surgical wounds. Therefore I conducted a large, epidemiological study on people with open surgical wounds that identifed the number of people with open surgical wounds, their nature, treatments and occurrence of unpleasant symptoms. The findings identified that people experience pain, exudate, malodour and pruritus. Finally, I conducted a longitudinal qualitative study which allowed me to explore the meaning of living with open surgical wounds in depth. I identified that people's well-being and everyday living are greatly impacted by open surgical wounds. Furthermore, the experience of an open surgical wound has a similar trajectory to other chronic conditions, which brings a new perspective to previous findings of studies on living with complex wounds.

The findings from this thesis are useful for clinical aspects of care for people with open surgical wounds; specifically, clinicians should individualise care pathways to promoting people's well-being, and use effective treatments for patients' benefit, which might also result in the rational spending of limited health resources. The findings also imply that policy makers should develop strategies to target areas of treatment uncertainty, directing resources to primary care where the majority of people with wounds are treated, and to educating health care professionals so they are able to provide best evidence care. This thesis also lays the groundwork for future research in this area. Research should be undertaken for further assessment of the complex wound burden, in particular in low- and middle-income countries. Furthermore, it sheds light on important questions related to uncertainty around topical treatment. Further research could usefully explore self-care behaviour and psychological, behavioural and social interventions, which could reduce the strain on people's well-being and improve their quality of life.

REFERENCES

Abbotts J. (2010). Patients' views on topical negative pressure: 'effective but smelly'. *British Journal of Nursing*, *19*, S37-41. jlh.

Ackumey, M. M., Gyapong, M., Pappoe, M., Kwakye-Maclean, C., & Weiss, M. G. (2012). Illness meanings and experiences for pre-ulcer and ulcer conditions of Buruli ulcer in the Ga-West and Ga-South Municipalities of Ghana. *BMC Public Health*, *12*(1), 264–264. jlh.

Agardh, E., Allebeck, P., Hallqvist, J., Moradi, T., & Sidorchuk, A. (2011). Type 2 diabetes incidence and socio-economic position: A systematic review and meta-analysis. *International Journal of Epidemiology*, *40*(3), 804–818. https://doi.org/10.1093/ije/dyr029

Al-Amer, R., Ramjan, L., Glew, P., Darwish, M., & Salamonson, Y. (2015). Translation of interviews from a source language to a target language: Examining issues in cross-cultural health care research. *Journal of Clinical Nursing*, *24*(9–10), 1151–1162. https://doi.org/10.1111/jocn.12681

Alexander, S. (2009). Malignant fungating wounds: Managing pain, bleeding and psychosocial issues. *Journal of Wound Care*, *18*(10), 418–425. https://doi.org/10.12968/jowc.2009.18.10.44603

Alexander, S. J. (2010). An intense and unforgettable experience: The lived experience of malignant wounds from the perspectives of patients, caregivers and nurses. *International Wound Journal*, *7*(6), 456–465. jlh. https://doi.org/10.1111/j.1742-481X.2010.00715.x

Al-Khamis, A., McCallum, I., King, P. M., & Bruce, J. (2010). Healing by primary versus secondary intention after surgical treatment for pilonidal sinus. *The Cochrane Database of Systematic Reviews*, *1*, CD006213. https://doi.org/10.1002/14651858.CD006213.pub3

Allen, J., David, M., & Veerman, J. L. (2018). Systematic review of the cost-effectiveness of preoperative antibiotic prophylaxis in reducing surgical-site infection. *BJS Open*, *2*(3), 81–98. https://doi.org/10.1002/bjs5.45

Allen, L. (2010). A Critique of Four Grounded Theory Texts. *The Qualitative Report*, *15*(6), 1606–1620.

Anderson, S., Allen, P., Peckham, S., & Goodwin, N. (2008). Asking the right questions: Scoping studies in the commissioning of research on the organisation and delivery of health services. *Health Research Policy and Systems*, *6*, 7. https://doi.org/10.1186/1478-4505-6-7

Andersson, A. E., Bergh, I., Karlsson, J., & Nilsson, K. (2010). Patients' experiences of acquiring a deep surgical site infection: An interview study. *American Journal of Infection Control*, *38*(9), 711–717. jlh. https://doi.org/10.1016/j.ajic.2010.03.017

Anney, V. N. (2014). Ensuring the quality of the findings of qualitative researc: Looking at trustworthiness criteria. *Journal of Emerging Trends in Educational Research and Policy Studies*, *2*(5), 272–281.

Antimicrobial consumption (Annual Epidemiological Report for 2016). (2018). European Centre for Disease Prevention and Control. https://ecdc.europa.eu/sites/portal/files/documents/AER_for_2016-AMC.pdf

Apelqvist, J., Bakker, K., van Houtum, W. H., & Schaper, N. C. (2008). Practical guidelines on the management and prevention of the diabetic foot. *Diabetes/Metabolism Research and Reviews*, *24*(S1), S181–S187. https://doi.org/10.1002/dmrr.848

Apelqvist, J., Willy, C., Fagerdahl, A.-M., Fraccalvieri, M., Malmsjö, M., Piaggesi, A., Probst, A., & Vowden, P. (2017). EWMA Document: Negative Pressure Wound Therapy. *Journal of Wound Care*, *26*(Sup3), S1–S154. https://doi.org/10.12968/jowc.2017.26.Sup3.S1

Arksey, H., & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology*, 19–32.

Arksey, H., O'Malley, L., Baldwin, S., Mason, A., & Godler, S. (2002). *Literature Review Report: Services to Support Carers of People with Mental Health Problems*. National Co-ordinating Centre for NHS Service Delivery and Organisation. https://pure.york.ac.uk/portal/en/publications/literature-review-report-services-to-support-carers-of-people-with-mental-health-problems(8ddaf6e8-7384-4b2c-b716-c3efa135db64)/export.html

Armstrong, D. G., Boulton, A. J. M., & Bus, S. A. (2017). Diabetic Foot Ulcers and Their Recurrence. *The New England Journal of Medicine*, *376*(24), 2367–2375. https://doi.org/10.1056/NEJMra1615439

Arthur, S., & Nazroo, J. (2003). Chapter 5: Designing Fieldwork Strategies and Materials. In J. Ritchie & J. Lewis (Eds.), *Qualitative Research Practice: A Guide for Social Science Students and Researchers* (pp. 109–137). Sage Publications.

Ashford, R. L., McGee, P., & Kinmond, K. (2000). Perception of quality of life by patients with diabetic foot ulcers. *Diabetic Foot Journal*, *3*(4), 150–155. jlh.

Atkins, S., Lewin, S., Smith, H., Engel, M., Fretheim, A., & Volmink, J. (2008). Conducting a meta-ethnography of qualitative literature: Lessons learnt. *BMC Medical Research Methodology*, *8*, 21. https://doi.org/10.1186/1471-2288-8-21

Atkinson, R. A., & Cullum, N. A. (2018). Interventions for pressure ulcers: A summary of evidence for prevention and treatment. *Spinal Cord*. https://doi.org/10.1038/s41393-017-0054-y

Aujoulat, I., Johnson, C., Zinsou, C., Guédénon, A., & Portaels, F. (2003). Psychosocial aspects of health seeking behaviours of patients with Buruli ulcer in southern Benin. *Tropical Medicine & International Health: TM & IH*, *8*(8), 750–759. https://doi.org/10.1046/j.1365-3156.2003.01089.x

Bale, S., Dealey, C., Defloor, T., Hopkins, A., & Worboys F. (2007). The experience of living with a pressure ulcer. *Nursing Times*, *103*(15), 42–43. jlh.

Barg, F. K., Cronholm, P. F., Easley, E. E., Davis, T., Hampton, M., Malay, D. S., Donohue, C., Song, J., Thom, S. R., & Margolis, D. J. (2017). A qualitative study of the experience of lower extremity wounds and amputations among people with diabetes in Philadelphia. *Wound Repair & Regeneration*, *25*(5), 864–870. jlh. https://doi.org/10.1111/wrr.12593

Barnett-Page, E., & Thomas, J. (2009). Methods for the synthesis of qualitative research: A critical review. *BMC Medical Research Methodology*, *9*(1), 59. https://doi.org/10.1186/1471-2288-9-59

Baruch, S. (2004). Transcendental Subjectivity in Husserl's Ideas I. *Journal of the British Society for Phenomenology*, *35*(2), 201–207. https://doi.org/10.1080/00071773.2004.11007436

Baumann, N. (2016). How to use the medical subject headings (MeSH). *International Journal of Clinical Practice*, *70*(2), 171–174. https://doi.org/10.1111/ijcp.12767

Benchimol, E. I., Smeeth, L., Guttmann, A., Harron, K., Moher, D., Petersen, I., Sørensen, H. T., von Elm, E., Langan, S. M., & RECORD Working Committee. (2015). The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. *PLoS Medicine*, *12*(10), e1001885. https://doi.org/10.1371/journal.pmed.1001885

Bengtsson, L., Jonsson, M., & Apelqvist, J. (2008). Wound-related pain is underestimated in patients with diabetic foot ulcers. *Journal of Wound Care*, *17*(10), 433–435. https://doi.org/10.12968/jowc.2008.17.10.31306

Bengtsson, M. (2016). How to plan and perform a qualitative study using content analysis. *NursingPlus Open*, *2*, 8–14. https://doi.org/10.1016/j.npls.2016.01.001

Bolas, N., & Holloway, S. (2012). Negative pressure wound therapy: A study on patient perspectives. *British Journal of Community Nursing*, S30-5. jlh.

Bondas, T. (2011). Husserlian phenomenology reflected in caring science childbearing research. In *Qualitative research in midwifery and childbirth: Phenomenological approaches* (pp. 1–18). Routledge.

Booth, A., Lewin, S., Glenton, C., Munthe-Kaas, H., Toews, I., Noyes, J., Rashidian, A., Berg, R. C., Nyakang'o, B., Meerpohl, J. J., Bohren, M. A., Carlsen, B., Garside, R., Tuncalp, Ö., Wainwright, M., & GRADE-CERQual Coordinating Team. (2018). Applying GRADE-CERQual to qualitative evidence synthesis findings–paper 7: Understanding the potential impacts of dissemination bias. *Implementation Science*, *13*(1), 12. https://doi.org/10.1186/s13012-017-0694-5

Boutron, I., Page, M. J., Higgins, J. P. T., Altman, D. G., Lundh, A., & Hróbjartsson, A. (2019). Chapter 7: Considering bias and conflicts of interest among the included studies. In J. P. T. Higgins, J. Thomas, J. Chandler, M. Cumpston, T. Li, M. J. Page,

& V. A. Welch (Eds.), *Ochrane Handbook for Systematic Reviews of Interventions version 6.0*. Cochrane. https://training.cochrane.org/handbook/current/chapter-07

Boyd, C. O. (2001). Phenomenology the method. In P. L. Munhall (Ed.), *Nursing research: A qualitative perspective* (3rd ed., pp. 93–122). Jones and Bartlett.

Bradbury, S. E., & Price, P. E. (2011a). Diabetic foot ulcer pain: The hidden burden (Part two). *EWMA Journal*, *11*(2), 25–37. jlh.

Bradbury, S., & Price, P. (2011b). The impact of diabetic foot ulcer pain on patient quality of life. *Wounds UK*, *7*(4), 32–49. jlh.

Bradby, H. (2002). Translating culture and language: A research note on multilingual settings. *Sociology of Health & Illness*, *24*(6), 842–855. https://doi.org/10.1111/1467-9566.00321

Bray, L., Appleton, V., & Sharpe, A. (2019). The information needs of children having clinical procedures in hospital: Will it hurt? Will I feel scared? What can I do to stay calm? *Child: Care, Health and Development*, *45*(5), 737–743. https://doi.org/10.1111/cch.12692

Brien, S. E., Lorenzetti, D. L., Lewis, S., Kennedy, J., & Ghali, W. A. (2010). Overview of a formal scoping review on health system report cards. *Implementation Science*, *5*(1), 2. https://doi.org/10.1186/1748-5908-5-2

Briggs, M., & Closs, S. J. (2003). The prevalence of leg ulceration: A review of the literature. *EWMA Journal*, *3*(2), 14–20.

Briggs, M., & Flemming, K. (2007). Living with leg ulceration: A synthesis of qualitative research. *Journal of Advanced Nursing*, *59*(4), 319–328. https://doi.org/10.1111/j.1365-2648.2007.04348.x

Brod, M. (1998). Quality of life issues in patients with diabetes and lower extremity ulcers: Patients and care givers. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, *7*(4), 365–372. https://doi.org/10.1023/a:1024994232353

Brown, A. (2005a). Leg ulcers. Chronic leg ulcers, part 1: Do they affect a patient’s social life? *British Journal of Nursing*, *14*(17), 894–898. jlh.

Brown, A. (2005b). Leg ulcers. Chronic leg ulcers, part 2: Do they affect a patient's social life? *British Journal of Nursing*, *14*(18), 986–989. jlh.

Brown, A. (2010). Managing chronic venous leg ulcers part 2: Time for a new pragmatic approach? *Journal of Wound Care*, *19*(3), 85–90. jlh.

Bruce, N., Pope, D., & Stanistreet, D. (2008). *Quantitative Methods for Health Research. A practical Interactive Guide to Epidemiology and Statistics*. Jon Wiley & Sons.

Buchanan, P. J., Kung, T. A., & Cederna, P. S. (2014). Evidence-based medicine: Wound closure. *Plastic and Reconstructive Surgery*, *134*(6), 1391–1404. https://doi.org/10.1097/PRS.0000000000000720

Bury, M. (1982). Chronic illness as biographical disruption. *Sociology of Health & Illness*, *4*(2), 167–182. https://doi.org/10.1111/1467-9566.ep11339939

Butzlaff, R. L., & Hooley, J. M. (1998). Expressed emotion and psychiatric relapse: A meta-analysis. *Archives of General Psychiatry*, *55*(6), 547–552.

Byrne, O., & Kelly, M. (2010). Living with a chronic leg ulcer. *Journal of Community Nursing*, *24*(5), 46–50. jlh.

Caelli, K. (2001). Engaging with Phenomenology: Is it more of a Challenge than it Needs to be? *Qualitative Health Research*, *11*(2), 273–281. https://doi.org/10.1177/104973201129118993

Calman, L., Brunton, L., & Molassiotis, A. (2013). Developing longitudinal qualitative designs: Lessons learned and recommendations for health services research. *BMC Medical Research Methodology*, *13*(1), 14. https://doi.org/10.1186/1471-2288-13-14

Carlsen, B., & Glenton, C. (2011). What about N? A methodological study of sample-size reporting in focus group studies. *BMC Medical Research Methodology*, *11*(1), 26. https://doi.org/10.1186/1471-2288-11-26

Carpenter, D. M., Elstad, E. A., Blalock, S. J., & DeVellis, R. F. (2014). Conflicting medication information: Prevalence, sources, and relationship to medication adherence. *Journal of Health Communication*, *19*(1), 67–81. https://doi.org/10.1080/10810730.2013.798380

Carpenter, D. M., Geryk, L. L., Chen, A. T., Nagler, R. H., Dieckmann, N. F., & Han, P. K. J. (2016). Conflicting health information: A critical research need. *Health Expectations:*

An International Journal of Public Participation in Health Care and Health Policy, *19*(6), 1173–1182. https://doi.org/10.1111/hex.12438

Carter, B., & Ford, K. (2013). Researching children's health experiences: The place for participatory, child-centered, arts-based approaches. *Research in Nursing & Health*, *36*(1), 95–107. https://doi.org/10.1002/nur.21517

Carter, B., Ford, K., Bray, L., Water, T., Arnott, J., Tichanow, C., & Dickinson, A. (2017). 'It's not who I am': Children's experiences of growing up with a long-term condition in England, Australia, and New Zealand. *Journal for Specialists in Pediatric Nursing: JSPN*, *22*(4). https://doi.org/10.1111/jspn.12197

Cartier, Y., Creatore, M. I., Hoffman, S. J., & Potvin, L. (2018). Priority-setting in public health research funding organisations: An exploratory qualitative study among five high-profile funders. *Health Research Policy and Systems*, *16*. https://doi.org/10.1186/s12961-018-0335-8

Casha, A. R., Manché, A., Gatt, R., Duca, E., Gauci, M., Schembri-Wismayer, P., Camilleri-Podesta, M.-T., & Grima, J. N. (2014). Mechanism of sternotomy dehiscence. *Interactive Cardiovascular and Thoracic Surgery*, *19*(4), 617–621. https://doi.org/10.1093/icvts/ivu184

Central Intelligence Agency: The world factbook. (2020). Central Intelligence Agency. https://www.cia.gov/library/publications/the-world-factbook/geos/si.html

Centre for Reviews and Dissemination. (2009). *Systematic Reviews: CRD's guidance for undertaking reviews in health care* (3rd ed.). Centre for Reviews and Dissemination, University of York. https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf

Cezar da Silva, D., Denardin Budó, M. de L., Schimith, M. D., Ecco, L., Fernandes Costa, I. K., & de Vasconcelos Torres, G. (2015). Experiences constructed in the process of living with a venous ulcer. *Cogitare Enfermagem*, *20*(1), 13–19. jlh.

Chadwick, P. (2002). An exploration of the knowledge, beliefs, behaviours and decisions of people with type 2 diabetes who develop a foot ulcer. *British Journal of Podiatry*, *5*(3), 60–63. jlh.

Chalmers, I., Bracken, M. B., Djulbegovic, B., Garattini, S., Grant, J., Gülmezoglu, A. M., Howells, D. W., Ioannidis, J. P. A., & Oliver, S. (2014). How to increase value and reduce waste when research priorities are set. *Lancet (London, England)*, *383*(9912), 156–165. https://doi.org/10.1016/S0140-6736(13)62229-1

Chalmers, I., Hedges, L. V., & Cooper, H. (2002). A Brief History of Research Synthesis. *Evaluation & the Health Professions*, *25*(1), 12–37. https://doi.org/10.1177/0163278702025001003

Chandler, J., Cumpston, M., Higgins, J. P. T., Deeks, J. J., & Clarke, M. J. (2019). Chapter I: Introduction. In J. P. T. Higgins, J. Thomas, J. Chandler, M. Cumpston, T. Li, M. J. Page, & V. A. Welch (Eds.), *Cochrane Handbook for Systematic Reviews of Interventions version 6.0*. Cochrane. /handbook/current/chapter-i

Charles, H. (1995). The impact of leg ulcers on patients' quality of life. *Professional Nurse (London, England)*, *10*(9), 571–572, 574.

Charmaz, K. (1995). The Body, Identity, and Self: *The Sociological Quarterly*, *36*(4), 657–680. https://doi.org/10.1111/j.1533-8525.1995.tb00459.x

Charmaz, K. (1997). *Good days, bad days: The self in chronic illness and time* (2nd ed.). Rutgers University Press.

Charmaz, K. (2006). *Constructing grounded theory: A practical guide through qualitative analysis*. Sage Publications.

Chase, S. K., Melloni, M., & Savage, A. (1997). A forever healing: The lived experience of venous ulcer disease. *Journal of Vascular Nursing*, *15*(2), 73–78. jlh.

Chen, H.-Y., & Boore, J. R. (2009). Using a synthesised technique for grounded theory in nursing research. *Journal of Clinical Nursing*, *18*(16), 2251–2260. https://doi.org/10.1111/j.1365-2702.2008.02684.x

Chen, H.-Y., & Boore, J. R. (2010). Translation and back-translation in qualitative nursing research: Methodological review. *Journal of Clinical Nursing*, *19*(1–2), 234–239. https://doi.org/10.1111/j.1365-2702.2009.02896.x

Chetter, I. C., Oswald, A. V., Fletcher, M., Dumville, J. C., & Cullum, N. A. (2017). A survey of patients with surgical wounds healing by secondary intention; an assessment of prevalence, aetiology, duration and management. *Journal of Tissue Viability*, *26*(2), 103–107. https://doi.org/10.1016/j.jtv.2016.12.004

Chetter, I. C., Oswald, A. V., McGinnis, E., Stubbs, N., Arundel, C., Buckley, H., Bell, K., Dumville, J. C., Cullum, N. A., Soares, M. O., & Saramago, P. (2019). Patients with surgical wounds healing by secondary intention: A prospective, cohort study. *International Journal of Nursing Studies*, *89*, 62–71. https://doi.org/10.1016/j.ijnurstu.2018.09.011

Chiumento, A., Rahman, A., Machin, L., & Frith, L. (2018). Mediated research encounters: Methodological considerations in cross-language qualitative interviews. *Qualitative Research*, *18*(6), 604–622. https://doi.org/10.1177/1468794117730121

Cipolletta, S., & Amicucci, L. (2017). Illness trajectories in patients suffering from leg ulcers: A qualitative study. *Journal of Health Psychology*, *22*(7), 932–942. https://doi.org/10.1177/1359105315619224

Cochrane Wounds. (n.d.). Cochrane Wounds. Retrieved 8 May 2020, from /home

Coffey, L., Mahon, C., & Gallagher, P. (2019). Perceptions and experiences of diabetic foot ulceration and foot care in people with diabetes: A qualitative meta-synthesis. *International Wound Journal*, *16*(1), 183–210. https://doi.org/10.1111/iwj.13010

Coggon, D., Rose, G., & Baker, D. (2003). *Epidemiology for the Uninitiated* (5th Edition). BMJ Books. https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated

Cohen, M. Z. (2000). Introduction. In M. Z. Cohen, D. L. Khan, & R. H. Steeves (Eds.), *Hermeneutic phenomenological research: A Practical Guide for Nurse Researchers* (pp. 1–12). Sage Publications Inc.

Coleman, S., Gorecki, C., Nelson, E. A., Closs, S. J., Defloor, T., Halfens, R., Farrin, A., Brown, J., Schoonhoven, L., & Nixon, J. (2013). Patient risk factors for pressure ulcer development: Systematic review. *International Journal of Nursing Studies*, *50*(7), 974–1003. https://doi.org/10.1016/j.ijnurstu.2012.11.019

Colquhoun, H. L., Levac, D., O'Brien, K. K., Straus, S., Tricco, A. C., Perrier, L., Kastner, M., & Moher, D. (2014). Scoping reviews: Time for clarity in definition, methods, and reporting. *Journal of Clinical Epidemiology*, *67*(12), 1291–1294. https://doi.org/10.1016/j.jclinepi.2014.03.013

Corbin, J. M. (1998). The Corbin and Strauss Chronic Illness Trajectory model: An update. *Scholarly Inquiry for Nursing Practice*, *12*(1), 33–41.

Corbin, J. M., & Strauss, A. (1991). A nursing model for chronic illness management based upon the Trajectory Framework. *Scholarly Inquiry for Nursing Practice*, *5*(3), 155–174.

Corrigan, P. W., & Watson, A. C. (2002). Understanding the impact of stigma on people with mental illness. *World Psychiatry*, *1*(1), 16–20.

Coull, A. F., Atherton, I., Taylor, A., & Watterson, A. E. (2014). Prevalence of skin problems and leg ulceration in a sample of young injecting drug users. *Harm Reduction Journal*, *11*, 22. https://doi.org/10.1186/1477-7517-11-22

Cowman, S., Gethin, G., Clarke, E., Moore, Z., Craig, G., Jordan-O'Brien, J., McLain, N., & Strapp, H. (2012). An international eDelphi study identifying the research and education priorities in wound management and tissue repair. *Journal of Clinical Nursing*, *21*(3–4), 344–353. https://doi.org/10.1111/j.1365-2702.2011.03950.x

Creswell, J. W. (1998). *Qualitative inquiry and research design: Choosing among five traditions.* Sage.

Crews, R. T., Schneider, K. L., Yalla, S. V., Reeves, N. D., & Vileikyte, L. (2016). Physiological and psychological challenges of increasing physical activity and exercise in patients at risk of diabetic foot ulcers: A critical review. *Diabetes/Metabolism Research & Reviews*, *32*(8), 791–804. jlh. https://doi.org/10.1002/dmrr.2817

Cullum, N., Buckley, H., Dumville, J., Hall, J., Lamb, K., Madden, M., Morley, R., O'Meara, S., Goncalves, P. S., Soares, M., & Stubbs, N. (2016). *Wounds research for patient benefit: A 5-year programme of research*. NIHR Journals Library. http://www.ncbi.nlm.nih.gov/books/NBK379923/

Cullum, N., & Dumville, J. C. (2015). Systematic Reviews of the Effects of Interventions. In D. A. Richards & I. R. Hallberg (Eds.), *Complex interventions in health: An overview of research methods* (pp. 57–65). Routledge.

Currie, C. J., Peyrot, M., Morgan, C. L., Poole, C. D., Jenkins-Jones, S., Rubin, R. R., Burton, C. M., & Evans, M. (2012). The Impact of Treatment Noncompliance on

Mortality in People With Type 2 Diabetes. *Diabetes Care*, *35*(6), 1279–1284. https://doi.org/10.2337/dc11-1277

Dabiri, G., & Falanga, V. (2013). Connective tissue ulcers. *Journal of Tissue Viability*, *22*(4), 92–102. https://doi.org/10.1016/j.jtv.2013.04.003

Dahlberg, H., & Dahlberg, K. (2019). The question of meaning—A momentous issue for qualitative research. *International Journal of Qualitative Studies on Health and Well-Being*, *14*(1). https://doi.org/10.1080/17482631.2019.1598723

Daudt, H. M., van Mossel, C., & Scott, S. J. (2013). Enhancing the scoping study methodology: A large, inter-professional team's experience with Arksey and O'Malley's framework. *BMC Medical Research Methodology*, *13*, 48. https://doi.org/10.1186/1471-2288-13-48

Davis, K., Drey, N., & Gould, D. (2009). What are scoping studies? A review of the nursing literature. *International Journal of Nursing Studies*, *46*(10), 1386–1400. https://doi.org/10.1016/j.ijnurstu.2009.02.010

De Ridder, D., Geenen, R., Kuijer, R., & van Middendorp, H. (2008). Psychological adjustment to chronic disease. *Lancet (London, England)*, *372*(9634), 246–255. https://doi.org/10.1016/S0140-6736(08)61078-8

De Vera, N. (2003). Perspectives on healing foot ulcers by Yaquis with diabetes. *Journal of Transcultural Nursing*, *14*(1), 39–47. jlh.

Degrie, L., Gastmans, C., Mahieu, L., Dierckx de Casterlé, B., & Denier, Y. (2017). How do ethnic minority patients experience the intercultural care encounter in hospitals? A systematic review of qualitative research. *BMC Medical Ethics*, *18*(1), 2. https://doi.org/10.1186/s12910-016-0163-8

Dekker, J., & de Groot, V. (2018). Psychological adjustment to chronic disease and rehabilitation—An exploration. *Disability and Rehabilitation*, *40*(1), 116–120. https://doi.org/10.1080/09638288.2016.1247469

Delea, S., Buckley, C., Hanrahan, A., McGreal, G., Desmond, D., & McHugh, S. (2015). Management of diabetic foot disease and amputation in the Irish health system: A qualitative study of patients' attitudes and experiences with health services. *BMC*

Health Services Research, *15*(1), 1–10. jlh. https://doi.org/10.1186/s12913-015-0926-9

Demidova-Rice, T. N., Hamblin, M. R., & Herman, I. M. (2012). Acute and Impaired Wound Healing: Pathophysiology and Current Methods for Drug Delivery, Part 1: Normal and Chronic Wounds: Biology, Causes, and Approaches to Care. *Advances in Skin & Wound Care*, *25*(7), 304–314. https://doi.org/10.1097/01.ASW.0000416006.55218.d0

Douglas, V. (2001). Living with a chronic leg ulcer: An insight into patients' experiences and feelings. *Journal of Wound Care*, *10*(9), 355–360. jlh.

Dowling, M. (2004). Hermeneutics: An exploration. *Nurse Researcher*, *11*(4), 30–39. https://doi.org/10.7748/nr2004.07.11.4.30.c6213

Downe-Wamboldt, B. (1992). Content analysis: Method, applications, and issues. *Health Care for Women International*, *13*(3), 313–321. https://doi.org/10.1080/07399339209516006

Driessens, C., Kingdon, D., Pilgrim, D., & Smith, P. W. F. (2020). Health and Social Care Diversity Among Individuals with Longstanding Physical and Psychological Health Problems: Pooled Repeated Cross Sectional Analyses. *Community Mental Health Journal*, *56*(5), 978–987. https://doi.org/10.1007/s10597-020-00566-y

Dudley, L., Kettle, C., Waterfield, J., & Ismail, K. M. K. (2017). Perineal resuturing versus expectant management following vaginal delivery complicated by a dehisced wound (PREVIEW): A nested qualitative study. *BMJ Open*, *7*(2), e013008 <78. >.

Dumville, J. C., Gray, T. A., Walter, C. J., Sharp, C. A., Page, T., Macefield, R., Blencowe, N., Milne, T. K., Reeves, B. C., & Blazeby, J. (2016). Dressings for the prevention of surgical site infection. *Cochrane Database of Systematic Reviews*, *12*. https://doi.org/10.1002/14651858.CD003091.pub4

Dumville, J. C., Owens, G. L., Crosbie, E. J., Peinemann, F., & Liu, Z. (2015). Negative pressure wound therapy for treating surgical wounds healing by secondary intention. In *Cochrane Database of Systematic Reviews*. John Wiley & Sons, Ltd. https://doi.org/10.1002/14651858.CD011278.pub2

Dwan, K., Altman, D. G., Arnaiz, J. A., Bloom, J., Chan, A.-W., Cronin, E., Decullier, E., Easterbrook, P. J., Von Elm, E., Gamble, C., Ghersi, D., Ioannidis, J. P. A., Simes, J., & Williamson, P. R. (2008). Systematic review of the empirical evidence of study publication bias and outcome reporting bias. *PloS One*, *3*(8), e3081. https://doi.org/10.1371/journal.pone.0003081

Dwan, K., Altman, D. G., Clarke, M., Gamble, C., Higgins, J. P. T., Sterne, J. A. C., Williamson, P. R., & Kirkham, J. J. (2014). Evidence for the Selective Reporting of Analyses and Discrepancies in Clinical Trials: A Systematic Review of Cohort Studies of Clinical Trials. *PLOS Medicine*, *11*(6), e1001666. https://doi.org/10.1371/journal.pmed.1001666

Ebbeskog, B., & Ekman, S. (2001). Elderly persons' experiences of living with venous leg ulcer: Living in a dialectal relationship between freedom and imprisonment. *Scandinavian Journal of Caring Sciences*, *15*(3), 235–243. jlh.

Ebbeskog, B., & Emami, A. (2005). Older patients' experience of dressing changes on venous leg ulcers: More than just a docile patient. *Journal of Clinical Nursing*, *14*(10), 1223–1231. jlh. https://doi.org/10.1111/j.1365-2702.2005.01194.x

Edwards, L. (2003). Compression therapy. Why patients do not comply with compression bandaging. *British Journal of Nursing*, *12*(11), S5–S10. jlh.

Eekhof, J. A. H., Van Wijk, B., Knuistingh Neven, A., & van der Wouden, J. C. (2012). Interventions for ingrowing toenails. *The Cochrane Database of Systematic Reviews*, *4*, CD001541. https://doi.org/10.1002/14651858.CD001541.pub3

Effah, A., Ersser, S. J., & Hemingway, A. (2017). Support needs of people living with Mycobacterium ulcerans (Buruli ulcer) disease in a Ghana rural community: A grounded theory study. *International Journal of Dermatology*, *56*(12), 1432–1437. https://doi.org/10.1111/ijd.13785

Egberts, M. R., Geenen, R., de Jong, A. E., Hofland, H. W., & Van Loey, N. E. (2018). The aftermath of burn injury from the child's perspective: A qualitative study. *Journal of Health Psychology*, 1359105318800826. https://doi.org/10.1177/1359105318800826

Elo, S., Kääriäinen, M., Kanste, O., Pölkki, T., Utriainen, K., & Kyngäs, H. (2014). Qualitative Content Analysis: A Focus on Trustworthiness. *SAGE Open*, *4*(1), 2158244014522633. https://doi.org/10.1177/2158244014522633

Elo, S., & Kyngäs, H. (2008). The qualitative content analysis process. *Journal of Advanced Nursing*, *62*(1), 107–115. https://doi.org/10.1111/j.1365-2648.2007.04569.x

Elstad, E., Carpenter, D. M., Devellis, R. F., & Blalock, S. J. (2012). Patient decision making in the face of conflicting medication information. *International Journal of Qualitative Studies on Health and Well-Being*, *7*. https://doi.org/10.3402/qhw.v7i0.18523

Eriksson, E., Wejåker, M., Danhard, A., Nilsson, A., & Kristofferzon, M.-L. (2019). Living with a spouse with chronic illness – the challenge of balancing demands and resources. *BMC Public Health*, *19*. https://doi.org/10.1186/s12889-019-6800-7

Eriksson, M., & Svedlund, M. (2006). ‘The intruder’: Spouses’ narratives about life with a chronically ill partner. *Journal of Clinical Nursing*, *15*(3), 324–333. https://doi.org/10.1111/j.1365-2702.2006.01290.x

Etkind, S. N., Bristowe, K., Bailey, K., Selman, L. E., & Murtagh, F. E. (2017). How does uncertainty shape patient experience in advanced illness? A secondary analysis of qualitative data. *Palliative Medicine*, *31*(2), 171–180. https://doi.org/10.1177/0269216316647610

European Commission EUROSTAT. (2016). Eurostat Database. https://ec.europa.eu/eurostat/home?

European Commission EUROSTAT. (2020). Eurostat Database. https://ec.europa.eu/eurostat/data/database

Evans, G. L. (2013). A Novice Researcher’s First Walk Through the Maze of Grounded Theory: Rationalization for Classical Grounded Theory. *Grounded Theory Review: An International Journal*, *12*(1), 37–55.

Fagerdahl, A.-M. (2014). The Patient’s Conceptions of Wound Treatment with Negative Pressure Wound Therapy. *Healthcare*, *2*(3), 272–281. https://doi.org/10.3390/healthcare2030272

Fagerdahl, A.-M., Boström, L., Ottosson, C., & Ulfvarson, J. (2013). Patients' Experience of Advanced Wound Treatment–A Qualitative Study. *Wounds: A Compendium of Clinical Research and Practice*, *25*, 205–211.

Faggion, C. M., Bakas, N. P., & Wasiak, J. (2017). A survey of prevalence of narrative and systematic reviews in five major medical journals. *BMC Medical Research Methodology*, *17*(1), 176. https://doi.org/10.1186/s12874-017-0453-y

Fahimi, J., Singh, A., & Frazee, B. W. (2015). The role of adjunctive antibiotics in the treatment of skin and soft tissue abscesses: A systematic review and meta-analysis. *CJEM*, *17*(4), 420–432. https://doi.org/10.1017/cem.2014.52

Fearns, N., Heller-Murphy, S., Kelly, J., & Harbour, J. (2017). Placing the patient at the centre of chronic wound care: A qualitative evidence synthesis. *Journal of Tissue Viability*, *26*(4), 254–259. jlh. https://doi.org/10.1016/j.jtv.2017.09.002

Ferrari, R. (2015). Writing narrative style literature reviews. *Medical Writing*, *24*(4), 230–235. https://doi.org/10.1179/2047480615Z.000000000329

Firth, J., Nelson, A., Briggs, M., & Gorecki, C. (2013). Experiences of Healthcare Provision for Foot Ulceration Occurring in People with Rheumatoid Arthritis. *Musculoskeletal Care*, *11*(3), 159–167. jlh. https://doi.org/10.1002/msc.1036

Firth, J., Nelson, E. A., Briggs, M., & Gorecki, C. (2011). A qualitative study to explore the impact of foot ulceration on health-related quality of life in patients with rheumatoid arthritis. *International Journal of Nursing Studies*, *48*(11), 1401–1408. https://doi.org/10.1016/j.ijnurstu.2011.05.010

Flanagan, M., Vogensen, H., & Haase, L. (2006). Case series investigating the experience of pain in patients with chronic venous leg ulcers treated with a foam dressing releasing ibuprofen. *World Wide Wounds*, 15p–15p. jlh.

Flick, U. (2007). *Designing Qualitative Research*. Sage Publications Ltd.

Fox, A. (2005). Innocent beginnings, uncertain futures: Exploring the challenges of living with diabetic foot ulcers. *Canadian Journal of Diabetes*, *29*(2), 105–110. jlh.

Fox, C. (2002). Living with a pressure ulcer: A descriptive study of patients' experiences. *British Journal of Community Nursing*, *7*(6), 10–14. jlh.

France, E. F., Cunningham, M., Ring, N., Uny, I., Duncan, E. A. S., Jepson, R. G., Maxwell, M., Roberts, R. J., Turley, R. L., Booth, A., Britten, N., Flemming, K., Gallagher, I., Garside, R., Hannes, K., Lewin, S., Noblit, G. W., Pope, C., Thomas, J., … Noyes, J. (2019). Improving reporting of meta-ethnography: The eMERGe reporting guidance. *BMC Medical Research Methodology*, *19*(1), 25. https://doi.org/10.1186/s12874-018-0600-0

France, E. F., Ring, N., Thomas, R., Noyes, J., Maxwell, M., & Jepson, R. (2014). A methodological systematic review of what's wrong with meta-ethnography reporting. *BMC Medical Research Methodology*, *14*, 119. https://doi.org/10.1186/1471-2288-14-119

Franks, P. J., Arnež, Z. M., Gantar, M., Matoh, M., Peric, H. K., Ručigaj, T., Triller, C., Debelak, A., Čermelj, N., Somrak, J., Franko, A., Luft, S., Lah, A., & Vilar, V. (2007). *Project report—Leg ulcers in Slovenia* (pp. 1–23). Slovenian Wound Management Association and European Wound Management Association.

Franks, P. J., & Moffatt, C. J. (1998). Who suffers most from leg ulceration? *Journal of Wound Care*, *7*(8), 383–385. https://doi.org/10.12968/jowc.1998.7.8.383

Franks, P. J., Moffatt, C. J., Doherty, D. C., Smithdale, R., & Martin, R. (2006). Longer-term changes in quality of life in chronic leg ulceration. *Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society*, *14*(5), 536–541. https://doi.org/10.1111/j.1743-6109.2006.00160.x

Franks, P. J., & Morgan, P. A. (2003). Health-related quality of life with chronic leg ulceration. *Expert Review of Pharmacoeconomics & Outcomes Research*, *3*(5), 611–622. https://doi.org/10.1586/14737167.3.5.611

Gagliardi, B. A., Frederickson, K., & Shanley, D. A. (2002). Living with multiple sclerosis: A Roy adaptation model-based study. *Nursing Science Quarterly*, *15*(3), 230–236. https://doi.org/10.1177/08918402015003009

Gasparyan, A. Y., Ayvazyan, L., Blackmore, H., & Kitas, G. D. (2011). Writing a narrative biomedical review: Considerations for authors, peer reviewers, and editors. *Rheumatology International*, *31*(11), 1409–1417. https://doi.org/10.1007/s00296-011-1999-3

Gemechu, F. W., Seemant, F., & Curley, C. A. (2013). Diabetic foot infections. *American Family Physician*, *88*(3), 177–184.

Giorgi, A. (2017). A Response to the Attempted Critique of the Scientific Phenomenological Method. *Journal of Phenomenological Psychology*, *48*(1), 83–144. https://doi.org/10.1163/15691624-12341319

Girouard, K., Harrison, M. B., & VanDenKerkof, E. (2008). The symptom of pain with pressure ulcers: A review of the literature. *Ostomy/Wound Management*, *54*(5), 30–40, 42.

Glaser, B. G. (1999). The Future of Grounded Theory. *Qualitative Health Research*, *9*(6), 836–845. https://doi.org/10.1177/104973299129122199

Glaser, B. G. (2001). *The grounded theory perspective: Conceptualization contrasted with description*. Sociology Press.

Glaser, B. G. (2003). *The grounded theory perspective II : description's remodeling of grounded theory methodology*. Sociology Press.

Glaser, B., & Strauss, A. (1967). *The Discovery of Grounded Theory: Strategies for Qualitative Research*. Sociology Press.

Gohel, M. S., & Poskitt, K. R. (2010). Chronic ulceration of the leg. *Surgery (Oxford)*, *28*(6), 273–276. https://doi.org/10.1016/j.mpsur.2010.02.005

González-Consuegra, R. V., & Verdú, J. (2011). Quality of life in people with venous leg ulcers: An integrative review. *Journal of Advanced Nursing*, *67*(5), 926–944. https://doi.org/10.1111/j.1365-2648.2010.05568.x

Goodridge, D., Trepman, E, & Embil, J. M. (2005). Health-related quality of life in diabetic patients with foot ulcers: Literature review. *Journal of Wound, Ostomy & Continence Nursing*, *32*(6), 368–377. jlh.

Gorecki, C., Brown, J., Nelson, A., Briggs, M., Schoonhoven, L., Dealey, C., Defloor, T., & Nixon, J. (2009). Impact of Pressure Ulcers on Quality of Life in Older Patients: A Systematic Review. *Journal of the American Geriatrics Society*, *57*(7), 1175–1183. https://doi.org/10.1111/j.1532-5415.2009.02307.x

Gorecki, C., Lamping, D., Brown, J., Madill, A., Firth, J., & Nixon, J. (2010). Development of a conceptual framework of health-related quality of life in pressure ulcers: A patient-focused approach. *International Journal of Nursing Studies*, *47*(12), 1525–1534. https://doi.org/10.1016/j.ijnurstu.2010.05.014

Gorecki, C., Nixon, J., Madill, A., Firth, J., & Brown, J. M. (2012). What influences the impact of pressure ulcers on health-related quality of life? A qualitative patient-focused exploration of contributory factors. *Journal of Tissue Viability*, *21*(1), 3–12. jlh. https://doi.org/10.1016/j.jtv.2011.11.001

Gorecki, C., Closs, S. J., Nixon, J., & Briggs, M. (2011). Patient-Reported Pressure Ulcer Pain: A Mixed-Methods Systematic Review. *Journal of Pain and Symptom Management*, *42*(3), 443–459. https://doi.org/10.1016/j.jpainsymman.2010.11.016

Gosmanova, E. O., Lu, J. L., Streja, E., Cushman, W. C., Kalantar-Zadeh, K., & Kovesdy, C. P. (2014). Association of Medical Treatment Nonadherence With All-Cause Mortality in Newly Treated Hypertensive US Veterans. *Hypertension*, *64*(5), 951–957. https://doi.org/10.1161/HYPERTENSIONAHA.114.03805

Gough, D., Thomas, J., & Oliver, S. (2012). Clarifying differences between review designs and methods. *Systematic Reviews*, *1*(1), 28. https://doi.org/10.1186/2046-4053-1-28

Graham, I. D., Harrison, M. B., Nelson, E. A., Lorimer, K. Ms., & Fisher, A. M. (2003). Prevalence of Lower-Limb Ulceration: A Systematic Review of Prevalence Studies. *Advances in Skin & Wound Care November 2003*, *16*(6), 305–316.

Graneheim, U. H., Lindgren, B.-M., & Lundman, B. (2017). Methodological challenges in qualitative content analysis: A discussion paper. *Nurse Education Today*, *56*, 29–34. https://doi.org/10.1016/j.nedt.2017.06.002

Graneheim, U. H., & Lundman, B. M. (2004). Qualitative content analysis in nursing research: Concepts, procedures and measures to achieve trustworthiness. *Nurse Education Today*, *24*(2), 105–112. https://doi.org/10.1016/j.nedt.2003.10.001

Gray, T. A., Dumville, J. C., Christie, J., & Cullum, N. A. (2017). Rapid research and implementation priority setting for wound care uncertainties. *PloS One*, *12*(12), e0188958. https://doi.org/10.1371/journal.pone.0188958

Gray, T. A., Rhodes, S., Atkinson, R. A., Rothwell, K., Wilson, P., Dumville, J. C., & Cullum, N. A. (2018). Opportunities for better value wound care: A multiservice, cross-sectional survey of complex wounds and their care in a UK community population. *BMJ Open*, *8*(3), e019440. https://doi.org/10.1136/bmjopen-2017-019440

Green, B. N., Johnson, C. D., & Adams, A. (2006). Writing narrative literature reviews for peer-reviewed journals: Secrets of the trade. *Journal of Chiropractic Medicine*, *5*(3), 101–117. https://doi.org/10.1016/S0899-3467(07)60142-6

Green, J., & Jester, R. (2009). Health-related quality of life and chronic venous leg ulceration: Part 1. *British Journal of Community Nursing*, *14*, S12-7. jlh.

Green, J., Jester, R., McKinley, R., & Pooler, A. (2014). The impact of chronic venous leg ulcers: A systematic review. *Journal of Wound Care*, *23*(12), 601–612. https://doi.org/10.12968/jowc.2014.23.12.601

Green, J., Jester, R., & Pooler, A. (2013). Patient perspectives of their leg ulcer journey. *Journal of Wound Care*, *22*(2), 58–66. jlh.

Green, J., Jester, R., McKinley, R., & Pooler, A. (2017). Chronic venous leg ulcer care—Are we missing a vital piece of the jigsaw? *Wounds UK*, *13*(1), 32–40. jlh.

Green, J., Jester, R., McKinley, R., & Pooler, A. (2018). Chronic venous leg ulcer care: Putting the patient at the heart of leg ulcer care. Part 1: Exploring the consultation. *British Journal of Community Nursing*, *23*, S30–S38. jlh. https://doi.org/10.12968/bjcn.2018.23.Sup3.S30

Greenhalgh, T. (2014). *How to read a papaer: The basics of evidence-based medicine* (5th ed.). John Wiley & Sons, Ltd.

Greenhalgh, T., Thorne, S., & Malterud, K. (2018). Time to challenge the spurious hierarchy of systematic over narrative reviews? *European Journal of Clinical Investigation*, *48*(6), e12931. https://doi.org/10.1111/eci.12931

Grey, J. E., Harding, K. G., & Enoch, S. (2006). Venous and arterial leg ulcers. *BMJ : British Medical Journal*, *332*(7537), 347–350.

Grocott, P., Gethin, G., & Probst, S. (2013). Malignant wound management in advanced illness: New insights. *Current Opinion in Supportive and Palliative Care*, *7*(1), 101–105. https://doi.org/10.1097/SPC.0b013e32835c0482

Grossoehme, D., & Lipstein, E. (2016). Analyzing longitudinal qualitative data: The application of trajectory and recurrent cross-sectional approaches. *BMC Research Notes*, *9*. https://doi.org/10.1186/s13104-016-1954-1

Guerci, B., Chanan, N., Kaur, S., Jasso-Mosqueda, J. G., & Lew, E. (2019). Lack of Treatment Persistence and Treatment Nonadherence as Barriers to Glycaemic Control in Patients with Type 2 Diabetes. *Diabetes Therapy: Research, Treatment and Education of Diabetes and Related Disorders*, *10*(2), 437–449. https://doi.org/10.1007/s13300-019-0590-x

Guest, G., Bunce, A., & Johnson, L. (2006). How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability. *Field Methods*, *18*(1), 59–82. https://doi.org/10.1177/1525822X05279903

Guest, J. F., Ayoub, N., McIlwraith, T., Uchegbu, I., Gerrish, A., Weidlich, D., Vowden, K., & Vowden, P. (2015). Health economic burden that wounds impose on the National Health Service in the UK. *BMJ Open*, *5*(12), e009283. https://doi.org/10.1136/bmjopen-2015-009283

Guest, J. F., Fuller, G. W., & Edwards, J. (2020). Cohort study evaluating management of burns in the community in clinical practice in the UK: Costs and outcomes. *BMJ Open*, *10*(4), e035345. https://doi.org/10.1136/bmjopen-2019-035345

Guest, J. F., Fuller, G. W., & Vowden, P. (2018a). Costs and outcomes in evaluating management of unhealed surgical wounds in the community in clinical practice in the UK: A cohort study. *BMJ Open*, *8*(12), e022591. https://doi.org/10.1136/bmjopen-2018-022591

Guest, J. F., Fuller, G. W., Vowden, P., & Vowden, K. R. (2018b). Cohort study evaluating pressure ulcer management in clinical practice in the UK following initial presentation in the community: Costs and outcomes. *BMJ Open*, *8*(7), e021769. https://doi.org/10.1136/bmjopen-2018-021769

Haesler, E. (Ed.). (2019). *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guidline* (3rd ed.). European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance.

Hall, J., Buckley, H. L., Lamb, K. A., Stubbs, N., Saramago, P., Dumville, J. C., & Cullum, N. A. (2014). Point prevalence of complex wounds in a defined United Kingdom population. *Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society*, *22*(6), 694–700. https://doi.org/10.1111/wrr.12230

Hallett, C. E., Austin, L., Caress, A., & Luker, K. A. (2000). Community nurses’ perceptions of patient ‘compliance’ in wound care: A discourse analysis. *Journal of Advanced Nursing*, *32*(1), 115–123.

Hammes, H. P. (2003). Pathophysiological mechanisms of diabetic angiopathy. *Journal of Diabetes and Its Complications*, *17*(2 Suppl), 16–19.

Haram, R. B., & Dagfinn, N. (2003). Errors and discrepancies: A patient perspective on leg ulcer treatment at home. *Journal of Wound Care*, *12*(5), 195–199. jlh.

Hareendran, A., Bradbury, A., Budd, J., Geroulakos, G., Hobbs, R., Kenkre, J., & Symonds, T. (2005). Measuring the impact of venous leg ulcers on quality of life. *Journal of Wound Care*, *14*(2), 53–57. jlh.

Harper, D., Young, A., & McNaught, C.-E. (2014). The physiology of wound healing. *Surgery (Oxford)*, *32*(9), 445–450. https://doi.org/10.1016/j.mpsur.2014.06.010

Harrison, H.-L., & Daker-White, G. (2019). Beliefs and challenges held by medical staff about providing emergency care to migrants: An international systematic review and translation of findings to the UK context. *BMJ Open*, *9*(7), e028748. https://doi.org/10.1136/bmjopen-2018-028748

Health Care and Health Insurance Act – NPB 30, Health Care and Health Insurance Act – NPB 30 (2019). http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO213

Heidegger, M. (2005). *Sein und Zeit/Bit in Čas* (T. Hribar, V. Kalan, A. Košar, D. Komel, A. Tonkli Komel, & I. Urbančič, Trans.). Slovenska matica.

Heinen, M., Evers, A., Van Uden, C., Van der Vleuten, C., van de Kerkhof, P., & Van Achterberg, T. (2007). Sedentary patients with venous or mixed leg ulcers: Determinants of physical activity. *Journal of Advanced Nursing*, *60*(1), 50–57. jlh. https://doi.org/10.1111/j.1365-2648.2007.04376.x

Held, K. (2003). Husserl’s Phenomenological Method. In D. Welton (Ed.), *The New Husserl: A Critical Reader*. Indiana University Press.

Hennink, M. M., Kaiser, B. N., & Marconi, V. C. (2017). Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? *Qualitative Health Research*, *27*(4), 591–608. https://doi.org/10.1177/1049732316665344

Herber, O. R., Schnepp, W., & Rieger, M. A. (2007). A systematic review on the impact of leg ulceration on patients’ quality of life. *Health and Quality of Life Outcomes*, *5*, 44. https://doi.org/10.1186/1477-7525-5-44

Herber, O. R., & Barroso, J. (2020). Lessons learned from applying Sandelowski and Barroso’s approach for synthesising qualitative research. *Qualitative Research*, *20*(4), 414–431. https://doi.org/10.1177/1468794119862440

Hertzog, M. A. (2008). Considerations in determining sample size for pilot studies. *Research in Nursing & Health*, *31*(2), 180–191. https://doi.org/10.1002/nur.20247

Hjelm, K., & Apelqvist, J. (2016). Influence of beliefs about health and illness on self-care and care-seeking in foreign-born people with diabetic foot ulcers: Dissimilarities related to origin. *Journal of Wound Care*, *25*(11), 602–616. jlh. https://doi.org/10.12968/jowc.2016.25.11.602

Hjelm, K., & Beebwa, E. (2013). The influence of beliefs about health and illness on foot care in ugandan persons with diabetic foot ulcers. *The Open Nursing Journal*, *7*, 123–132. https://doi.org/10.2174/1874434601307010123

Hjelm, K., Nyberg, P., & Apelqvist, J. (2002a). The diabetic foot—Multidisciplinary management from the patient’s perspective. *Clinical Effectiveness in Nursing*, *6*(2), 66–77. jlh.

Hjelm, K., Nyberg, P., & Apelqvist, J. (2002b). Gender influences beliefs about health and illness in diabetic subjects with severe foot lesions. *Journal of Advanced Nursing*, *40*(6), 673–684. https://doi.org/10.1046/j.1365-2648.2002.02427.x

Ho, P. M., Rumsfeld, J. S., Masoudi, F. A., McClure, D. L., Plomondon, M. E., Steiner, J. F., & Magid, D. J. (2006). Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients With Diabetes Mellitus. *Archives of Internal Medicine*, *166*(17), 1836–1841. https://doi.org/10.1001/archinte.166.17.1836

Hoffman, S. J., Gunn, E., Rogers Van Katwyk, S., & Nixon, S. (2020). Systematic analysis of global health research funding in Canada, 2000–2016. *Canadian Journal of Public Health*, *111*(1), 80–95. https://doi.org/10.17269/s41997-019-00247-8

Holloway, W., & Jefferson, T. (2013). *Doing Qualitative Research Differently: A Psychosocial Approach* (2nd ed.). SAGE. https://uk.sagepub.com/en-gb/eur/doing-qualitative-research-differently/book239246

Holman, N., Young, R. J., & Jeffcoate, W. J. (2012). Variation in the recorded incidence of amputation of the lower limb in England. *Diabetologia*, *55*(7), 1919–1925. https://doi.org/10.1007/s00125-012-2468-6

Hopia, H., Latvala, E., & Liimatainen, L. (2016). Reviewing the methodology of an integrative review. *Scandinavian Journal of Caring Sciences*, *30*(4), 662–669. https://doi.org/10.1111/scs.12327

Hopkins, A. (2004). Disrupted lives: Investigating coping strategies for non-healing leg ulcers. *British Journal of Nursing*, *13*(9), 556–563. jlh.

Hopkins, A., Dealey, C., Bale, S., Defloor, T., & Worboys, F. (2006). Patient stories of living with a pressure ulcer. *Journal of Advanced Nursing*, *56*(4), 345–353. jlh. https://doi.org/10.1111/j.1365-2648.2006.04007.x

Hribar, T. (1993). *Fenomenologija 1 Bretano, Heidegger, Huserl*. Slovenska matica.

Hsieh, H.-F., & Shannon, S. E. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research*, *15*(9), 1277–1288. https://doi.org/10.1177/1049732305276687

Hultsjö, S., & Hjelm, K. (2005). Immigrants in emergency care: Swedish health care staff's experiences. *International Nursing Review*, *52*(4), 276–285. https://doi.org/10.1111/j.1466-7657.2005.00418.x

Humphries, M. D., Brunson, A., Li, C. S., Melnikow, J., & Romano, P. S. (2016, December). *Amputation trends for patients with lower extremity ulcers due to diabetes and peripheral artery disease using statewide data*. Journal of Vascular Surgery; J Vasc Surg. https://doi.org/10.1016/j.jvs.2016.06.096

Husband, L. L. (2001). Shaping the trajectory of patients with venous ulceration in primary care. *Health Expectations : An International Journal of Public Participation in Health*

Care and Health Policy, *4*(3), 189–198. https://doi.org/10.1046/j.1369-6513.2001.00133.x

Husserl, E. (1997). *Ideen zu einer reinen Phänomenologie in phänomenologischen Philosophie/ Ideje za čisto fenomenologijo in fenomenološko filozofijo* (F. Jerman, Trans.). Slovenska matica.

Hyde, C., Ward, B., Horsfall, J., & Winder, G. (1999). Older women's experience of living with chronic leg ulceration. *International Journal of Nursing Practice*, *5*(4), 189–198. https://doi.org/10.1046/j.1440-172x.1999.00170.x

Iraj, B., Khorvash, F., Ebneshahidi, A., & Askari, G. (2013). Prevention of Diabetic Foot Ulcer. *International Journal of Preventive Medicine*, *4*(3), 373–376.

Izon, E., Berry, K., Law, H., & French, P. (2018). Expressed emotion (EE) in families of individuals at-risk of developing psychosis: A systematic review. *Psychiatry Research*, *270*, 661–672. https://doi.org/10.1016/j.psychres.2018.10.065

Jackson, D., Durrant, L., Bishop, E., Walthall, H., Betteridge, R., Gardner, S., Coulton, W., Hutchinson, M., Neville, S., Davidson, P. M., & Usher, K. (2017). Pain associated with pressure injury: A qualitative study of community-based, home-dwelling individuals. *Journal of Advanced Nursing*, *73*(12), 3061–3069. jlh. https://doi.org/10.1111/jan.13370

Jackson, D. E., Durrant, L. A., Hutchinson, M., Ballard, C. A., Neville, S., & Usher, K. (2018). Living with multiple losses: Insights from patients living with pressure injury. *Collegian*, *25*(4), 409–414. jlh. https://doi.org/10.1016/j.colegn.2017.10.008

Jelen, A. (2013). *Prevalenca razjede zaradi pritiska v Univerzitetnem kliničnem centru Ljubljana—Presečna študija* [University of Ljubljana]. https://repozitorij.uni-lj.si/IzpisGradiva.php?id=72500&lang=slv

Jemal, A., Bray, F., Center, M. M., Ferlay, J., Ward, E., & Forman, D. (2011). Global cancer statistics. *CA: A Cancer Journal for Clinicians*, *61*(2), 69–90. https://doi.org/10.3322/caac.20107

Joachim, G., & Acorn, S. (2000). Stigma of visible and invisible chronic conditions. *Journal of Advanced Nursing*, *32*(1), 243–248. https://doi.org/10.1046/j.1365-2648.2000.01466.x

Johnson, M., Long, T., & White, A. (2001). Arguments for 'British Pluralism' in qualitative health research. *Journal of Advanced Nursing*, *33*(2), 243–249.

Jones, J., Robinson, J., Barr, W., & Carlisle, C. (2008). Impact of exudate and odour from chronic venous leg ulceration. *Nursing Standard*, *22*(45), 53–58. jlh.

Jull, A. B., Cullum, N., Dumville, J. C., Westby, M. J., Deshpande, S., & Walker, N. (2015). Honey as a topical treatment for wounds. *Cochrane Database of Systematic Reviews*, *3*. https://doi.org/10.1002/14651858.CD005083.pub4

Kadivec, S. (2000). Prevention of decubitus ulcers—Activityof quality assurance at the university hospital for respiratory and allergic diseases Golnik. *Obzornik zdravstvene nege*, *34*(5–6), 193–196.

Kahn, D. L. (2000). How to Conduct Research. In M. Z. Cohen, D. L. Kahn, & R. H. Steeves (Eds.), *Hermeneutic phenomenological research: A Practical Guide for Nurse Researchers.* (pp. 57–70). Sage Publications Inc.

Kane, R., Wellings, K., Free, C., & Goodrich, J. (2000). Uses of routine data sets in the evaluation of health promotion interventions: Opportunities and limitations. *Health Education*, *100*(1), 33–41. https://doi.org/10.1108/09654280010309030

Kapp, S., & Annells, M. (2010). Pressure ulcers: Home-based nursing. *British Journal of Community Nursing*, *15*, S6–S13. jlh.

Kapp, S., Simpson, K., & Santamaria, N. (2014). Perspectives on living with and self-treating venous leg ulcers: A person's story and a health care perspective. *Wound Practice & Research*, *22*(2), 98–101. jlh.

Kapp, S., Miller, C., & Santamaria, N. (2018). The quality of life of people who have chronic wounds and who self-treat. *Journal of Clinical Nursing*, *27*(1–2), 182–192. https://doi.org/10.1111/jocn.13870

Kaushansky, D., Cox, J., Dodson, C., McNeeley, M., Kumar, S., & Iverson, E. (2017). Living a secret: Disclosure among adolescents and young adults with chronic illnesses. *Chronic Illness*, *13*(1), 49–61. https://doi.org/10.1177/1742395316655855

Kenig, J., Richter, P., Lasek, A., Zbierska, K., & Zurawska, S. (2014). The efficacy of risk scores for predicting abdominal wound dehiscence: A case-controlled validation study. *BMC Surgery*, *14*, 65. https://doi.org/10.1186/1471-2482-14-65

King, H., Aubert, R. E., & Herman, W. H. (1998). Global Burden of Diabetes, 1995–2025: Prevalence, numerical estimates, and projections. *Diabetes Care*, *21*(9), 1414–1431. https://doi.org/10.2337/diacare.21.9.1414

Kinmond, K., McGee, P., Gough, S., & Ashford, R. (2003). 'Loss of self': A psychosocial study of the quality of life of adults with diabetic foot ulceration [corrected] [published erratum appears in Journal of Tissue Viability 2003 Apr;13(2):80]. *Journal of Tissue Viability*, *13*(1), 6–10. jlh.

Kirupa, P. (2014). Inscience, day to day struggle and distress: lived experiences of patients with chronic leg and foot ulcer. *Nitte University Journal of Health Science*, *4*(3), 19–24.

Kottner, J., Raeder, K., Halfens, R., & Dassen, T. (2009). A systematic review of interrater reliability of pressure ulcer classification systems. *Journal of Clinical Nursing*, *18*(3), 315–336. https://doi.org/10.1111/j.1365-2702.2008.02569.x

Krasner D. (1998). Painful venous ulcers: Themes and stories about living with the pain and suffering. *Journal of Wound, Ostomy & Continence Nursing*, *25*(3), 158–168. jlh.

Krippendorff, K. (2004). *Content Analysis: An Introduction to Its Methodology*. SAGE.

Kvale, S., & Birnkmann, S. (2009). *InterViews: Learning the craft of qualitative research interviewing* (2nd ed.). Sage Publications Inc.

Kyngäs, H. (2000). Compliance of adolescents with chronic disease. *Journal of Clinical Nursing*, *9*(4), 549–556.

Kyngäs, H., Duffy, M. E., & Kroll, T. (2000). Conceptual analysis of compliance. *Journal of Clinical Nursing*, *9*(1), 5–12. https://doi.org/10.1046/j.1365-2702.2000.00309.x

Langemo, D. K., Melland, H., Hanson, D., Olson, B., & Hunter, S. (2000). The lived experience of having a pressure ulcer: A qualitative analysis. *Advances in Skin & Wound Care*, *13*(5), 225–235.

Larkin, P. J., Dierckx de Casterlé, B., & Schotsmans, P. (2007). Multilingual translation issues in qualitative research: Reflections on a metaphorical process. *Qualitative Health Research*, *17*(4), 468–476. https://doi.org/10.1177/1049732307299258

Lasserson, T., Thomas, J., & Higgins, J. P. T. (2019). Chapter 1: Starting a review. In J. P. T. Higgins, J. Thomas, J. Chandler, M. Cumpston, T. Li, M. J. Page, & V. A. Welch

(Eds.), *Cochrane Handbook for Systematic Reviews of Interventions version 6.0*. Cochrane. /handbook/current/chapter-01

Lavallée, J. F., Gray, T. A., Dumville, J., Russell, W., & Cullum, N. (2017). The effects of care bundles on patient outcomes: A systematic review and meta-analysis. *Implementation Science: IS*, *12*(1), 142. https://doi.org/10.1186/s13012-017-0670-0

Lazarus, G. S., Cooper, D. M., Knighton, D. R., & et al. (1994). Definitions and guidelines for assessment of wounds and evaluation of healing. *Archives of Dermatology*, *130*(4), 489–493. https://doi.org/10.1001/archderm.1994.01690040093015

Lefebvre, C., Glanville, J., Briscoe, S., Littlewood, A., Marshall, C., Metzendorf, M. I., Noel-Storr, A., Rader, T., Shokraneh, F., & Wieland, L. S. (2019). Chapter 4: Searching for and selecting studies. In J. P. T. Higgins, J. Thomas, J. Chandler, M. Cumpston, T. Li, M. J. Page, & V. A. Welch (Eds.), *Cochrane Handbook for Systematic Reviews of Interventions version 6.0*. Cochrane. /handbook/current/chapter-04

Leigh-Hunt, N., Bagguley, D., Bash, K., Turner, V., Turnbull, S., Valtorta, N., & Caan, W. (2017). An overview of systematic reviews on the public health consequences of social isolation and loneliness. *Public Health*, *152*, 157–171. https://doi.org/10.1016/j.puhe.2017.07.035

Lernevall, L. S. D., Fogh, K., Nielsen, C. B., Dam, W., & Dreyer, P. S. (2017). Lived experiences of life with a leg ulcer—A life in hell. *EWMA Journal*, *17*(1), 15–21. jlh.

Levac, D., Colquhoun, H., & O’Brien, K. K. (2010). Scoping studies: Advancing the methodology. *Implementation Science: IS*, *5*, 69. https://doi.org/10.1186/1748-5908-5-69

Lewis C. (2007). Healthcare beliefs of Indian patients living with leg and foot ulcers. *British Journal of Nursing*, *16*(11), S22-6. jlh.

Li, J., Chen, J., & Kirsner, R. (2007). Pathophysiology of acute wound healing. *Clinics in Dermatology*, *25*(1), 9–18. https://doi.org/10.1016/j.clindermatol.2006.09.007

Lindahl, E., Norberg, A., & Söderberg, A. (2007). The meaning of living with malodorous exuding ulcers. *Journal of Clinical Nursing*, *16*(3A), 68–75. https://doi.org/10.1111/j.1365-2702.2005.01550.x

Lindsay, E., & Hawkins, J. (2003). Care study: The Leg Club Model and the sharing of knowledge. *British Journal of Nursing (Mark Allen Publishing)*, *12*(13), 784–790. https://doi.org/10.12968/bjon.2003.12.13.11346

Lindseth, A., & Norberg, A. (2004). A phenomenological hermeneutical method for researching lived experience. *Scandinavian Journal of Caring Sciences*, *18*(2), 145–153. https://doi.org/10.1111/j.1471-6712.2004.00258.x

Listewnik, M. J., Jędrzejczak, T., Majer, K., Szylińska, A., Mikołajczyk, A., Mokrzycki, K., Górka, E., & Brykczyński, M. (2019). Complications in cardiac surgery: An analysis of factors contributing to sternal dehiscence in patients who underwent surgery between 2010 and 2014 and a comparison with the 1990-2009 cohort. *Advances in Clinical and Experimental Medicine: Official Organ Wroclaw Medical University*, *28*(7), 913–922. https://doi.org/10.17219/acem/94154

Littell, J. H. (2008). Evidence-based or biased? The quality of published reviews of evidence-based practices. *Children and Youth Services Review*, *30*(11), 1299–1317. https://doi.org/10.1016/j.childyouth.2008.04.001

Liu, Z., Dumville, J. C., Norman, G., Westby, M. J., Blazeby, J., McFarlane, E., Welton, N. J., O'Connor, L., Cawthorne, J., George, R. P., Crosbie, E. J., Rithalia, A. D., & Cheng, H.-Y. (2018). Intraoperative interventions for preventing surgical site infection: An overview of Cochrane Reviews. *The Cochrane Database of Systematic Reviews*, *2*, CD012653. https://doi.org/10.1002/14651858.CD012653.pub2

Lo, S., Hu, W., Hayter, M., Chang, S., Hsu, M., & Wu, L. (2008). Experiences of living with a malignant fungating wound: A qualitative study. *Journal of Clinical Nursing*, *17*(20), 2699–2708. jlh. https://doi.org/10.1111/j.1365-2702.2008.02482.x

Lo, S.-F., Hayter, M., Hu, W.-Y., Tai, C.-Y., Hsu, M.-Y., & Li, Y.-F. (2012). Symptom burden and quality of life in patients with malignant fungating wounds. *Journal of Advanced Nursing*, *68*(6), 1312–1321. jlh. https://doi.org/10.1111/j.1365-2648.2011.05839.x

Lockwood, C., Porritt, K., Munn, Z., Rittenmeyer, L., Salmond, S., Bjerrum, M., Loveday, H., Carrier, J., & Stannard, D. (2017). Chapter 2: Systematic reviews of qualitative evidence. In E. Aromataris & Z. Munn (Eds.), *Joanna Briggs Institute Reviewer's Manual*. The Joanna Briggs Institute. https://reviewersmanual.joannabriggs.org/

Lund, J., Tou, S., Doleman, B., & Williams, J. P. (2017). Fibrin glue for pilonidal sinus disease. *The Cochrane Database of Systematic Reviews*, *1*, CD011923. https://doi.org/10.1002/14651858.CD011923.pub2

Lund-Nielsen, B., Müller, K., & Adamsen, L. (2005a). Malignant wounds in women with breast cancer: Feminine and sexual perspectives. *Journal of Clinical Nursing*, *14*(1), 56–64. jlh. https://doi.org/10.1111/j.1365-2702.2004.01022.x

Lund-Nielsen, B., Müller, K., & Adamsen, L. (2005b). Qualitative and quantitative evaluation of a new regimen for malignant wounds in women with advanced breast cancer. *Journal of Wound Care*, *14*(2), 69–73. jlh.

Lund-Nielsen, B., Midtgaard, J., Rorth, M., Gottrup, F., & Adamsen, L. (2011). An Avalanche of Ignoring-A Qualitative Study of Health Care Avoidance in Women With Malignant Breast Cancer Wounds. *Cancer Nursing July/August 2011*, *34*(4), 277–285. https://doi.org/10.1097/NCC.0b013e3182025020

Madden, M. (2015). The ghost of Nora Batty: A qualitative exploration of the impact of footwear, bandaging and hosiery interventions in chronic wound care. *Chronic Illness*, *11*(3), 218–229. jlh. https://doi.org/10.1177/1742395314566824

Mader, L. B., Harris, T., Kläger, S., Wilkinson, I. B., & Hiemstra, T. F. (2018). Inverting the patient involvement paradigm: Defining patient led research. *Research Involvement and Engagement*, *4*. https://doi.org/10.1186/s40900-018-0104-4

Maida, V., Ennis, M., & Corban, J. (2012). Wound outcomes in patients with advanced illness. *International Wound Journal*, *9*(6), 683–692. https://doi.org/10.1111/j.1742-481X.2012.00939.x

Maida, V., Ennis, M., Kuziemsky, C., & Trozzolo, L. (2009). Symptoms Associated with Malignant Wounds: A Prospective Case Series. *Journal of Pain and Symptom Management*, *37*(2), 206–211. https://doi.org/10.1016/j.jpainsymman.2008.01.009

Manorama, A. A., Baek, S., Vorro, J., Sikorskii, A., & Bush, T. R. (2010). Blood perfusion and transcutaneous oxygen level characterizations in human skin with changes in normal and shear loads—Implications for pressure ulcer formation. *Clinical Biomechanics*, *25*(8), 823–828. https://doi.org/10.1016/j.clinbiomech.2010.06.003

Manorama, A., Meyer, R., Wiseman, R., & Bush, T. R. (2013). Quantifying the effects of external shear loads on arterial and venous blood flow: Implications for pressure ulcer development. *Clinical Biomechanics*, *28*(5), 574–578. https://doi.org/10.1016/j.clinbiomech.2013.04.001

Martinengo, L., Olsson, M., Bajpai, R., Soljak, M., Upton, Z., Schmidtchen, A., Car, J., & Järbrink, K. (2019). Prevalence of chronic wounds in the general population: Systematic review and meta-analysis of observational studies. *Annals of Epidemiology*, *29*, 8–15. https://doi.org/10.1016/j.annepidem.2018.10.005

McCaughan, D., Cullum, N., Dumville, J., & VenUS II Team. (2015). Patients' perceptions and experiences of venous leg ulceration and their attitudes to larval therapy: An in-depth qualitative study. *Health Expectations: An International Journal of Public Participation in Health Care and Health Policy*, *18*(4), 527–541. https://doi.org/10.1111/hex.12053

McCaughan, D., Sheard, L., Cullum, N., Dumville, J., & Chetter, I. (2018). Patients' perceptions and experiences of living with a surgical wound healing by secondary intention: A qualitative study. *International Journal of Nursing Studies*, *77*, 29–38. jlh. https://doi.org/10.1016/j.ijnurstu.2017.09.015

McGinnis, E., Andrea Nelson, E., Gorecki, C., & Nixon, J. (2015). What is different for people with MS who have pressure ulcers: A reflective study of the impact upon people's quality of life? *Journal of Tissue Viability*, *24*(3), 83–90. https://doi.org/10.1016/j.jtv.2015.05.003

McPherson MV, & Binning J. (2002). Chronic foot ulcers associated with diabetes: Patients' views. *Diabetic Foot Journal*, *5*(4), 198–204. jlh.

Mekkes, J. R., Loots, M. A. M., Van Der Wal, A. C., & Bos, J. D. (2003, March). *Causes, investigation and treatment of leg ulceration*. The British Journal of Dermatology; Br J Dermatol. https://doi.org/10.1046/j.1365-2133.2003.05222.x

Menke, N. B., Ward, K. R., Witten, T. M., Bonchev, D. G., & Diegelmann, R. F. (2007). Impaired wound healing. *Clinics in Dermatology*, *25*(1), 19–25. https://doi.org/10.1016/j.clindermatol.2006.12.005

Merleau-Ponty, M. (1995). *Phénomènologie de la perception/ Phenomenology of perception* (C. Smith, Trans.). Routledge.

Metcalfe, J., & Brooks, M. (2010). Acute and chronic ischaemia of the lower limb. *Surgery (Oxford)*, *28*(6), 277–283. https://doi.org/10.1016/j.mpsur.2010.02.003

Meyer, V., Kerk, N., Meyer, S., & Goerge, T. (2011). Differential diagnosis and therapy of leg ulcers. *JDDG: Journal Der Deutschen Dermatologischen Gesellschaft*, *9*(12), 1035–1052. https://doi.org/10.1111/j.1610-0387.2011.07814.x

Ministry of Health of the Republic of Slovenia. (2020). Ministry of Health of the Republic of Slovenia. https://www.gov.si/podrocja/zdravje/organiziranost-zdravstvenega-varstva/

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & PRISMA Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Medicine*, *6*(7), e1000097. https://doi.org/10.1371/journal.pmed.1000097

Monsen, C., Acosta, S., & Kumlien, C. (2017). Patients experiences of negative pressure wound therapy at home for the treatment of deep perivascular groin infection after vascular surgery. *Journal of Clinical Nursing*, *26*(9/10), 1405–1413. jlh. https://doi.org/10.1111/jocn.13702

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T., Wight, D., & Baird, J. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*, *350*. https://doi.org/10.1136/bmj.h1258

Moran, D. (2000). *Introduction to Phenomenology* (1 edition). Routledge.

Moran, D. (2007). *Introduction to phenomenology*. Routledge.

Morgan, P. A., & Moffatt, C. J. (2008). Non healing leg ulcers and the nurse-patient relationship. Part 1: The patient's perspective. *International Wound Journal*, *5*(2), 340–348. https://doi.org/10.1111/j.1742-481X.2007.00373.x

Morris, S., Sutton, M., & Gravelle, H. (2005). Inequity and inequality in the use of health care in England: An empirical investigation. *Social Science & Medicine (1982)*, *60*(6), 1251–1266. https://doi.org/10.1016/j.socscimed.2004.07.016

Morse, J. M., Barrett, M., Mayan, M., Olson, K., & Spiers, J. (2002). Verification Strategies for Establishing Reliability and Validity in Qualitative Research. *International Journal of Qualitative Methods*, *1*(2), 13–22. https://doi.org/10.1177/160940690200100202

Mudge, E., Holloway, S., Simmonds, W., & Price, P. (2006). Leg ulcers. Living with venous leg ulceration: Issues concerning adherence. *British Journal of Nursing*, *15*(21), 1166–1171. jlh.

Mudge, E., Spanou, C., & Price, P. (2008). A focus group study into patients' perception of chronic wound pain. *Wounds UK*, *4*(2), 21–26. jlh.

Munir, F., Leka, S., & Griffiths, A. (2005). Dealing with self-management of chronic illness at work: Predictors for self-disclosure. *Social Science & Medicine (1982)*, *60*(6), 1397–1407. https://doi.org/10.1016/j.socscimed.2004.07.012

Murray, S. A., Kendall, M., Carduff, E., Worth, A., Harris, F. M., Lloyd, A., Cavers, D., Grant, L., & Sheikh, A. (2009). Use of serial qualitative interviews to understand patients' evolving experiences and needs. *BMJ*, *339*, b3702. https://doi.org/10.1136/bmj.b3702

Nather, A., & Wong, K. L. (2013). Distal amputations for the diabetic foot. *Diabetic Foot & Ankle*, *4*. https://doi.org/10.3402/dfa.v4i0.21288

Neal, P. K. (2015). An exploration of the experiences of wound healing in military traumatic amputees and its impact on their rehabilitation. *Journal of the Royal Army Medical Corps*, *161 Suppl 1*, i64–i68. https://doi.org/10.1136/jramc-2015-000589

Nelms, T. (2015). Phenomenological Philosophy and Research. In *Nursing research using phenomenology: Qualitative designs and methods in nursing* (pp. 2–23). Springer Publishing Compani, LLC.

Nelson, E. A., & Jones, J. (2008). Venous leg ulcers. *Clinical Evidence*, *2008*. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2908003/

Nelzén, O., Bergqvist, D., & Lindhagen, A. (1996). The prevalence of chronic lower-limb ulceration has been underestimated: Results of a validated population questionnaire. *British Journal of Surgery*, *83*(2), 255–258. https://doi.org/10.1046/j.1365-2168.1996.02099.x

Nelzén, O. (2010). Fifty percent reduction in venous ulcer prevalence is achievable—Swedish experience. *Journal of Vascular Surgery*, *52*(5, Supplement), 39S-44S. https://doi.org/10.1016/j.jvs.2010.05.122

Newcombe, R. G. (1998). Two-sided confidence intervals for the single proportion: Comparison of seven methods. *Statistics in Medicine*, *17*(8), 857–872.

Ngaage, M., & Agius, M. (2018). The Psychology of Scars: A Mini-Review. *Psychiatria Danubina*, *30*(Suppl 7), 633–638.

Noble, H., & Smith, J. (2018). Reviewing the literature: Choosing a review design. *Evidence-Based Nursing*, *21*(2), 39–41. https://doi.org/10.1136/eb-2018-102895

Norman, G., Atkinson, R. A., Smith, T. A., Rowlands, C., Rithalia, A. D., Crosbie, E. J., & Dumville, J. C. (2017). Intracavity lavage and wound irrigation for prevention of surgical site infection. *The Cochrane Database of Systematic Reviews*, *10*, CD012234. https://doi.org/10.1002/14651858.CD012234.pub2

Norman, G., Dumville, J. C., Mohapatra, D. P., Owens, G. L., & Crosbie, E. J. (2016). Antibiotics and antiseptics for surgical wounds healing by secondary intention. *The Cochrane Database of Systematic Reviews*, *3*, CD011712. https://doi.org/10.1002/14651858.CD011712.pub2

Norman, G., Goh, E. L., Dumville, J. C., Shi, C., Liu, Z., Chiverton, L., Stankiewicz, M., & Reid, A. (2020). Negative pressure wound therapy for surgical wounds healing by primary closure. *Cochrane Database of Systematic Reviews*, *5*. https://doi.org/10.1002/14651858.CD009261.pub5

O'Brien, J., Finlayson, K., Kerr, G., & Edwards, H. (2014). The perspectives of adults with venous leg ulcers on exercise: An exploratory study. *Journal of Wound Care*, *23*(10), 496–498, 500–509. https://doi.org/10.12968/jowc.2014.23.10.496

O'Connor, A., Carpenter, B. A., & Coughlan, B. (2018). An Exploration of Key Issues in the Debate Between Classic and Constructivist Grounded Theory. *Grounded Theory Review: An International Journal*, *17*(1), 90–103.

Orb, A., Eisenhauer, L., & Wynaden, D. (2001). Ethics in Qualitative Research. *Journal of Nursing Scholarship*, *33*(1), 93–96. https://doi.org/10.1111/j.1547-5069.2001.00093.x

Ottosen, B., & Pedersen, B. D. (2013). Patients’ experiences of NPWT in an outpatient setting in Denmark. *Journal of Wound Care*, *22*(4), 197–198, 200–202, 204–206. https://doi.org/10.12968/jowc.2013.22.4.197

Oyibo, S. O., Jude, E. B., Tarawneh, I., Nguyen, H. C., Harkless, L. B., & Boulton, A. J. M. (2001). A Comparison of Two Diabetic Foot Ulcer Classification Systems The Wagner and the University of Texas wound classification systems. *Diabetes Care*, *24*(1), 84–88. https://doi.org/10.2337/diacare.24.1.84

Pađen, L., Griffiths, J., & Cullum, N. (2019). A cross-sectional survey of patients with open surgical wounds in Slovenia. *Health & Social Care in the Community*, *27*(4), e213–e222. https://doi.org/10.1111/hsc.12700

Pagliaro Borges Soares, P., Aparecida Ferreira, L., Ribeiro Luiz GonÃ§alves, J., & Bonato Zuffi, F. (2013). Impact of arterial ulcers in the quality of life through the perception of patients. *Journal of Nursing UFPE / Revista de Enfermagem UFPE*, *7*(8), 5225–5231. jlh. https://doi.org/10.5205/reuol.3452-28790-4-ED.0708201321

Paley, J. (2017). *Phenomenology as Qualitative Research: A Critical Analysis of Meaning Attribution*. Routledge.

Palfreyman, S. J., Tod, A. M., King, B., Tomlinson, D., Brazier, J. E., & Michaels, J. A. (2007). Impact of intravenous drug use on quality of life for patients with venous ulcers. *Journal of Advanced Nursing*, *58*(5), 458–467. https://doi.org/10.1111/j.1365-2648.2007.04251.x

Palinkas, L. A., Horwitz, S. M., Green, C. A., Wisdom, J. P., Duan, N., & Hoagwood, K. (2015). Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Administration and Policy in Mental Health*, *42*(5), 533–544. https://doi.org/10.1007/s10488-013-0528-y

Parry, K. K., Mobley, T., & Allen, O. (1996). Use of folk treatments for diabetic plantar ulcers among African Americans with Type II diabetes. *International Journal of Rehabilitation & Health*, *2*(4), 265–275. jlh.

Parry, O., & Mauthner, N. S. (2004). Whose Data are They Anyway?: Practical, Legal and Ethical Issues in Archiving Qualitative Research Data. *Sociology*, *38*(1), 139–152. https://doi.org/10.1177/0038038504039366

Parslow, R. M., Harris, S., Broughton, J., Alattas, A., Crawley, E., Haywood, K., & Shaw, A. (2017). Children’s experiences of chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME): A systematic review and meta-ethnography of qualitative studies. *BMJ Open*, *7*(1), e012633. https://doi.org/10.1136/bmjopen-2016-012633

Pascal, J. (2010). Phenomenology as a Research Method for Social Work Contexts: Understanding the Lived Experience of Cancer Survival. *Currents: Scholarship in the Human Services*, *9*(2). https://journalhosting.ucalgary.ca/index.php/currents/article/view/15905

Paton, J. S., Roberts, A., Bruce, G. K., & Marsden, J. (2014). Patients’ Experience of therapeutic footwear whilst living at risk of neuropathic diabetic foot ulceration: An interpretative phenomenological analysis (IPA). *Journal of Foot and Ankle Research*, *7*, 16. https://doi.org/10.1186/1757-1146-7-16

Paul, J. (2013). A cross-sectional study of chronic wound-related pain and itching. *Ostomy/Wound Management*, *59*(7), 28–34.

Pearce, N. (1999). Epidemiology as a population science. *International Journal of Epidemiology*, *28*(5), S1015-1018. https://doi.org/10.1093/oxfordjournals.ije.a019904

Pearce, N. (2012). Classification of epidemiological study designs. *International Journal of Epidemiology*, *41*(2), 393–397. https://doi.org/10.1093/ije/dys049

Persoon, A., Heinen, M. M., Van Der Vleuten, C. J. M., De Rooij, M. J., Van De Kerkhof, P. C. M., & Van Achterberg, T. (2004). Leg ulcers: A review of their impact on daily life. *Journal of Clinical Nursing*, *13*(3), 341–354. https://doi.org/10.1046/j.1365-2702.2003.00859.x

Peters, M. D. J., Godfrey, C. M., Mclnerney, P., Baldini Soares, C., Khalil, H., & Parker, D. (2017). Chapter 11: Scoping reviews. In E. Aromataris & Z. Munn (Eds.), *Joanna Briggs Institute Reviewer’s Manual*. The Joanna Briggs Institute. https://reviewersmanual.joannabriggs.org/

Petrovskaya, O. (2014). Is there nursing phenomenology after Paley? Essay on rigorous reading. *Nursing Philosophy: An International Journal for Healthcare Professionals*, *15*(1), 60–71. https://doi.org/10.1111/nup.12045

Petticrew, M., Egan, M., Thomson, H., Hamilton, V., Kunkler, R., & Roberts, H. (2008). Publication bias in qualitative research: What becomes of qualitative research presented at conferences? *Journal of Epidemiology and Community Health*, *62*(6), 552–554. https://doi.org/10.1136/jech.2006.059394

Pham, M. T., Rajić, A., Greig, J. D., Sargeant, J. M., Papadopoulos, A., & McEwen, S. A. (2014). A scoping review of scoping reviews: Advancing the approach and enhancing the consistency. *Research Synthesis Methods*, *5*(4), 371–385. https://doi.org/10.1002/jrsm.1123

Phillips, P., Lumley, E., Duncan, R., Aber, A., Woods, H. B., Jones, G. L., & Michaels, J. (2018). A systematic review of qualitative research into people's experiences of living with venous leg ulcers. *Journal of Advanced Nursing*, *74*(3), 550–563. jlh. https://doi.org/10.1111/jan.13465

Piggin, C., & Jones, V. (2007). Malignant fungating wounds: An analysis of the lived experience. *International Journal of Palliative Nursing*, *13*(8), 384–391. jlh.

Polit, D. F., & Beck, C. T. (2010). Generalization in quantitative and qualitative research: Myths and strategies. *International Journal of Nursing Studies*, *47*(11), 1451–1458. https://doi.org/10.1016/j.ijnurstu.2010.06.004

Polit, D. F., & Beck, C. T. (2011). *Nursing Research: Generating and Assessing Evidence for Nursing Practice, 9th Edition* (9th edition). LWW.

Porta, M. S., Greenland, S., Hernán, M., Silva, I. dos S., & Last, J. M. (2014). *A Dictionary of Epidemiology*. Oxford University Press.

Pragnell, J., & Neilson, J. (2010). The social and psychological impact of hard-to-heal wounds. *British Journal of Nursing (Mark Allen Publishing)*, *19*(19), 1248–1252.

Probst, S., Arber, A., & Faithfull, S. (2013a). Coping with an exulcerated breast carcinoma: An interpretative phenomenological study. *Journal of Wound Care*, *22*(7), 352–360. jlh.

Probst, S., Arber, A., & Faithfull, S. (2013b). Malignant fungating wounds: The meaning of living in an unbounded body. *European Journal of Oncology Nursing: The Official Journal of European Oncology Nursing Society*, *17*(1), 38–45. https://doi.org/10.1016/j.ejon.2012.02.001

Prompers, L., Huijberts, M., Apelqvist, J., Jude, E., Piaggesi, A., Bakker, K., Edmonds, M., Holstein, P., Jirkovska, A., Mauricio, D., Tennvall, G. R., Reike, H., Spraul, M., Uccioli, L., Urbancic, V., Acker, K. V., Baal, J. van, Merode, F. van, & Schaper, N. (2007). High prevalence of ischaemia, infection and serious comorbidity in patients with diabetic foot disease in Europe. Baseline results from the Eurodiale study. *Diabetologia*, *50*(1), 18–25. https://doi.org/10.1007/s00125-006-0491-1

Rao, V., & Bowman, S. (2013). Latest advances in connective tissue disorders. *Therapeutic Advances in Musculoskeletal Disease*, *5*(4), 234–249. https://doi.org/10.1177/1759720X13480280

Reger, S. I., Ranganathan, V. K., Orsted, H. L., Ohura, T., & Gefen, A. (2010). *Shear and friction in context*. http://www.woundsinternational.com/media/issues/300/files/content_8925.pdf

Regmi, K., Naidoo, J., & Pilkington, P. (2010). Understanding the Processes of Translation and Transliteration in Qualitative Research. *International Journal of Qualitative Methods*, *9*(1), 16–26. https://doi.org/10.1177/160940691000900103

Ribu, L., Rustøen, T., Birkeland, K., Hanestad, B. R., Paul, S. M., & Miaskowski, C. (2006). The Prevalence and Occurrence of Diabetic Foot Ulcer Pain and Its Impact on Health-Related Quality of Life. *The Journal of Pain*, *7*(4), 290–299. https://doi.org/10.1016/j.jpain.2005.12.002

Ribu L, & Wahl A. (2004). Living with diabetic foot ulcers: A life of fear, restrictions, and pain. *Ostomy Wound Management*, *50*(2), 57–67. jlh.

Rich, A., & McLachlan, L. (2003). How living with a leg ulcer affects people’s daily life: A nurse-led study. *Journal of Wound Care*, *12*(2), 51–54. jlh.

Rieger, K. L. (2019). Discriminating among grounded theory approaches. *Nursing Inquiry*, *26*(1), e12261. https://doi.org/10.1111/nin.12261

Robinson, O. C. (2014). Sampling in Interview-Based Qualitative Research: A Theoretical and Practical Guide. *Qualitative Research in Psychology*, *11*(1), 25–41. https://doi.org/10.1080/14780887.2013.801543

Rolfe, G. (2006). Validity, trustworthiness and rigour: Quality and the idea of qualitative research. *Journal of Advanced Nursing*, *53*(3), 304–310. https://doi.org/10.1111/j.1365-2648.2006.03727.x

Rømsing, J., Dremstrup Skovgaard, C., Friis, S. M., & Henneberg, S. W. (2014). Procedure-related pain in children in a Danish University Hospital. A qualitative study. *Paediatric Anaesthesia*, *24*(6), 602–607. https://doi.org/10.1111/pan.12402

Roundtree, A. K., Kallen, M. A., Lopez-Olivo, M. A., Kimmel, B., Skidmore, B., Ortiz, Z., Cox, V., & Suarez-Almazor, M. E. (2009). Poor reporting of search strategy and conflict of interest in over 250 narrative and systematic reviews of two biologic agents in arthritis: A systematic review. *Journal of Clinical Epidemiology*, *62*(2), 128–137. https://doi.org/10.1016/j.jclinepi.2008.08.003

Rowan-Legg, A., Weijer, C., Gao, J., & Fernandez, C. (2009). A comparison of journal instructions regarding institutional review board approval and conflict-of-interest disclosure between 1995 and 2005. *Journal of Medical Ethics*, *35*(1), 74–78. https://doi.org/10.1136/jme.2008.024299

Sale, J. E. M., & Brazil, K. (2004). A Strategy to Identify Critical Appraisal Criteria for Primary Mixed-Method Studies. *Quality & Quantity*, *38*(4), 351–365. https://doi.org/10.1023/b:ququ.0000043126.25329.85

Sandelowski, M. (1993). Rigor or rigor mortis: The problem of rigor in qualitative research revisited. *ANS. Advances in Nursing Science*, *16*(2), 1–8. https://doi.org/10.1097/00012272-199312000-00002

Sandelowski, M. (1995). Sample size in qualitative research. *Research in Nursing & Health*, *18*(2), 179–183. https://doi.org/10.1002/nur.4770180211

Sandy-Hodgetts, K., Carville, K., & Leslie, G. D. (2015). Determining risk factors for surgical wound dehiscence: A literature review. *International Wound Journal*, *12*(3), 265–275. https://doi.org/10.1111/iwj.12088

Santos, H. P. O., Black, A. M., & Sandelowski, M. (2015). Timing of translation in cross-language qualitative research. *Qualitative Health Research*, *25*(1), 134–144. https://doi.org/10.1177/1049732314549603

Saurina, C., Vall-llosera, L., & Saez, M. (2010). A qualitative analysis of immigrant population health practices in the Girona Healthcare Region. *BMC Public Health*, *10*(1), 379. https://doi.org/10.1186/1471-2458-10-379

Sautter, J. M., Tulsky, J. A., Johnson, K. S., Olsen, M. K., Burton-Chase, A. M., Lindquist, J. H., Zimmerman, S., & Steinhauser, K. E. (2014). Caregiver Experience During Patients' Advanced Chronic Illness and Last Year of Life. *Journal of the American Geriatrics Society*, *62*(6), 1082–1090. https://doi.org/10.1111/jgs.12841

Scambler, G. (2006). Sociology, social structure and health-related stigma. *Psychology, Health & Medicine*, *11*(3), 288–295. https://doi.org/10.1080/13548500600595103

Scambler, G. (2009). Health-related stigma. *Sociology of Health & Illness*, *31*(3), 441–455. https://doi.org/10.1111/j.1467-9566.2009.01161.x

Schreier, M. (2012). *Qualitative Content Analysis in Practive*. Sage.

Searle, A., Campbell, R., Tallon, D., Fitzgerald, A., & Vedhara, K. (2005). Psychosocial aspects in wound care. A qualitative approach to understanding the experience of ulceration and healing in the diabetic foot: Patient and podiatrist perspectives. *Wounds: A Compendium of Clinical Research & Practice*, *17*(1), 16–26. jlh.

Seidel, D., Diedrich, S., Herrle, F., Thielemann, H., Marusch, F., Schirren, R., Talaulicar, R., Gehrig, T., Lehwald-Tywuschik, N., Glanemann, M., Bunse, J., Hüttemann, M., Braumann, C., Heizman, O., Miserez, M., Krönert, T., Gretschel, S., & Lefering, R. (2020). Negative Pressure Wound Therapy vs Conventional Wound Treatment in Subcutaneous Abdominal Wound Healing Impairment: The SAWHI Randomized Clinical Trial. *JAMA Surgery*. https://doi.org/10.1001/jamasurg.2020.0414

Sen, C. K., Gordillo, G. M., Roy, S., Kirsner, R., Lambert, L., Hunt, T. K., Gottrup, F., Gurtner, G. C., & Longaker, M. T. (2009). Human skin wounds: A major and snowballing threat to public health and the economy. *Wound Repair and Regeneration: Official Publication of the Wound Healing Society [and] the European Tissue Repair Society*, *17*(6), 763–771. https://doi.org/10.1111/j.1524-475X.2009.00543.x

Shahin, W., Kennedy, G. A., & Stupans, I. (2019). The impact of personal and cultural beliefs on medication adherence of patients with chronic illnesses: A systematic review.

Patient Preference and Adherence, *13*, 1019–1035. https://doi.org/10.2147/PPA.S212046

Shai, A., & Halevy, S. (2005). Direct triggers for ulceration in patients with venous insufficiency. *International Journal of Dermatology*, *44*(12), 1006–1009. https://doi.org/10.1111/j.1365-4632.2005.02317.x

Shanmugam, V. K., Price, P., Attinger, C. E., & Steen, V. D. (2010). Lower Extremity Ulcers in Systemic Sclerosis: Features and Response to Therapy. *International Journal of Rheumatology*, *2010*. https://doi.org/10.1155/2010/747946

Shanmugam, V. K., Steen, V. D., & Cupps, T. R. (2008). Lower extremity ulcers in connective tissue disease. *The Israel Medical Association Journal: IMAJ*, *10*(7), 534–536.

Shave, K., Ali, S., Scott, S. D., & Hartling, L. (2018). Procedural pain in children: A qualitative study of caregiver experiences and information needs. *BMC Pediatrics*, *18*(1), 324. https://doi.org/10.1186/s12887-018-1300-y

Shaw, R. L., Booth, A., Sutton, A. J., Miller, T., Smith, J. A., Young, B., Jones, D. R., & Dixon-Woods, M. (2004). Finding qualitative research: An evaluation of search strategies. *BMC Medical Research Methodology*, *4*, 5. https://doi.org/10.1186/1471-2288-4-5

Shi, C., Dumville, J. C., & Cullum, N. (2018a). Skin status for predicting pressure ulcer development: A systematic review and meta-analyses. *International Journal of Nursing Studies*, *87*, 14–25. https://doi.org/10.1016/j.ijnurstu.2018.07.003

Shi, C., Dumville, J. C., & Cullum, N. (2018b). Support surfaces for pressure ulcer prevention: A network meta-analysis. *PloS One*, *13*(2), e0192707. https://doi.org/10.1371/journal.pone.0192707

Shiroky, J., Lillie, E., Muaddi, H., Sevigny, M., Choi, W. J., & Karanicolas, P. J. (2020). The impact of negative pressure wound therapy for closed surgical incisions on surgical site infection: A systematic review and meta-analysis. *Surgery*. https://doi.org/10.1016/j.surg.2020.01.018

Short, K., & Bull, R. (2009). Leg ulcers and lymphoedema. *Medicine*, *37*(6), 269–272. https://doi.org/10.1016/j.mpmed.2009.02.012

Siribumrungwong, B., Noorit, P., Wilasrusmee, C., & Thakkinstian, A. (2014). A systematic review and meta-analysis of randomised controlled trials of delayed primary wound closure in contaminated abdominal wounds. *World Journal of Emergency Surgery*, *9*(1), 49. https://doi.org/10.1186/1749-7922-9-49

SI-STAT Data Portal. (2018). Republic of Slovenia Statistical Office RS. http://www.stat.si/statweb/en/home

SI-STAT Data Portal. (2020). Republic of Slovenia Statistical Office RS. https://pxweb.stat.si/SiStat

Skavberg Roaldsen, K., Biguet, G., & Elfving, B. (2011). Physical activity in patients with venous leg ulcer—Between engagement and avoidance. A patient perspective. *Clinical Rehabilitation*, *25*(3), 275–286. jlh. https://doi.org/10.1177/0269215510371424

Sligo, J., Jones, B., Davies, C., Egan, R., Ingham, T., Hancox, R. J., & Richards, R. (2019). The experiences of young people with chronic illness in New Zealand: A qualitative study. *Child: Care, Health and Development*, *45*(5), 660–669. https://doi.org/10.1111/cch.12696

Slovenia/ UNESCO UIS. (2020). Slovenia/ Unesco UIS. http://uis.unesco.org/en/country/si

Smith, B. A. (1999). Ethical and methodologic benefits of using a reflexive journal in hermeneutic-phenomenologic research. *Image--the Journal of Nursing Scholarship*, *31*(4), 359–363. https://doi.org/10.1111/j.1547-5069.1999.tb00520.x

Smith, F., Dryburgh, N., Donaldson, J., & Mitchell, M. (2013). Debridement for surgical wounds. *Cochrane Database of Systematic Reviews*, *9*. https://doi.org/10.1002/14651858.CD006214.pub4

Smith, S. R., Newton, K., Smith, J. A., Dumville, J. C., Iheozor-Ejiofor, Z., Pearce, L. E., Barrow, P. J., Hancock, L., & Hill, J. (2016). Internal dressings for healing perianal abscess cavities. *The Cochrane Database of Systematic Reviews*, *8*, CD011193. https://doi.org/10.1002/14651858.CD011193.pub2

Smith-Morris, C. (2010). The chronicity of life, the actueness of diagnosis. In L. Manderson & C. Smith-Morris (Eds.), *Chronic conditions, fluid states: Chornicity and the anthropology of illness*. Rutgers University Press.

Smythe, E. A., Ironside, P. M., Sims, S. L., Swenson, M. M., & Spence, D. G. (2008). Doing Heideggerian hermeneutic research: A discussion paper. *International Journal of Nursing Studies*, *45*(9), 1389–1397. https://doi.org/10.1016/j.ijnurstu.2007.09.005

Sokolowski, R. (2006). *Introduction to phenomenology* (7th ed.). Cambridge university Press.

Squires, A. (2008). Language barriers and qualitative nursing research: Methodological considerations. *International Nursing Review*, *55*(3), 265–273. https://doi.org/10.1111/j.1466-7657.2008.00652.x

Squires, A. (2009). Methodological Challenges in Cross-Language Qualitative Research: A Research Review. *International Journal of Nursing Studies*, *46*(2), 277–287. https://doi.org/10.1016/j.ijnurstu.2008.08.006

Srinivasaiah, N., Dugdall, H., Barrett, S., & Drew, P. J. (2007). A point prevalence survey of wounds in north-east England. *Journal of Wound Care*, *16*(10), 413–416, 418–419. https://doi.org/10.12968/jowc.2007.16.10.27910

Srivastava, D., & McGuire, A. (2015). Patient access to health care and medicines across low-income countries. *Social Science & Medicine (1982)*, *133*, 21–27. https://doi.org/10.1016/j.socscimed.2015.03.021

Stanton, A. L., Revenson, T. A., & Tennen, H. (2007). Health psychology: Psychological adjustment to chronic disease. *Annual Review of Psychology*, *58*, 565–592. https://doi.org/10.1146/annurev.psych.58.110405.085615

Starks, H., & Brown Trinidad, S. (2007). Choose Your Method: A Comparison of Phenomenology, Discourse Analysis, and Grounded Theory. *Qualitative Health Research*, *17*(10), 1372–1380. https://doi.org/10.1177/1049732307307031

Steeves, R. H. (2000). Sampling. In M. Z. Cohen, D. L. Khan, & R. H. Steeves (Eds.), *Hermeneutic phenomenological research: A practical Guide for Nurse Researchers* (pp. 45–56). Sage Publications Ltd.

Stevens H. (2006). The impact of venous ulcer pain: What can the patient teach us? *British Journal of Community Nursing*, *11*, S27-30. jlh.

Strauss, A., & Corbin, J. M. (1990). *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. Sage Publications.

Strauss, A. L. (2003). *Qualitative analysis for social scientists*. Cambridge University Press.

Ströker, E. (1997). Phenomenology as First Philosophy: Reflections on Husserl. In E. Ströker (Ed.), *The Husserlian Foundations of Science* (pp. 251–269). Springer Netherlands. https://doi.org/10.1007/978-94-015-8824-9_12

Tanner, J., Padley, W., Davey, S., Murphy, K., & Brown, B. (2012). Patients' experiences of surgical site infection. *Journal of Infection Prevention*, *13*(5), 164–168. jlh. https://doi.org/10.1177/1757177412452677

Tanner, J., Padley, W., Davey, S., Murphy, K., & Brown, B. (2013). Patient narratives of surgical site infection: Implications for practice. *Journal of Hospital Infection*, *83*(1), 41–45. jlh. https://doi.org/10.1016/j.jhin.2012.07.025

Taverner, T., Closs, J., & Briggs, M. (2011). A meta-synthesis of research on leg ulceration and neuropathic pain. *British Journal of Nursing*, *20*(Sup12), S18–S27. https://doi.org/10.12968/bjon.2011.20.Sup12.S18

Taverner, T., Closs, S. J., & Briggs, M. (2014). The journey to chronic pain: A grounded theory of older adults' experiences of pain associated with leg ulceration. *Pain Management Nursing: Official Journal of the American Society of Pain Management Nurses*, *15*(1), 186–198. https://doi.org/10.1016/j.pmn.2012.08.002

Tedstone, J. E., & Tarrier, N. (1997). An investigation of the prevalence of psychological morbidity in burn-injured patients. *Burns: Journal of the International Society for Burn Injuries*, *23*(7–8), 550–554.

Temple, B. (2005). Nice and Tidy: Translation and Representation. *Sociological Research Online*, *10*(2), 1–10. https://doi.org/10.5153/sro.1058

Temple, B., & Young, A. (2004). Qualitative Research and Translation Dilemmas. *Qualitative Research*, *4*(2), 161–178. https://doi.org/10.1177/1468794104044430

Thom, H., Norman, G., Welton, N. J., Crosbie, E. J., Blazeby, J., & Dumville, J. C. (2020). Intra-Cavity Lavage and Wound Irrigation for Prevention of Surgical Site Infection: Systematic Review and Network Meta-Analysis. *Surgical Infections*. https://doi.org/10.1089/sur.2019.318

Thorne, S. (2017). Metasynthetic Madness: What Kind of Monster Have We Created? *Qualitative Health Research*, *27*(1), 3–12. https://doi.org/10.1177/1049732316679370

Thrift, A. G. (2010). Design and Methods of Population Surveys. *Neuroepidemiology*, *34*(4), 267–269. https://doi.org/10.1159/000297758

Toews, I., Booth, A., Berg, R. C., Lewin, S., Glenton, C., Munthe-Kaas, H. M., Noyes, J., Schroter, S., & Meerpohl, J. J. (2017). Further exploration of dissemination bias in qualitative research required to facilitate assessment within qualitative evidence syntheses. *Journal of Clinical Epidemiology*, *88*, 133–139. https://doi.org/10.1016/j.jclinepi.2017.04.010

Toews, I., Glenton, C., Lewin, S., Berg, R. C., Noyes, J., Booth, A., Marusic, A., Malicki, M., Munthe-Kaas, H. M., & Meerpohl, J. J. (2016). Extent, Awareness and Perception of Dissemination Bias in Qualitative Research: An Explorative Survey. *PLOS ONE*, *11*(8), e0159290. https://doi.org/10.1371/journal.pone.0159290

Toye, F., Seers, K., Allcock, N., Briggs, M., Carr, E., & Barker, K. (2014). Meta-ethnography 25 years on: Challenges and insights for synthesising a large number of qualitative studies. *BMC Medical Research Methodology*, *14*, 80. https://doi.org/10.1186/1471-2288-14-80

Treatment of pressure ulcers: Quick Reference Guide. (2009). National Pressure Ulcer Advisory Panel. https://www.npuap.org/wp-content/uploads/2012/03/Final_Quick_Treatment_for_web_2010.pdf

Tricco, A. C., Cogo, E., Isaranuwatchai, W., Khan, P. A., Sanmugalingham, G., Antony, J., Hoch, J. S., & Straus, S. E. (2015). A systematic review of cost-effectiveness analyses of complex wound interventions reveals optimal treatments for specific wound types. *BMC Medicine*, *13*. https://doi.org/10.1186/s12916-015-0326-3

Tricco, A. C., Lillie, E., Zarin, W., O’Brien, K. K., Colquhoun, H., Levac, D., Moher, D., Peters, M. D. J., Horsley, T., Weeks, L., Hempel, S., Akl, E. A., Chang, C., McGowan, J., Stewart, L., Hartling, L., Aldcroft, A., Wilson, M. G., Garritty, C., … Straus, S. E. (2018). PRISMA Extension for Scoping Reviews (PRISMA-ScR):

Checklist and Explanation. *Annals of Internal Medicine*, *169*(7), 467–473. https://doi.org/10.7326/M18-0850

Tsai, J. H.-C., Choe, J. H., Lim, J. M. C., Acorda, E., Chan, N. L., Taylor, V., & Tu, S.-P. (2004). Developing Culturally Competent Health Knowledge: Issues of Data Analysis of Cross-Cultural, Cross-Language Qualitative Research. *International Journal of Qualitative Methods*, *3*(4), 16–27. https://doi.org/10.1177/160940690400300402

Turner, J., & Kelly, B. (2000). Emotional dimensions of chronic disease. *Western Journal of Medicine*, *172*(2), 124–128.

Twinn, S. (1997). An exploratory study examining the influence of translation on the validity and reliability of qualitative data in nursing research. *Journal of Advanced Nursing*, *26*(2), 418–423. https://doi.org/10.1046/j.1365-2648.1997.1997026418.x

UK Health Research Analysis 2018. (2020). HRCS Online. Retrieved 22 July 2020, from https://hrcsonline.net/reports/analysis-reports/uk-health-research-analysis-2018/

Umeh, N. I., Ajegba, B., Buscetta, A. J., Abdallah, K. E., Minniti, C. P., & Bonham, V. L. (2017). The psychosocial impact of leg ulcers in patients with sickle cell disease: I don’t want them to know my little secret. *PloS One*, *12*(10), e0186270. https://doi.org/10.1371/journal.pone.0186270

Upton, D., & Andrews, A. (2013). Negative pressure wound therapy: Improving the patient experience Part 3 of 3. *Journal of Wound Care*, *22*(12), 671–677. jlh.

U.S. National Library of Medicine. (2015). *Medical Subject Headings 2015* [Technical Documentation]. U.S. National Library of Medicine. Retrieved 5 March 2015, from https://meshb.nlm.nih.gov/search

Van Brakel, W. H. (2006). Measuring health-related stigma—A literature review. *Psychology, Health & Medicine*, *11*(3), 307–334. https://doi.org/10.1080/13548500600595160

Van Hauwermeiren, E., Iosifidis, E., Kärki, T., Suetens, C., Kinross, P., & Plachouras, D. (2019). Development of case vignettes for assessment of the inter-rater variability of national validation teams for the point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals. *Journal of Hospital Infection*, *101*(4), 455–460. https://doi.org/10.1016/j.jhin.2019.01.018

Van Hecke, A., Beeckman, D., Grypdonck, M., Meuleneire, F., Hermie, L., & Verhaeghe, S. (2013). Knowledge Deficits and Information-Seeking Behavior in Leg Ulcer Patients: An Exploratory Qualitative Study. *Journal of Wound, Ostomy & Continence Nursing*, *40*(4), 381–387. jlh. https://doi.org/10.1097/WON.0b013e31829a2f4d

Van Hecke, A., Grypdonck, M., Beele, H., Vanderwee, K., & Defloor, T. (2011a). Adherence to leg ulcer lifestyle advice: Qualitative and quantitative outcomes associated with a nurse-led intervention. *Journal of Clinical Nursing*, *20*(3/4), 429–443. jlh. https://doi.org/10.1111/j.1365-2702.2010.03546.x

Van Hecke, A, Verhaeghe, S., Grypdonck, M., Beele, H., & Defloor, T. (2011b). Processes underlying adherence to leg ulcer treatment: A qualitative field study. *International Journal of Nursing Studies*, *48*(2), 145–155. jlh. https://doi.org/10.1016/j.ijnurstu.2010.07.001

Van Hecke, A., Grypdonck, M., & Defloor, T. (2009). A review of why patients with leg ulcers do not adhere to treatment. *Journal of Clinical Nursing*, *18*(3), 337–349. https://doi.org/10.1111/j.1365-2702.2008.02575.x

Van Laer, L., Proost, D., & Loeys, B. L. (2013). Connective tissue disorders with vascular involvement: From gene to therapy. *European Journal of Pediatrics*, *172*(8), 997–1005. https://doi.org/10.1007/s00431-012-1773-x

Van Manen, M. (1990). *Researching Lived Experience: Human Science for an Action Sensitive Pedagogy*. The University of Western Ontario.

Van Manen, M. (2017). Phenomenology and Meaning Attribution. *Indo-Pacific Journal of Phenomenology*, *17*(1). https://doi.org/10.1080/20797222.2017.1368253

Van Nes, F., Abma, T., Jonsson, H., & Deeg, D. (2010). Language differences in qualitative research: Is meaning lost in translation? *European Journal of Ageing*, *7*(4), 313–316. https://doi.org/10.1007/s10433-010-0168-y

Van Ramshorst, G. H., Nieuwenhuizen, J., Hop, W. C. J., Arends, P., Boom, J., Jeekel, J., & Lange, J. F. (2010). Abdominal wound dehiscence in adults: Development and validation of a risk model. *World Journal of Surgery*, *34*(1), 20–27. https://doi.org/10.1007/s00268-009-0277-y

Vann-Ward, T., Morse, J. M., & Charmaz, K. (2017). Preserving Self: Theorizing the Social and Psychological Processes of Living With Parkinson Disease. *Qualitative Health Research*, *27*(7), 964–982. https://doi.org/10.1177/1049732317707494

Vasileiou, K., Barnett, J., Thorpe, S., & Young, T. (2018). Characterising and justifying sample size sufficiency in interview-based studies: Systematic analysis of qualitative health research over a 15-year period. *BMC Medical Research Methodology*, *18*. https://doi.org/10.1186/s12874-018-0594-7

Vermeulen, H., Ubbink, D., Goossens, A., de Vos, R., & Legemate, D. (2004). Dressings and topical agents for surgical wounds healing by secondary intention. *The Cochrane Database of Systematic Reviews*, *2*, CD003554. https://doi.org/10.1002/14651858.CD003554.pub2

Vermeulen, H., van Hattem, J. M., Storm-Versloot, M. N., & Ubbink, D. T. (2007). Topical silver for treating infected wounds. *The Cochrane Database of Systematic Reviews*, *1*, CD005486. https://doi.org/10.1002/14651858.CD005486.pub2

Vogl, S., Zartler, U., Schmidt, E.-M., & Rieder, I. (2018). Developing an analytical framework for multiple perspective, qualitative longitudinal interviews (MPQLI). *International Journal of Social Research Methodology*, *21*(2), 177–190. https://doi.org/10.1080/13645579.2017.1345149

Vogrinc, J. (2008). *Kvalitativno raziskovanje na pedagoškem področju*. Pedagoška fakulteta.

Von Beckerath, O., Zapenko, A., Dissemond, J., Kröger, K., & Initiative Chronische Wunden (ICW) e.V. (2017). Ten-year analyses of the German DRG data about negative pressure wound therapy. *International Wound Journal*, *14*(3), 501–507. https://doi.org/10.1111/iwj.12635

Vowden, K. R., & Vowden, P. (2009a). A survey of wound care provision within one English health care district. *Journal of Tissue Viability*, *18*(1), 2–6. https://doi.org/10.1016/j.jtv.2008.11.003

Vowden, K. R., & Vowden, P. (2009b). The prevalence, management and outcome for acute wounds identified in a wound care survey within one English health care district. *Journal of Tissue Viability*, *18*(1), 7–12. https://doi.org/10.1016/j.jtv.2008.11.004

Walburn, J., Weinman, J., Scott, S., & Vedhara, K. (2012). Exploring the characteristics of a venous leg ulcer that contribute to the emotional distress experienced by patients. *EWMA Journal*, *12*(2), 36–36. jlh.

Walsh, D., & Downe, S. (2005). Meta-synthesis method for qualitative research: A literature review. *Journal of Advanced Nursing*, *50*(2), 204–211. https://doi.org/10.1111/j.1365-2648.2005.03380.x

Walshe C. (1995). Living with a venous leg ulcer: A descriptive study of patients' experiences. *Journal of Advanced Nursing*, *22*(6), 1092–1100. jlh. https://doi.org/10.1111/j.1365-2648.1995.tb03110.x

Walter, C. J., Dumville, J. C., Sharp, C. A., & Page, T. (2012). Systematic review and meta-analysis of wound dressings in the prevention of surgical-site infections in surgical wounds healing by primary intention. *British Journal of Surgery*, *99*(9), 1185–1194. https://doi.org/10.1002/bjs.8812

Watson-Miller S. (2006). Living with a diabetic foot ulcer: A phenomenological study. *Journal of Clinical Nursing*, *15*(10), 1336–1337. jlh. https://doi.org/10.1111/j.1365-2702.2006.01521.x

Wellborn, J., & Moceri, J. T. (2014). The lived experiences of persons with chronic venous insufficiency and lower extremity ulcers. *Journal of Wound, Ostomy, and Continence Nursing: Official Publication of The Wound, Ostomy and Continence Nurses Society*, *41*(2), 122–126. https://doi.org/10.1097/WON.0000000000000010

Weller, C. D., Buchbinder, R., & Johnston, R. V. (2013). Interventions for helping people adhere to compression treatments for venous leg ulceration. *The Cochrane Database of Systematic Reviews*, *9*, CD008378. https://doi.org/10.1002/14651858.CD008378.pub2

Westby, M. J., Norman, G., Dumville, J. C., Stubbs, N., & Cullum, N. (2016). Protease-modulating matrix treatments for healing venous leg ulcers. *The Cochrane Database of Systematic Reviews*, *12*, CD011918. https://doi.org/10.1002/14651858.CD011918.pub2

Whittemore, R., Chao, A., Jang, M., Minges, K. E., & Park, C. (2014). Methods for knowledge synthesis: An overview. *Heart & Lung*, *43*(5), 453–461. https://doi.org/10.1016/j.hrtlng.2014.05.014

Whittemore, R., & Knafl, K. (2005). The integrative review: Updated methodology. *Journal of Advanced Nursing*, *52*(5), 546–553. https://doi.org/10.1111/j.1365-2648.2005.03621.x

Wojnar, D. M., & Swanson, K. M. (2007). Phenomenology: An exploration. *Journal of Holistic Nursing: Official Journal of the American Holistic Nurses' Association*, *25*(3), 172–180; discussion 181-182; quiz 183–185. https://doi.org/10.1177/0898010106295172

Woldemichael, A., Takian, A., Akbari Sari, A., & Olyaeemanesh, A. (2019). Availability and inequality in accessibility of health centre-based primary healthcare in Ethiopia. *PLoS ONE*, *14*(3). https://doi.org/10.1371/journal.pone.0213896

World Union of Wound Healing Societies. (2018). *Consensus Document. Surgical wound dehiscence: Improving prevention and outcomes.* Wounds International.

Young, A., & McNaught, C.-E. (2011). The physiology of wound healing. *Surgery (Oxford)*, *29*(10), 475–479. https://doi.org/10.1016/j.mpsur.2011.06.011

Yu, I. T. S., & Tse, S. L. A. (2012a). Workshop 4—Sources of bias in case-referent studies. *Hong Kong Medical Journal = Xianggang Yi Xue Za Zhi*, *18*(1), 46–47.

Yu, I. T. S., & Tse, S. L. A. (2012b). Workshop 6—Sources of bias in cross-sectional studies; summary on sources of bias for different study designs. *Hong Kong Medical Journal = Xianggang Yi Xue Za Zhi*, *18*(3), 226–227.

Zhu, X. L., & Kath, R. (2017). 'When Can I be Free from My Miserable Leg?' A Qualitative Study of Patients' Experiences of Chronic Leg Ulceration in Primary Healthcare. *International Archives of Nursing and Health Care*, *3*(3), 1–8. https://doi.org/10.23937/2469-5823/1510073

APPENDICES

APPENDIX 1

PEOPLES’ EXPERIENCES OF LIVING WITH COMPLEX WOUNDS: PROTOCOL FOR SCOPING REVIEW

Ljubiša Pađen (a, b), Jane Griffiths (a) and Nicky Cullum (a,c)

(a) Division of Nursing, Midwifery and Social Work
The University of Manchester
Oxford Road
Manchester, M13 9PL, UK
E-mail: ljubisa.paden@postgrad.manchester.ac.uk

(b) Department of Nursing, Faculty of Health Sciences
University of Ljubljana
Zdravstvena pot 5
1000 Ljubljana, Slovenia

(c) Research & Innovation Division, Manchester University NHS Foundation Trust
Research Office
1st Floor, Nowgen Building
29 Grafton Street
Manchester, M13 9WU, UK

Correspondence:
Ljubiša Pađen (Ljubisa Paden)
Division of Nursing, Midwifery and Social Work
The University of Manchester
Oxford Road
Manchester, M13 9PL, UK
E-mail: ljubisa.paden@postgrad.manchester.ac.uk
Phone: +38640187949

Pađen, L., Griffiths, J., & Cullum, N. (2020). People’s perspective of living with complex wounds – a scoping study protocol. Retrieved from osf.io/pk5ny

Introduction

Having a wound at some point in life is probably a common experience for the majority of people. Most of them will probably have wounds which are related to injury or surgery; these are called acute wounds. Acute wounds normally heal in an orderly sequence of phases within days or weeks (Li et al., 2007) without any complications; however when a delay in healing occurs and the wound fails to heal within 6 - 8 weeks it is regarded as a “complex wound”, often also known in the literature as a “chronic” or “hard to heal” wound (Menke et al., 2007, Pragnell and Neilson, 2010). Complex wounds are one of the common long-term conditions to affect people and impacts the health care sector as various resources are used for their treatment, furthermore costs for managing such wounds are measured in billions of dollars (Guest et al., 2015, Sen et al., 2009).

Complex wounds have various underlying aetiologies such as peripheral vascular disorders (venous, arterial or mixed), neuropathy, pressure and other systemic diseases; when interacting with other complex intrinsic and extrinsic factors, such wounds result in a complex healing process and also in complex treatment (Armstrong et al., 2017; Coleman et al., 2013; Dabiri and Falanga, 2013; Alexander, 2009).

Recently, Hall et al. (2014) carried out a point prevalence study of complex wounds in Leeds (United Kingdom), a city with a population of 751,485. It was found that the prevalence of all complex wounds (superficial, partial or full thickness skin loss healing by secondary intention) was estimated at 1.47 per 1,000 of the population. Complex wound prevalence was also found to be higher in older people and females (Hall et al., 2014), which is similar to the findings of previous studies (Cullum et al., 2016). As for subtypes of complex wounds, the prevalence for malignant fungating wounds is estimated at 0.02 per 1,000 population, pressure ulcers at 0.31 per 1000 population, diabetic foot ulcers at 0.13 per 1,000 population, non-diabetic foot ulcers at 0.9 per 1,000 population, leg ulcers at 0.44 per 1,000 population and surgical wound healing by secondary intention at 0.21 per 1,000 population (Hall et al., 2014).

In UK and beyond, nurses often manage wounds and wound-related symptoms in their daily practice within a hospital setting or in the community (Chetter et al., 2017), which might have resulted in a growing body of nursing research related to wound care. A glance at the existing literature in this area shows that research is oriented towards various aspects of wound care, such as: exploring the nature of wounds and wound epidemiology; testing interventions that might work in promoting wound healing or preventing wounds; economic evaluations such as cost-effectiveness analysis and cost-benefit analysis; and lastly, a large corpus of studies have explored the experience of having complex wounds from the patient’s perspective, and how wounds affect people’s quality of life and their well-being.

Based on the fact that there is a large existing evidence base on wound care, the aim is to explore and scope the qualitative studies that have explored patient perspectives. The findings from this review will help us to better understand this phenomenon and to illuminate what needs to be researched in future, so that clinical nurses may deliver the best possible care, improve practice and outcomes for patients' benefit.

Methods

Study design

Scoping review methodology will be used to carry out this review. Scoping studies (also scoping reviews) are used to address broad range of research questions and to scope the available literature. Arksey & O'Malley (2005) defined 4 common reasons for undertaking scoping studies, namely: exploring the extent, range and the nature of available research evidence, determining the value of undertaking full systematic review, summarizing and disseminate research findings and identifying research gaps in the existing literature. There have been development of Arksey & O'Malley (2005) framework, mainly in developing clear guidance how to conduct scoping reviews (Levac, Colquhoun, & O'Brien, 2010; Davis, Drey, & Gould, 2009). The Arksey & O'Malley (2005) framework is designed in six stages: 1) identifying the research question, 2) identifying relevant studies, 3) study selection, 4) charting the data, 5) collating, summarizing and reporting results and 6) consultation exercise, which is optional. In this study we will carried out 5 stages only, as involving 6th stage exceeds the aims and objectives of this study.

1) Identifying the research question

The aim of this scoping review is to answer the question, "What is the nature and the extent of research on people's perceptions and views of their everyday experience of having complex wounds?" This includes exploring patients' perceptions and views of their everyday experience of having complex wounds, in their home environment.

The objectives of this scoping review are:

- to investigate and describe the nature, extent and range of published research regarding patients' experiences of living with complex wounds,
- to map the body of evidence regarding patients' experiences of living with complex wounds, with relevance to existing epidemiological data on complex wounds,
- to identify potential overlaps and gaps in the existing evidence base,
- to visually present literature characteristics.

2) Identifying relevant studies

A systematic literature search will be conducted through electronic databases: MEDLINE (with option “In-Process & Other Non-Indexed Citations and Epub Ahead of Print”), EMBASE and CINAHL. No date restrictions will applied during the search process.

In addition to the electronic search, a manual search will be conducted in the latest issues of journals (Journal of Tissue Viability, Journal of Wound Care, and International Wound Journal) and conference proceedings (EWMA 2014, EWMA 2015, EWMA 2016).

Also, the snow-ball technique will be applied to reference lists and used to identify potentially relevant studies.

Search terms will be built (formed) to reflect the set inclusion and exclusion criteria and was peer-reviewed by experienced information specialist. MeSH (Medical Subject Headings, version 2015) will be used to identify other relevant terms beyond the main term. For example: “pressure ulcer” is the main heading, but it has also synonyms such as “bed sore”, “pressure sore”, and “decubitus” (MeSH, 2014). Since there are many types of complex wounds, additional search terms will be used to narrow the hits and to prevent a possibility of missing relevant studies. To identify qualitative studies Shaw et al.’s (2005) search strategy will be used partially, as search terms are already built. We will use thesaurus terms, for example “qualitative research or phenomenology”, free-text terms such as “lived experience” and broad based terms such as “interview”. To capture broad range of studies additional commands will be used, for example the truncation symbol (*/$) which retrieves terms with various endings. In addition, for narrowing the search, Boolean logic operators such as “AND” will be used (CRD, 2009).

The search of the electronic databases will be designed as a three step process. In the first step, search terms related to different types of wound will be combined, then in the second step terms related to phenomenon of interest (experience of having complex wounds) will be combined. Hits that emerge from both the first and second step will be then combined using “AND” with search terms related to methods (see example of search strategy below).

We expect to identify extensive evidence related to the search terms; therefore the search will be restricted to titles and abstracts, which will help to reduce the hits returned.

Example of search strategy via OVID

1	(skin ulcer* or ulcer* or wound* or complex wound* or non-healing wound* or chronic wound*).ti.
2	(pressure or bed sore or bedsore or pressure sore or decubitus).ti.
3	(leg ulcer or f??t ulcer).ti.
4	(varicose or venous or venous stasis or stasis).ti.
5	(arterial or arterial leg or ischaemic or ischemic).ti.
6	(diabetic foot or diabetic feet or diabetic).ti.
7	(connective tissue or rheumatoid).ti.
8	(malignant or fungating).ti.
9	(surgical or broken surgical or postoperative dehiscence or surgical dehiscence or dehiscence or secondary intention or secondary closure).ti.
10	1 and 2
11	1 and 3
12	1 and 4
13	1 and 5
14	1 and 6
15	1 and 7
16	1 and 8
17	1 and 9
18	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19	(unpleasant symptom* or pain or malodour or odour or smell or itch or pruritus or leakage or exudate).ti.
20	(quality of life or QoL or well being).ti.
21	18 and 19
22	18 and 20
23	19 or 20
24	18 and 23
25	(qualitative research or focus group* or interview* or discourse analysis or content analysis or thematic analysis or narrative analysis or narrativ* or ethnograph* research or ethnograph* or ethnolog* research or ethnonursing research or constant comp* method or field stud* or phenomenolog* research or phenomenolog* or hermeneutic* or grounded theory or life experience or lived experience or perception or data synthesis or meta synthesis or meta-synthesis or synthesis).ti.
26	21 and 25
27	24 and 25

3) Study selection

Studies will be eligible for inclusion in this review if they will meet following inclusion criteria:

Types of participants

In this review we will include studies that focus on human participants of both genders, regardless of age.

Phenomenon of interest (observed outcomes)

We will include studies which aim to explore the impact on everyday life of having complex wounds (all types), or to explore how unpleasant symptoms associated with complex wounds interfere with daily living.

Context

We will include studies that focus on exploring the lived experience in a home (community) setting.

Studies that focus on exploring perspectives of having complex wounds in health care or social-care institutions will be excluded, as they are not exploring the phenomenon of everyday living.

Types of study design, *language and type of publication*

In this review the studies with following study design will be included: qualitative studies (regardless of philosophical background or data collection or analysis method), mixed-method studies, systematic reviews of qualitative and/or quantitative studies, meta-synthesis of qualitative studies written in English language. No restriction as to time of publication or publication type will be set.

Selection process

All citations from all sources will be combined into one file (Microsoft Excel) and the references will be deduplicated. First all retrieved search hits will be screened for eligibility based on the titles meeting the inclusion criteria. All irrelevant references will be rejected immediately, while if a publication addresses the topic of interest but it is not clear enough from the title whether it meets the inclusion criteria, the abstract will be read and its relevance assessed. The study will be rejected if it does not meet the pre-set criteria, while if it meets or appears to meet the inclusion criteria it will be considered for further assessment. In the second phase, attempts will be made to obtain full text copies of potentially relevant studies through electronic databases, through the University of Manchester Library, British Library or directly (journal publishers, hard copies of conference proceedings from conference organisers). In cases where a full copy of the study cannot be obtained, the citation will be excluded from further assessment. All retrieved full text copies of publications will then be assessed.

Two reviewers will independently determine which studies will be included or excluded. Disagreements will be resolved by discussion and consensus of all three reviewers.

4) Charting the data

A data charting protocol has been developed and will be used to chart the data, with adherence to the research question and the objectives of the review. The first researcher will extract the data while the second and third researcher will independently review that work for accuracy of extraction, and disagreements will be resolved by discussion and reaching the consensus between all three.

For data charting from primary qualitative studies we will extract the items listed below:

1. Author; title; year of publication and source of reference.
2. Aims of the study
3. Study setting.
4. Study design (including approach to data collection and data analysis).
5. Recruitment and sample size.
6. Inclusion/exclusion criteria.
7. Age of participants and gender of participants.
8. Wound type (definition).
9. Whether any funding declared and nature of funding.

For data charting from systematic reviews and meta-synthesis of qualitative studies we will extract the items listed below:

1. Authors’ details; year of publication and source of reference.
2. Review objectives.
3. Search strategies.
4. Study inclusion and exclusion criteria.

5. Included settings.
6. Included populations (age of participants, gender of participants, sample size).
7. Included wound types (definition).
8. The number of included qualitative studies or mixed method studies.
9. Whether any funding declared and nature of funding.

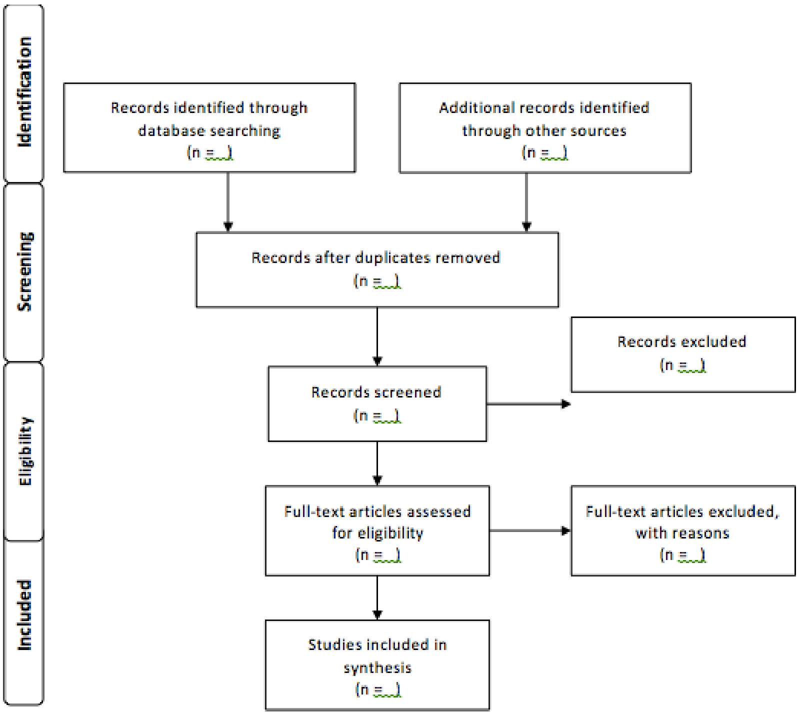
Two reviewers will independently test a draft of the data extraction form on five studies as recommended by Levac et al. (2010). If needed, the data extraction form will be revised; all three researchers will discuss all modifications and reach agreement before using a revised form. In the case of missing data or if data is unclear, the reviewers will attempt to contact the corresponding authors for clarification. All communication will be documented.

Data charting form (Appendix 1a, 1b)-

5) Collating, summarising and reporting results

The numbers of identified records, and excluded and selected studies will be reported using a PRISMA flow diagram (Moher et al., 2009) as presented bellow.

Flow diagram



In the analysis we will describe the overall characteristics of the included studies in terms of general and specific aspects of study, such as: author, year of publication, study setting, country of origin, characteristics of the included population, methodological approaches, observed phenomena, etc. This part of the analysis will be visually presented in table form table (Appendix 2) and in narrative format.

Overlaps and knowledge gaps with relevance to existing epidemiological data on complex wounds will be visually presented in the form of a table and a data map (diagram). The presentation format might change during the data charting and results collating, when we will know more about what research evidence we will identify.

6) Consultation with stakeholders

This review will not include the optional stage of the Arksey & O'Malley (2005) framework as we think that this would exceed the objectives of the study.

Ethical considerations

As this review involves secondary data, no formal ethical review is needed. The review will be conducted according to international standards for conducting reviews.

Dissemination plan

The paper from this scoping review will be submitted to scientific journal. Findings from the review will be used as a part of the PhD thesis of Ljubiša Pađen.

This protocol will be registered with OSF.

Conflict of interest

The authors declare no conflict of interest associated with this study.

References

Alexander, S. (2009). Malignant fungating wounds: managing pain, bleeding and psychosocial issues. Journal of Wound Care, 18(10), 418–425. https://doi.org/10.12968/jowc.2009.18.10.44603

Arksey, H., & O'Malley, L. (2005). Scoping studies: towards a methodological framework. International Journal of Social Research Methodology, 19–32.

Armstrong, D. G., Boulton, A. J. M., & Bus, S. A. (2017). Diabetic Foot Ulcers and Their Recurrence. The New England Journal of Medicine, 376(24), 2367–2375. https://doi.org/10.1056/NEJMra1615439

Chetter, I. C., Oswald, A. V., Fletcher, M., Dumville, J. C., & Cullum, N. A. (2017). A survey of patients with surgical wounds healing by secondary intention; an assessment of prevalence, aetiology, duration and management. Journal of Tissue Viability, 26(2), 103–107. https://doi.org/10.1016/j.jtv.2016.12.004

Coleman, S., Gorecki, C., Nelson, E. A., Closs, S. J., Defloor, T., Halfens, R., … Nixon, J. (2013). Patient risk factors for pressure ulcer development: Systematic review. International Journal of Nursing Studies, 50(7), 974–1003. https://doi.org/10.1016/j.ijnurstu.2012.11.019

CRD. (2009) Systematic Reviews CRD`s guidance for undertaking reviews in health care. Centre for Reviews and Dissemination, University of York. [online]. Available at: http://www.york.ac.uk/inst/crd/pdf/Systematic_Reviews.pdf (Accessed: 2.10.2013).

Cullum, N., Buckley, H., Dumville, J., Hall, J., Lamb, K., Madden, M., Morley, R., O'Meara, S., Goncalves, P.S., Soares, M., Stubbs, N., 2016. Wounds research for patient benefit: a 5-year programme of research, Programme Grants for Applied Research. NIHR Journals Library, Southampton (UK).

Dabiri, G., & Falanga, V. (2013). Connective tissue ulcers. Journal of Tissue Viability, 22(4), 92–102. https://doi.org/10.1016/j.jtv.2013.04.003

Davis, K., Drey, N., & Gould, D. (2009). What are scoping studies? A review of the nursing literature. International Journal of Nursing Studies, 46(10), 1386–1400. https://doi.org/10.1016/j.ijnurstu.2009.02.010

Guest, J.F., Ayoub, N., McIlwraith, T., Uchegbu, I., Gerrish, A., Weidlich, D., Vowden, K., Vowden, P., 2015. Health economic burden that wounds impose on the National Health Service in the UK. BMJ Open 5, e009283. doi:10.1136/bmjopen-2015-009283

Hall, J., Buckley, H.L., Lamb, K.A., Stubbs, N., Saramago, P., Dumville, J.C., Cullum, N.A., 2014. Point prevalence of complex wounds in a defined United Kingdom population. Wound Repair Regen. n/a-n/a. doi:10.1111/wrr.12230

Levac, D., Colquhoun, H., & O'Brien, K. K. (2010). Scoping studies: advancing the methodology. Implementation Science: IS, 5, 69. https://doi.org/10.1186/1748-5908-5-69

Li, J., Chen, J., Kirsner, R., 2007. Pathophysiology of acute wound healing. Clin. Dermatol. 25, 9–18. doi:10.1016/j.clindermatol.2006.09.007

Lindahl, E., Norberg, A., Söderberg, A., 2008. The meaning of caring for people with malodorous exuding ulcers. J. Adv. Nurs. 62, 163–171. doi:10.1111/j.1365-2648.2007.04551.x

Menke, N.B., Ward, K.R., Witten, T.M., Bonchev, D.G., Diegelmann, R.F., 2007. Impaired wound healing. Clin. Dermatol. 25, 19–25. doi:10.1016/j.clindermatol.2006.12.005

Moher, D., Liberati,A., Tetzlaff, J., Altman, D.G., and PRISMA Group. 2009. 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement'. PLoS Medicine 6(7):e1000097.

Pragnell, J., Neilson, J., 2010. The social and psychological impact of hard-to-heal wounds. Br. J. Nurs. Mark Allen Publ. 19, 1248–1252.

Shaw, R.L., Booth, A., Sutton, A.J., Miller, T., Smith, J.A., Young, B., Jones, D.R., Dixon-Woods, M., 2004. Finding qualitative research: an evaluation of search strategies. BMC Med. Res. Methodol. 4, 5. doi:10.1186/1471-2288-4-5

Sen, C. K., Gordillo, G. M., Roy, S., Kirsner, R., Lambert, L., Hunt, T. K., … Longaker, M. T. (2009). Human Skin Wounds: A Major and Snowballing Threat to Public Health and the Economy. Wound Repair and Regeneration : Official Publication of the Wound Healing Society [and] the European Tissue Repair Society, 17(6), 763–771. https://doi.org/10.1111/j.1524-475X.2009.00543.x

Shaw, R.L., Booth, A., Sutton, A.J., Miller, T., Smith, J.A., Young, B., Jones, D.R., Dixon-Woods, M., 2004. Finding qualitative research: an evaluation of search strategies. BMC Med. Res. Methodol. 4, 5. doi:10.1186/1471-2288-4-5

Appendix 1a: Data extraction form for primary studies

1. Author; title; year of publication and source of reference	2. Aims of the study	3. Study setting	4. Study design (including approach of data collection and data analysis)	5. Recruitment and sample size	6. Inclusion/exclusion criteria	7. Age of participants and gender of participants	8. Wound type (definition)	9. Whether any funding declared and nature of funding

Appendix 1b: Data extraction form for reviews

1. Author details; year of publication and source of reference	2. Review objectives	3. Search strategies	4. Study inclusion and exclusion criteria	5. Included settings	6. Included populations (age of participants, gender of participants, sample)	7. Included wound type (definition)	8. The number of included qualitative studies or mix method studies	9. Whether any funding declared and nature of funding

Appendix 2: Summary of included studies (example of result presentation)

Author, Year, Study location	Aim of the study	Design, Data collection technique, Data analysis approach	Sampling strategy	Sample size	Age (years) and gender (F-female, M-male) of participants

APPENDIX 2: Data capture form in English and Slovene

STUDY OF PREVALENCE OF OPEN SURGICAL WOUNDS (SWHSI) – DATA CAPTURE FORM

Q1 - Date of wound assessment:

Q2 Job title

	Registered Nurse	Nursing Assistant	General Practitioner	Surgeon	Other:____________________
Job title:	○	○	○	○	○

Q3 Main area of work (tick one only)

	Acute Setting - Hospital	Wound Care Clinic	General Practitioner Surgery	Community Health Care Services	Nursing Homes	Learning Disabilities Services	Other:
Service:	○	○	○	○	○	○	○

Q4 – Where are you currently treating this patient?

(Please state in which service)

Q5 - Patient age (in years):

Q6 - Patient gender

○ Male ○ Female

Q7 - Patient ethnicity:

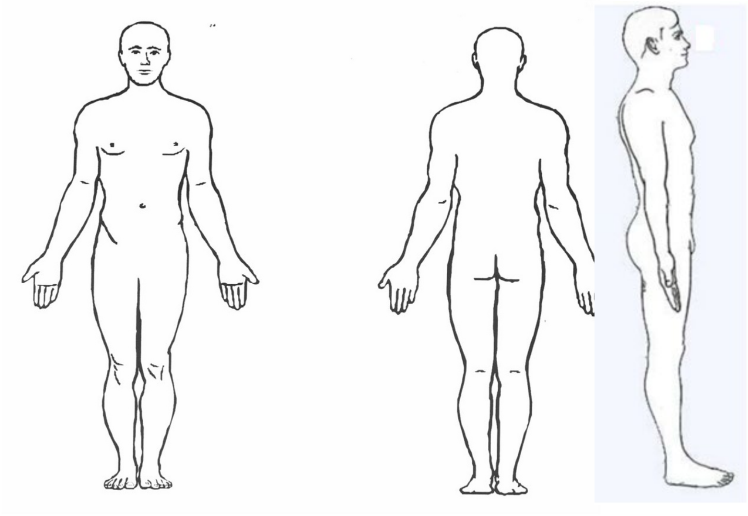
	White	Black	Asian	Mixed	Don’t know	Other:________________ ____
Ethnicity	○	○	○	○	○	○

Q8 - How many open surgical wounds does this patient have?

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

IF PATIENT HAS MORE THAN ONE SWHSI PLEASE ANSWER THE FOLOWING QUESTION FOR THE WOUND THAT YOU THINK IS THE LARGEST IN AREA

Q9 - Location of the wound (anatomical description):



Q10 - How long has the patient had the largest (by area) SWHSI?

Weeks OR Days

Q11 - What type of surgery led to this SWHSI?

○ Orthopaedic ○ Trauma ○ Vascular ○ Colorectal ○ Plastics ○ Urology ○ Breast

○ Cardiothoracic ○ Upper gastrointestinal ○ Neurosurgery ○ Oral or maxillofacial surgery

○ Obs/gynaecological ○ Other__________________________ ○ Don't know

Q12 - Please record the specific type of surgery if possible (eg: hernia repair, Caesarean section, excision of pilonidal sinus)

Q13 - Please record the date of original surgery that led to the SWHSI:

		20
Day	Month	Year

Q14 - Was this surgery:

○ Emergency? ○ Elective? ○ Don't know?

Q15 - Is the SWHSI a result of:

○ A planned healing by secondary intention
○ A broken down surgically closed wound
○ A surgically closed wound intentionally re-opened
○ Don't know
○ Other (please give details)____

Q16 – If this SWHSI is broken down (dehisced) is it:

○ Fully broken open (dehisced along its entire length)
○ Partially broken open (partially dehisced)

Q17 - To the best of your knowledge, is this wound healing by secondary (as opposed to primary) intention because of an infection developed after surgery?

○ Yes ○ No ○ Don't know

Q18 - Is this patient currently receiving antibiotic therapy for their SWHSI?

○ Yes ○ No ○ Don't know

Q19 - Please record how long after surgery the wound dehisced and where the patient was located when this occurred?

Number of days: __________ ○ In hospital ○ In the community ○ Don't know

Q20 – Treatment objectives (select as many as relevant)

Treatment objectives	Debridement	Absorption	Hydration	Bacterial load management	Odour management
	☐	☐	☐	☐	☐
	Reduce overgranulation	Encourage granulation	Protection	Other: ____________	Don't know
	☐	☐	☐	☐	☐

Q21 - Which treatments are this patient currently receiving for their open surgical wound? (Please cross all that apply)

○ Dressings
If selected, please indicate frequency of dressing changes = ________ per **WEEK**

If selected, please record what dressing (primary and secondary) is used:

Primary (a dressing that comes into direct contact with the wound bed):
____

Secondary (a dressing which is applied on the primary dressing - cover):
____

○ Negative pressure wound therapy
If selected, please indicate frequency of application = ________ per **WEEK**

○ Other, if other please state which: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
If selected, please indicate frequency of application = ________ per **WEEK**

Q22 - Duration of most recent consultation (in min):

☐

Q23 - Is this patient also receiving treatment for their SWHSI elsewhere?

○ Yes - if yes, please state where:___________________________________
○ No
○ Don't know

Q24 - Did the patient experience any of these wound related symptoms in the past week.

	Yes	No	Don't know
Pain	☐	☐	☐
Exudate	☐	☐	☐
Malodour	☐	☐	☐
Pruritus	☐	☐	☐

Q25 - Please add any comments you have may have regarding this SWHSI:

ŠTUDIJA RAZŠIRJENOSTI ODPRTIH KIRURŠKIH RAN (OKR) – OBRAZEC ZA PRIDOBIVANJE PODATKOV

V1 – Datum ocene rane:

V2 Naziv delovnega mesta

	Dilpmirana medicinska sestra	Zdravstveni tehnik	Družinski zdravnik	Kirurg	Drugo:____________________
Označite:	○	○	○	○	○

V3 Področje, kjer ste zaposleni (označite eno izmed navedenih)

	Akutno oskrba – Bolnišnica	Ambulanta za rane	Splošna ambulanta	Patronaža	Domovi za starejše	Zavodi za osebe z motnjo v duševnem razvoju	Drugo:________________________________
Označite	○	○	○	○	○	○	○

V4 – Kje je v tem trenutku obravnavan paceint?

(Prosim opredelite tip zavoda, enote)

V5 – Starost pacienta (v letih):

V6 – Spol pacienta:

○ Moški ○ Ženski

V7 – Etnična pripadnost:

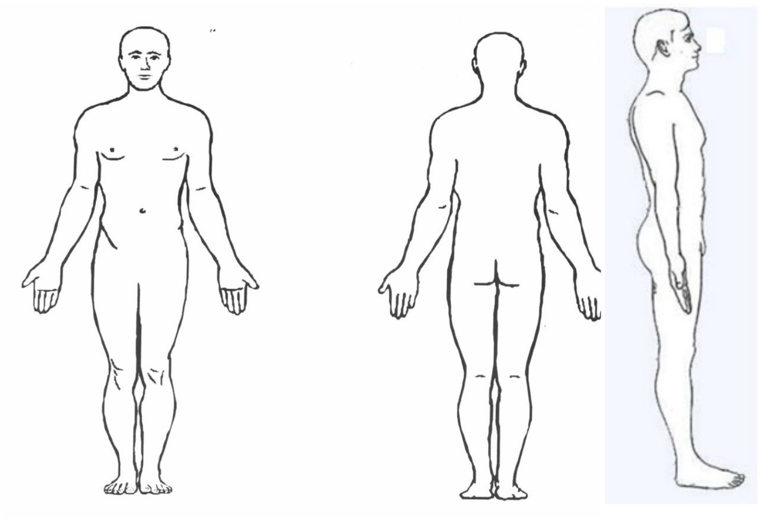
	Belec	Temnopolt	Azijec	Mešan	Ne želim odgovoriti	Drugo:________________ ___
Označite	○	○	○	○	○	○

V8 – Koliko odprtih kirurških ran ima pacient?

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

V KOLIKOR IMA PACIENT VEČ KOT ENO OKR PROSIMO, DA NA SLEDEČA VPRAŠANJA ODGOVORITE ZA TISTO ZA KATERO MENITE, DA JE NAJVEČJA PO POVRŠINI

V9 – Lokacija rane (anatomski opis):



V10 – Kako dolgo ima pacient najbolj obsežno odprto kirurško rano (po površini)?

Tedni ☐ ALI dni ☐

V11 – Kateri tip operacije je privedel do OKR?

○ Ortopedska ○ Travmatološka ○ Žilna ○ Kolorektalna ○ Plastična ○ Urološka

○ Operacija prsi ○ Kardiotorakalna ○ Zgornjih prebavil ○ Nevrokirurška

○ Ustna, čeljustna in obrazna ○ Porodniško-ginekološka ○ Drugo_________________________

○ Ni znano

V12 – Prosimo v kolikor je možno specificirajte operacijo (npr: operacija kile, carski rez, ekscizija pilonidalnega sinusa)

V13 – Prosimo označite datum operacije, ki je privedla do OKR:

		20
Dan	Mesec	Leto

V14 – Ali je bila operacija:

○ Nujna? ○ Načrtovana? ○ Ni znano?

V15 – Ali je OKR posledica:

○ načrtovanega celjenja per secundam
○ spontanega razprtja kiruško zašite rane (dehiscenca)
○ namenskega razprtja kirurško zašite rane (iatrogena dehiscenca)
○ ni znano
○ drugo (prosimo opišite)____

V16 – V kolikor je OKR posledica dehiscence, ali je:

○ Popolna (dehiscence po celotni dolžini rane)
○ Delna (dehiscenca le v delu dolžine rane)

V17 – Ali je OKR posledica okužbe, ki se je razvila po operaciji?

○ Da ○ Ne ○ Ne vem

V18 – Ali pacient trenutno prejema antibiotika z namenom zdravljenja OKR?

○ Da ○ Ne ○ Ne vem

V19 – Prosimo označite, koliko časa po operaciji se je rana razprla in kje je bil pacient v obravnavi, ko se je razprtje zgodilo?

Število dni: _________ ○ V bolnišnici ○ V domačem okolju ○ Ne vem

V20 – Cilj zdravljenja (označite vse kar je relevantno)

Cilj zdravljenja	Nekrektomija	Nadzor izločka	Vlaženje rane	Nadzor bakterijske obremenitve	Nadzor vonja
	☐	☐	☐	☐	☐
	Zmanjševanje prekomernih granulacij	Spodbujanje granulacije	Zaščita	Drugo: ____________	Ne vem
	☐	☐	☐	☐	☐

V21 – Kakšno oskrbo trenutno prejema pacient z OKR? (označite vse kar je relevantno)

○ Obloge

V kolikor ste izbrali obloge prosimo napišite frekvenco menjave le teh=_______ na **TEDEN**

V kolikor ste izbrali obloge prosimo označite katera obloga je uporabljena (primarna in sekundarna):

Primarna (obloga, ki je v neposrednem stiku z dnom rane): ____

Sekundarna (obloga, ki je nameščena preko primarne obloge): ____

○ Terapija z negativnim tlakom (TNT)

V kolikor ste izbrali TNT, prosimo napišite število aplikacij =___________ na **TEDEN**

○ Drugo, prosimo napišite kaj: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

V kolikor ste izbrali drugo, prosimo napišite število aplikacij =___________na **TEDEN**

V22 – Dolžina zadnjega obiska (v minutah):

☐

V23 – Ali je pacient obravnavan zaradi OKR v drugem zavodu oziroma enoti?

○ Da – v kolikor ste izbrali DA, prosimo napišite kje:___________________________________

○ Ne

○ Ne vem

V24 – Ali vam je pacient poročal, da je imel katerega izmed navedenih simptomov v zadnjem tednu?

	Da	Ne	Ne vem
Bolečina	☐	☐	☐
Izloček	☐	☐	☐
Vonj	☐	☐	☐
Srbečica	☐	☐	☐

V25 – V kolikor menite, da bi nam morali sporočiti eventuelna druga opažanja v zvezi z OKR, vas prosimo, da le ta zapišete v spodnjem okencu:

APPENDIX 3: Guide for health care professionals in English and Slovene

STUDY OF PREVALENCE OF OPEN SURGICAL WOUNDS
Information and Guidance for Health Care Professionals

Dear Sir or Madam,

Please take time to read the following information carefully and discuss it with others if you wish. Please contact the researcher (contact information given below) if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

ABOUT THE STUDY

This study is a part of the PhD project of Ljubiša Pađen at the University of Manchester. His PhD aims to provide information about the numbers of people with open surgical wounds (surgical wounds healing by secondary intention, or SWHSI) and illustrate what is like to live with such wounds in Slovenia.

The purpose of this part of the study is to ascertain the numbers of the people (of all ages) with open surgical wounds (SWSHI) in Ljubljana (Slovenia). Furthermore the aim of this study is to describe the nature of these wounds and how they are managed.

We are asking you to provide details of ALL the patients with one or more SWHSI who you have provided care for during a two-week period between 27th March and 9th April. For data collection you will use a special form. Furthermore, later in this guidance notes it is explained in more detail what to do and how to complete the form.

Data collected on the form are anonymised. We will not ask for any of your personal details or those of your patients. We ask about the healthcare professional providing care and where the wound care is provided in order to build up an overall picture of care delivery.
We are only able to undertake this research with your help and support in completing these forms. We recognise and appreciate the extra burden this places on you during the two-week period and would like to thank you in advance for your help. We are confident the data that emerge will be useful to all.

GENERAL INFORMATION AND GUIDANCE

Please complete **one** Data Capture Form for each person with a SWHSI for whom you (or your service) deliver wound care. Please **complete one form per eligible patient** you see as part of normal practice between 27th March and 9th April inclusively. You only need to record wound details for each person once. Please do **not** complete more than one form for each patient.

If a particular patient receives wound care from more than one service (GP, special wound clinic, community care, etc), please decide amongst you who will complete the form in order to avoid duplication.

It is important that **you complete the form away from the patient's 'bedside'** or home to ensure that it does not interfere with the care that they receive in any way and to preserve their anonymity. Please use information available in the case notes and your memory to answer the questions.

The Data Capture Form consists of two double-sided, printed sheets. It collects anonymised data about you as the treating health professional, general patient information, information about the current SWHSI and its treatment.

The majority of questions require you to put a 'cross' in the appropriate box. A smaller number of questions ask you to write your answer. **If you cross the wrong box please mark it as a wrong and cross the correct one.**

Once you have completed the form please check if you **have completed all questions which you could** and **hand the form to the Nurse Educator.**

After the (9th of April) **please give all unused forms to Nurse Educator**.

If you have **a query about any of the questions**, would like further information or assistance, require more data capture forms or collection of unused forms, please don't hesitate to **contact: Ljubiša Pađen** (Tel: 040 187 949; Email: ljubisa.paden@zf.uni-lj.si).

GUIDANCE TO HELP COMPLETE THE DATA CAPTURE FORM

Please check that the patient meets the inclusion criteria (page 3 of this guidance).

Please remember, **all sections must be completed away from the patient and we do not want any patient identifiable information.**

Section 1 - Information about the care provider.

This section asks for some information about you as the care provider and where treatment is given. We would also like you to note the date on which the form is completed.

Section 2 - Patient details:

This section asks for general information about the patient (age, gender, and ethnicity)

Section 3 - Current SWHSI:

This section asks about the total number, location, duration of this open surgical wound, information about the preceding surgery. If the patient has more than one SWHSI **please note** that you are asked to **complete the data for the wound that you think is the largest in area**.

Section 4 - Treatment of SWHSI:

You are asked to supply information regarding the treatment and treatment objectives of the assessed wound (which is the largest SWHSI if there are more than one). Please note that you will be asked whether the patient has experienced any unpleasant symptoms such as pain, exudate, pruritus, malodour – **note that you must fill out the form away from patient** and therefore please complete this section based on your memory and your previous assessment of the patient and their wound.

INCLUSION CRITERIA:

We ask that you complete forms for anybody you are treating who has at least one active SWHSI (matching with the definition given bellow), the existence of which is clinically confirmed by a medical doctor or registered nurse.

Definition of SWHSI: any wound following surgical intervention and has been intentionally left open to heal spontaneously or has been surgically closed (sutured) and has completely or partially broken open due to infection or other causes (i.e. wounds healing by secondary intention).

EXCLUSION CRITERIA:

i. Wounds healing by primary intention

ii. Surgical wounds which were healing by secondary intention but have now been surgically closed

iii. Wounds left open without planned healing (i.e. stoma)

iv. Surgery which did not involve an incision on the skin surface (e.g. tonsillectomy, dilation and curettage of the uterus, dental extractions, procedure for prolapsed haemorrhoids)

v. Wounds resulting from operations involving the eyeball (i.e. cataract surgery and removal of the eyeball)

vi. Non-surgical wounds healing by secondary intention (venous or arterial ulcers, diabetic foot ulcers, pressure ulcers)

vii. Non-surgical wounds healing by secondary intention (see vi. above) which were recently surgically debrided

viii. Fistulae (abnormal connection between internal organ and skin surface)

Thank you once again for taking the time to help us with this study.

Ljubiša Pađen

RAZISKAVA RAZŠIRJENOSTI ODPRTIH KIRURŠKIH RAN

Informacije in navodila za zdravstvene delavce

Spoštovani gospod, gospa!
Spoštovani kolega, kolegica!

Vzemite si čas in skrbno preberite naslednje informacije in v kolikor želite, se o tem pogovorite tudi s sodelavci. Prosim vas, da stopite v stik z raziskovalcem (kontaktni podatki so navedeni spodaj) v kolikor potrebujete več informacij oziroma imate kakšno vprašanje. Hvala Vam, ker ste si vzeli čas, da ste prebrali ta navodila.

INFORMACIJE O RAZISKAVI

Ta študija je del projekta doktorske disertacije Ljubiše Pađena na Univerzi v Manchestru, Združeno Kraljestvo Velike Britanije in Severne Irske. Namen raziskave, ki poteka v okviru doktorske disertacije je pridobiti informacijo o številu ljudi, ki imajo odprto kirurško rano (kirurška rana, ki se celi sekundarno). Prav tako je cilj študije ugotoviti, kako je živeti s takimi ranami v Sloveniji.

Namen tega dela raziskave je ugotoviti število ljudi (vseh starosti) z odprtimi kirurškimi ranami (OKR) v Ljubljani (Slovenija). Poleg tega je cilj te raziskave opisati naravo in oskrba odprtih kirurških ran.

Prosimo Vas, da nam pomagate pri pridobivanju podatkov o vseh bolnikov z eno ali več OKR, ki ste jih oskrbovali v obdobju dveh tednov, in sicer med 27 marcem in 9 aprilom. Za zbiranje podatkov boste uporabili poseben obrazec. Poleg tega so v nadaljevanju teh navodil, podrobneje razloženo kaj storiti in kako izpolniti obrazec.

Podatki, zbrani na obrazcu so anonimni, kar pomeni, da ne zahtevami niti vaših niti pacientovih podatkov preko katerih bi Vas lahko identificirali. Prosimo Vas, da navedete vase delovno mesto in delovno področje, da bomo lahko ugotovili, kje so oskrbovani pacienti.

To raziskavo lahko izvedemo samo z Vašo podporo in pomočjo. Zavedamo se, da raziskava predstavlja dodatno breme za Vas, zato se se Vam v naprej zahvaljujemo za Vašo pomoč. Prepričani smo, da bodo podatki, ki jih bomo pridobili s pomočjo te študije, koristni za vse.

SPLOŠNE INFORMACIJE IN NAVODILA

Prosimo, izpolnite **en obrazec** za vsako osebo z OKR katero (oz. je bila v vaši delovni enoti) orkbujete. Prosimo, izpolnite en obrazec na pacienta, ki izpolnjuje vključitvene kriterije in jih oskrbujete/zdravite v času vključno med 27 marcem in 9 aprilom. **Izpolnite podatke o rani le za enega pacienta**. Prosimo **ne izpolnjujte več obrazcev** za enega pacienta.

V kolikor je pacient deležen oskrbe s strani različnih zdravstvenih strokovnjakov (družinski zdravnik, patronažna medicinska sestra, ambulanta za splošno kirurgijo) vas prosimo, da se med seboj dogovorite, kdo bo izpolnil obrazec, da ne pride do podvajanja.

Zelo je pomembno, **da obrazec izpolnjujete ko pacienta ni poleg**, to pomeni, da, boste podatke vnesli po informacijah, ki ste jih vnesli v vašo dokumentacijo oziroma po spominu, saj lahko le na tašken način zagotovimo popolno anonimnost.

Obrazec je sestavljen iz dveh dvostransko natisnjenih listov. Namenjen je zbiranju anonimnih podatkov o vas, ki oskrbuhjete rano, splošnih podatkih pacienta, podatkih o rani in načinu zdravljenja oziroma oskrbe rane.

Na večino vprašanj boste odgovorili na način, da boste označili odgovor s križcem. Manjši del vprašanj od Vas zahteva, da napišete odgovor. **V kolikor se pri odgovoru zmotite Vas prosimo, da odgovor nedvoumno popravite oziroma označite pravilen odgovor (npr. Pripišete pravilno).**

Ko ste končali z izpolnjevanjem vas prosimo, da **še enkrat preverite ali ste odgovorili na vsa vprašanja**. **Nato izročite vprašalnik pedagoški medicinski sestri**.

Prosimo Vas, da po izteku obdobja študije, in sicer po 9. aprilu vse neuporabljene obrazce izročite pedagoški medicinski sestri.

V kolikor imate kakršnokoli vprašanje, potrebujete dodatne informacije, pomoč ali pa potrebujete dodatne obrazce prosimo kontaktirajte **Ljubišo Pađena** (Telefon: 040 187 949; elektronska pošta: ljubisa.paden@zf.uni-lj.si).

NAVODILA, KAKO IZPOLNITI OBRAZEC ZA ZBIRANJE PODATKOV

Prosimo preverite ali pacient izpolnjuje vključitvene kriterije, kot je navedeno na strani 3.

Prosimo vas, da imate v mislih, **da morate obrazec izpolniti po zaključeni obravnavi brez prisotnosti pacienta, saj le na takšen način lahko zagotovimo popolno anonimnost**.

Prvi del – Podatki o izvajalcu zdravstvene obravnave

V tem delu vas prosimo za nekaj anonimnih podatkov o Vas, kot izvajalcu zdravstvene obravnave. Prav tako Vas prosimo, da zabeležite datum, ko ste izpolnili obrazec.

Drugi del – Podatki o pacientih:

V tem delu vas prosimo, da izpolnite nekaj splošnih informacij o pacientu (spol, starost, etnična pripadnost).

Tretji del – Podatki o odprti kirurški rani:

V tem delu vprašalnika vas sprašujemo o skupnem številu OKR, lokaciji , času trajanja te odprte kirurške rane, informacije o predhodni operaciji. Če ima bolnik več kot eno OKR **upoštevajte**, da boste **morali izpolniti podatke za rano, za katero menite, da je največja po površini.**

Četrti del – Oskrba OKR

V tem delu obrazca vas prosimo, da izpolnite podatke o ciljih zdravljenja oz. oskrbe in o trenutnem načinu zdravljenja/ oskrbe (izpolnjujete le za eno rano, ki je največja po površini). Upoštevajte, da boste vprašani, ali je bolnik imel, navedel katerega izmed neprijetnih simptomov, kot so bolečina, izcedek, srbenje, neprijetni vonj – **upoštevajte, da morate obrazec izpolniti brez prisotnosti pacienta**, torej tudi ta del izpolnite po vaši dokumentaciji in spominu.

VKLJUČITVENI KRITERIJI:

Prosimo, da ste izpolnite obrazec za vsakogar, ki ga obravnavate in ima vsaj eno aktivno OKR (ki se ujema s spodnjo opredelitvijo) ter katere obstoj je klinično potrjena s strani zdravnika ali medicinske sestre.

Opredelitev odprte kirurške rane: je vsaka rana, ki je nastala kot posledica kirurškega posega in pri kateri so zaradi tveganja za okužbo ali drugih vzrokov robovi rane namenoma razmaknjeni (celjenje iz globine) ali pa se je sicer kirurško zašita (speta) rana delno ali popolno razprla zaradi okužbe ali drugih vzrokov (celjenje per secundam).

IZKLJUČITVENI KRITERIJI:

i. Rana, ki se celi per primam.

ii. Kirurška rana, ki se je sprva celila sekundarno in je bila kasneje zašita.

iii. Odpra rana brez namena celjenja (na primer stoma).

iv. Operativni poseg, ki ni vključeval incizije kože (odstranitev mandljev, dilatacija in kiretaža maternice, puljenje zoba, oskrba zdrsa/izpada hemeroidov).

v. Rane, ki so posledica operativnih posegov, ki vključujejo oko (operacija katarakte, enukleacija očesa).

vi. ne-kirurške rane, ki se celijo sekundarno (venski ali arterijski ulkusi, diabetična razjeda stopala, razjeda zaradi pritiska).

vii. ne-kirurške rane, ki se celijo sekundarno pri katerih je bila nedavno opravljena kirurška nekrektomija.

viii. fistula (nenormalna povezava med notranjim organom in kožo).

Še enkrat se Vam zahvaljujemo za čas in pomoč pri izvedbi raziskave.
Ljubiša Pađen

APPENDIX 4: Research Ethics Approval

MANCHESTER
1824
The University of Manchester

The University of Manchester
Oxford Road
Manchester
M13 9PT
+44(0)161 306 0100
www.manchester.ac.uk

Secretary to Research Ethics Committee 1
Email: katy.boyle@manchester.ac.uk
Phone: +44(0)161 275 1360

Ref: ethics/16301

Mr Ljubisa Paden / Professor Dame Nicky Cullum,
Division of Nursing, Midwifery and Social Work
Faculty of Biology, Medicine and Health
University of Manchester
M13 9PL

Ljubisa.paden@postgrad.manchester.ac.uk / nicky.cullum@manchester.ac.uk

16 August 2016

Dear Mr Paden, Professor Dame Cullum,

Study title: Living with the unpleasant symptoms associated with surgical wounds healing by secondary intention (Ref 16301)

Research Ethics Committee 1

Many thanks for attending the University Research Ethics Committee meeting held on 7th July 2016 to discuss the above study. I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form and supporting documentation, as submitted to and approved by the Committee.

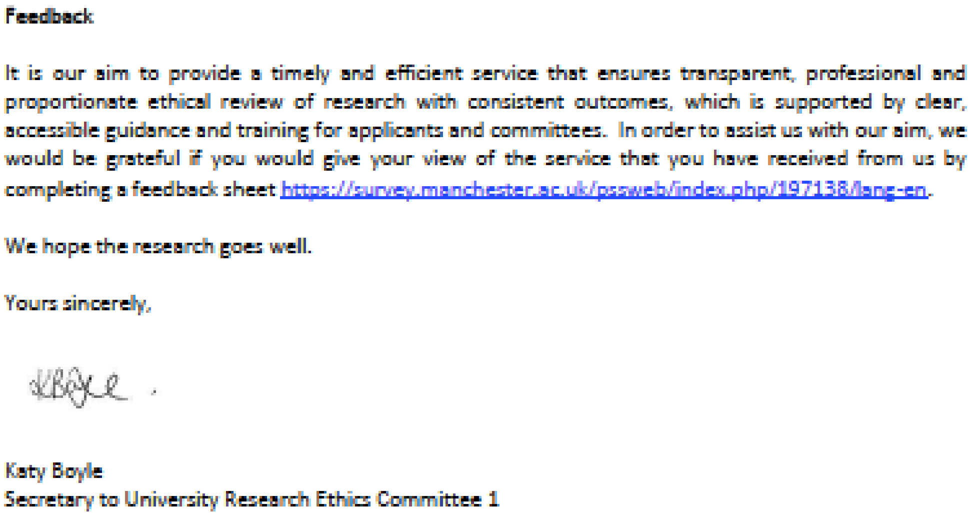
This approval is effective for a period of five years. If the project continues beyond that period an application for amendment must be submitted for review. Likewise, any proposed changes to the way the research is conducted must be approved via the amendment process (see below). Failure to do so could invalidate the insurance and constitute research misconduct.

You are reminded that, in accordance with University policy, any data carrying personal identifiers must be encrypted when not held on a secure university computer or kept securely as a hard copy in a location which is accessible only to those involved with the research.

Reporting Requirements:

You are required to report to us the following:

1. Amendments
2. Breaches and adverse events
3. Notification of Progress/End of the Study



Feedback

It is our aim to provide a timely and efficient service that ensures transparent, professional and proportionate ethical review of research with consistent outcomes, which is supported by clear, accessible guidance and training for applicants and committees. In order to assist us with our aim, we would be grateful if you would give your view of the service that you have received from us by completing a feedback sheet https://survey.manchester.ac.uk/pssweb/index.php/197138/lang-en.

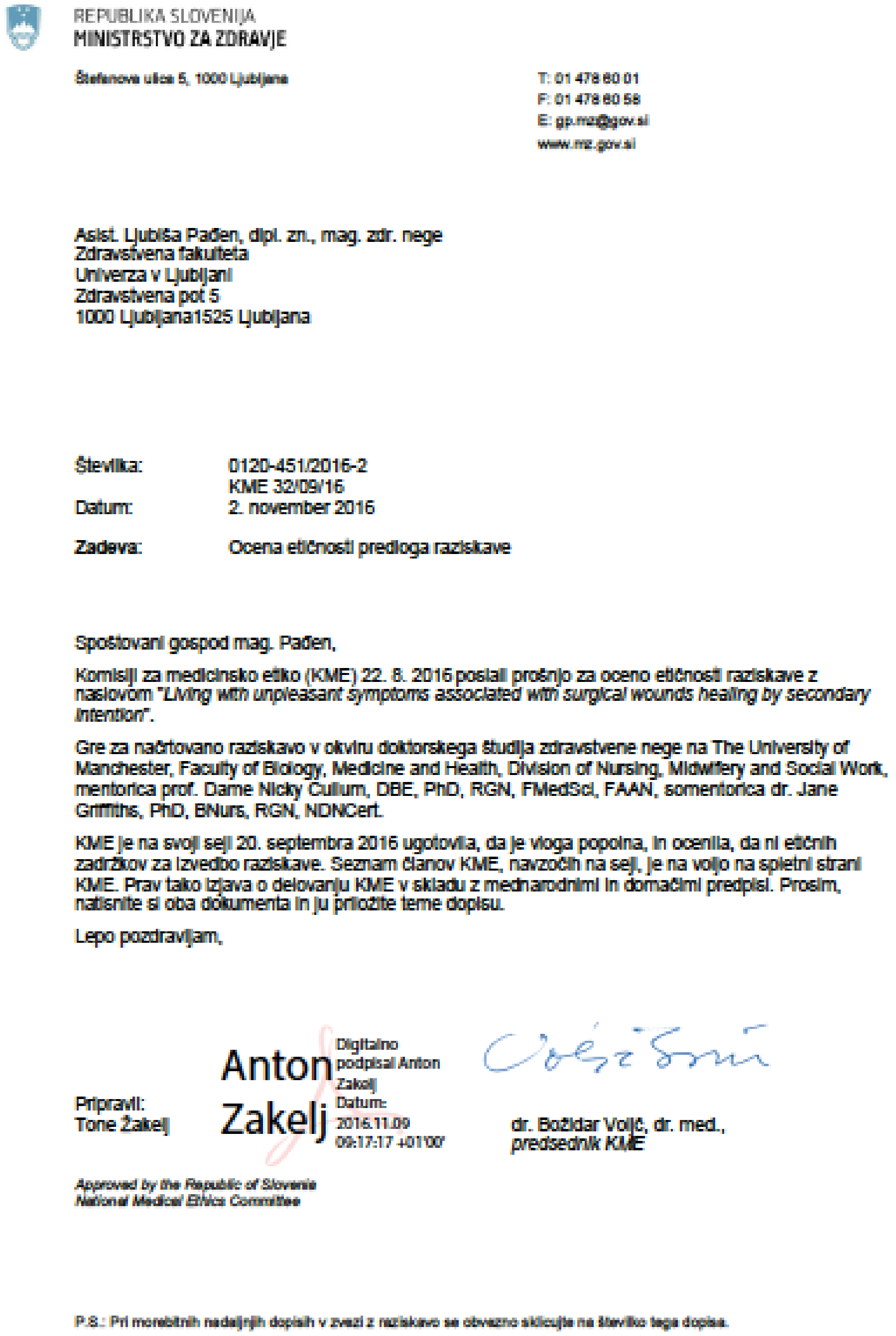
We hope the research goes well.

Yours sincerely,

KBoyle

Katy Boyle
Secretary to University Research Ethics Committee 1

APPENDIX 5: National Medical Ethics Committee Approval



REPUBLIKA SLOVENIJA
MINISTRSTVO ZA ZDRAVJE

Štefanova ulica 5, 1000 Ljubljana

T: 01 478 60 01
F: 01 478 60 58
E: gp.mz@gov.si
www.mz.gov.si

Asist. Ljubiša Pađen, dipl. zn., mag. zdr. nege
Zdravstvena fakulteta
Univerza v Ljubljani
Zdravstvena pot 5
1000 Ljubljana1525 Ljubljana

Številka: 0120-451/2016-2
KME 32/09/16
Datum: 2. november 2016

Zadeva: Ocena etičnosti predloga raziskave

Spoštovani gospod mag. Pađen,

Komisiji za medicinsko etiko (KME) 22. 8. 2016 poslali prošnjo za oceno etičnosti raziskave z naslovom "*Living with unpleasant symptoms associated with surgical wounds healing by secondary intention*".

Gre za načrtovano raziskavo v okviru doktorskega študija zdravstvene nege na The University of Manchester, Faculty of Biology, Medicine and Health, Division of Nursing, Midwifery and Social Work, mentorica prof. Dame Nicky Cullum, DBE, PhD, RGN, FMedSci, FAAN, somentorica dr. Jane Griffiths, PhD, BNurs, RGN, NDNCert.

KME je na svoji seji 20. septembra 2016 ugotovila, da je vloga popolna, in ocenila, da ni etičnih zadržkov za izvedbo raziskave. Seznam članov KME, navzočih na seji, je na voljo na spletni strani KME. Prav tako izjava o delovanju KME v skladu z mednarodnimi in domačimi predpisi. Prosim, natisnite si oba dokumenta in ju priložite teme dopisu.

Lepo pozdravljam,

Pripravil:
Tone Žakelj

Anton Zakelj
Digitalno podpisal Anton Zakelj
Datum: 2016.11.09 09:17:17 +01'00'

dr. Božidar Voljč, dr. med.,
predsednik KME

Approved by the Republic of Slovenia
National Medical Ethics Committee

P.S.: Pri morebitnih nadaljnjih dopisih v zvezi z raziskavo se obvezno sklicujte na številko tega dopisa.

APPENDIX 6: Guide for health care professionals in English and Slovene

QUALITATIVE STUDY OF PATIENT EXPERIENCES
Information and Guidance for Health Care Professionals

Dear Sir or Madam,

Please take time to read the following information carefully and discuss it with others if you wish. Please contact the researcher (contact information given below) if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

ABOUT THE STUDY

This study is a part of the PhD project of Ljubiša Pađen at the University of Manchester. His PhD aims to provide information about the numbers of people with open surgical wounds (surgical wounds healing by secondary intention, or SWHSI) and illustrate what is like to live with such wounds in Slovenia.

The purpose of this part of the study is to explore the patient's journey of living with open surgical wounds from their very beginning to the time when they have been living with this kind of wound for several weeks or months. This study aims to collect in-depth, rich data from a small number of patients. Patients will be invited to take part in the interview (between 2 and 4 interviews) where the researcher will ask open-ended questions to evoke the experience of living with open surgical wounds and patients' experiences of symptoms of open surgical wounds and how these wounds and treatment affect their everyday life.

We are only able to undertake this research with your help and support in recruitment process. We recognise and appreciate the extra burden this places on you during the study period and would like to thank you in advance for your help. We are confident the data that emerge will be useful to all!

GENERAL INFORMATION AND GUIDANCE

1. **You are asked to approach the potential participants** (who are meeting inclusion criteria) and briefly **inform them about the on-going study**.

2. **Please hand out a Participant Information Sheet** about the study **and ask potential participants to read it and to consider if they would like to participate**.

3. **On the next patient visit** (ensure that at least 24 hours has passed) **please ask patient if they are prepared to participate**.

4. If patient decide to take part in the research **please ask them if they are willing to share their contact details** with the researcher so that researcher can contact them (**Please contact Ljubiša Pađen –** Tel: 040 187 949; Email: ljubisa.paden@zf.uni-lj.si).

5. If you have **a query about any of the questions**, would like further information or assistance, require more participant information sheet forms, please don't hesitate to **contact: Ljubiša Pađen** (Tel: 040 187 949; Email: ljubisa.paden@zf.uni-lj.si).

INCLUSION CRITERIA:

i. Adult patients
ii. Clinically confirmed existence of active open surgical wound
iii. Able to understand and communicate in Slovene and give informed consent to participate.

Definition of open surgical wound: any wound following surgical intervention and has been intentionally left open to heal spontaneously or has been surgically closed (sutured) and has completely or partially broken open due to infection or other causes (i.e. wounds healing by secondary intention).

EXCLUSION CRITERIA:

i. Patients with impaired cognitive capacity (dementia, memory loss).
ii. Adult healthy volunteers (i.e. not under medical care for a condition which is directly relevant to the application)
iii. Children under 16
iv. Adults who have a terminal illness
v. Adults with mental illness (particularly if detained under mental health legislation)
vi. Adults in care homes
vii. Adults or children in emergency situations
viii. Prisoners
ix. Young offenders
x. Those who could be considered to have a particularly dependent relationship with the researcher, e.g. students taught or examined by the researcher.

xi. Patients with any other complex wounds besides wounds matching with our definition for inclusion, as this might influence patients' descriptions of observed phenomena e.g.:

    a. Wounds healing by primary intention
    b. Surgical wounds which were healing by secondary intention but have now been surgically closed
    c. Wounds left open without planned healing (i.e. stoma)
    d. Surgery which did not involve an incision on the skin surface (e.g. tonsillectomy, dilation and curettage of the uterus, dental extractions, procedure for prolapsed haemorrhoids)
    e. Wounds resulting from operations involving the eyeball (i.e. cataract surgery and removal of the eyeball)
    f. non-surgical wounds healing by secondary intention (venous or arterial ulcers, diabetic foot ulcers, pressure ulcers)
    g. non-surgical wounds healing by secondary intention which was recently surgically debrided
    h. fistula (abnormal connection between internal organ and skin surface)

Thank you once again for taking the time to help us with this study.

Ljubiša Pađen

KVALITATIVNA RAZISKAVA IZKUŠENJ ŽIVLJENJA Z RANO

Informacije in navodila za zdravstvene delavce

Spoštovani gospod, gospa!
Spoštovani kolega, kolegica!

Vzemite si čas in skrbno preberite naslednje informacije in v kolikor želite, se o tem pogovorite tudi s sodelavci. Prosim vas, da stopite v stik z raziskovalcem (kontaktni podatki so navedeni spodaj) v kolikor potrebujete več informacij oziroma imate kakšno vprašanje. Hvala Vam, ker ste si vzeli čas, da ste prebrali ta navodila.

INFORMACIJE O RAZISKAVI

Ta študija je del projekta doktorske disertacije Ljubiše Pađena na Univerzi v Manchestru, Združeno Kraljestvo Velike Britanije in Severne Irske. Namen raziskave, ki poteka v okviru doktorske disertacije je pridobiti informacijo o številu ljudi, ki imajo odprto kirurško rano (kirurška rana, ki se celi sekundarno). Prav tako je cilj študije ugotoviti, kako je živeti s takimi ranami v Sloveniji.

Namen tega dela študije je raziskati pacientovo izkušnjo, kako je živeti z odprto kirurško rano od njenega nastanka do nekaj tednov ali mesecev. Cilj te študije je zbrati poglobljene, bogate podatke s pomočjo odprtih intervjujev majhnega števila udeležencev. Udeležence, ki bodo povabljeni k sodelovanju v intervjuju (sodelovali bodo med 2 in 4 intervjuji), bo raziskovalec spodbudil h odgovarjanju na odprta vprašanja o tem kako je živeti s simptomi odprte kirurške rane, kako te rane in zdravljenje (oskrba) le te, vplivajo na njihovo vsakdanje življenje.

To raziskavo lahko izvedemo samo z Vašo podporo in pomočjo. Zavedamo se, da raziskava predstavlja dodatno breme za Vas, zato se se Vam v naprej zahvaljujemo za Vašo pomoč. Prepričani smo, da bodo podatki, ki jih bomo pridobili s pomočjo te študije, koristni za vse.

SPLOŠNE INFORMACIJE IN NAVODILA

1. **Prosimo vas, da pristopite k potencialnemu udeležencu, ki izpolnjuje vključitvene kriterije in ga seznanite o raziskavi.**

2. **Prosimo vas, da potencialnemu udeležencu izročite obrazec s pisnimi pojasnili o raziskavi in ga prosite, da ga prebere in razmisli ali bi bil pripravljen sodelovati v raziskavi.**

3. **Ob naslednjem obisku pacienta** (prosimo bodite pozorni, da je minilo več kot 24 ur) **vprašajte pacienta ali je pripravljen sodelovati v raziskavi.**

4. **Udeležence, ki so se odločili, da bodo sodelovali v raziskavi, prosite za soglasje, da lahko njihove kontaktne podatke delite z raziskovalcem, da bo le ta lahko stopil v stik z njimi.** (Prosimo posredujte kontaktne podatke Ljubiši Pađenu, po telefonu 040 187 949 ali po elektronski pošti: ljubisa.paden@zf.uni-lj.si).

5. V kolikor imate kakršnokoli vprašanje, potrebujete dodatne informacije, pomoč ali pa potrebujete dodatne obrazce "pisno pojasnilo o raziskavi", kontaktirajte **Ljubišo Pađena** (Telefon: 040 187 949; elektronska pošta: ljubisa.paden@zf.uni-lj.si).

VKLJUČITVENI KRITERIJI:

i. Odrasli pacienti
ii. Klinično potrjena prisotnost kirurške rane, ki se celi sekundarno
iii. Sposoben razumeti in komunicirati v Slovenskem jeziku in dati izjavo o zavestni in svobodni privolitvi za vključitev v raziskavo.

Opredelitev odprte kirurške rane: je vsaka rana, ki je nastala kot posledica kirurškega posega in pri kateri so zaradi tveganja za okužbo ali drugih vzrokov robovi rane namenoma razmaknjeni (celjenje iz globine) ali pa se je sicer kirurško zašita (speta) rana delno ali popolno razprla zaradi okužbe ali drugih vzrokov (celjenje per secundam).

IZKLJUČITVENI KRITERIJI:

i. Pacienti z zmanjšano kognitivno zmožnostjo (osebe z demenco, izgubo spomina).
ii. odrasli zdravi prostovoljci (tisti, ki niso v zdravstveni oskrbi zaradi stanja, ki ga zadeva ta prijava).
iii. Otroci mlajši od 16 let.
iv. Odrasli, ki imajo terminalno bolezen.
v. Odrasli z duševno boleznijo (še posebej tisti, ki so hospitalizirani skladno z zakonodajo o duševnem zdravju).
vi. Odrasli v domovih starejših in negovalnih bolnišnicah.
vii. Odrasli in otroci, ki so nenadno oboleli in potrebujejo nujno medicinsko pomoč.
viii. Zaporniki.
ix. Mladi prestopniki.
x. Vsi tisti, za katere bi menili, da obstaja nasprotje interesov med njimi in raziskovalcem (na primer študent, ki ga poučuje ali ocenjuje raziskovalec).
xi. Pacienti, ki imajo poleg odprte kirurške rane tudi drugo kompleksno rano (glej spodnji seznam), saj bi le te lahko vplivale na opise pacientovih izkušenj kako je živeti z odprto kirurško rano:

a. Rana, ki se celi per primam.

b. Kirurška rana, ki se je sprva celila sekundarno in je bila kasneje zašita.

c. Odpra rana brez namena celjenja (na primer stoma).

d. Operativni poseg, ki ni vključeval incizije kože (odstranitev mandljev, dilatacija in kiretaža maternice, puljenje zoba, oskrba zdrsa/izpada hemeroidov).

e. Rane, ki so posledica operativnih posegov, ki vključujejo oko (operacija katarakte, enukleacija očesa).

f. ne-kirurške rane, ki se celijo sekundarno (venski ali arterijski ulkusi, diabetična razjeda stopala, razjeda zaradi pritiska).

g. ne-kirurške rane, ki se celijo sekundarno pri katerih je bila nedavno opravljena kirurška nekrektomija.

h. fistula (nenormalna povezava med notranjim organom in kožo).

Še enkrat se Vam zahvaljujemo za čas in pomoč pri izvedbi raziskave.

Ljubiša Pađen

APPENDIX 7: Patient information sheet and consent form in English and Slovene

THE EXPERIENCE OF UNPLEASANT SYMPTOMS ASSOCIATED WITH OPEN SURGICAL WOUNDS

Participant Information Sheet

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

Who will conduct the research?

Ljubisa Paden, PhD Student, ljubisa.paden@postgrad.manchester.ac.uk;

Professor Nicky Cullum, supervisor; nicky.cullum@manchester.ac.uk;

Dr Jane Griffiths, supervisor; jane.griffiths@manchester.ac.uk;

School of Nursing, Midwifery and Social Work

University of Manchester

Jean McFarlane Building

Oxford Road

Manchester

M13 9PL

What is the purpose of the research?

The aim of the study is to better understand what is like to live with wounds after surgical operations. We are particularly interested in surgical wounds that have become “open” or were left open after the operation. These wounds may take some time to heal. Findings from this research will help nurses and other health professionals to better understand how patients such as you experience symptoms related to open surgical wounds and what impact these wounds have on daily living. This knowledge will potentially help nurses when planning their care and help them understand any additional needs that you have.

Why have I been chosen?

You have been asked to participate in this study because you have a wound after a surgical operation and it has become open or it was left open at the operation. In total I want to talk to up to 20 people like you about their experiences of having such wounds.

What would I be asked to do if I took part?

As part of this study you will be invited to take part in an interview with me; I am a researcher and a nurse. During the interview, you will be asked some general background information and then you will be asked about what it is like for you to have an open surgical wound like the one you have.

You will be invited to take part in between two and up to four interviews, each of which will last between 15 and 60 minutes. The interviews will be audio-recorded with your permission so that the researcher can listen to what you have to say without having to write everything down.

You may experience some inconvenience due to the time involved in being interviewed. You may feel uncomfortable discussing your experience of living with a wound. If you will feel discomfort talking about your experience you can stop at any time. Similarly if you feel that the interview is too long and you are tired you can stop at any time. You are free to withhold any information you prefer not to discuss and can refuse to answer any question we ask.

It is not expected that your participation in study would impair or have negative impact on your health.

If you are willing to participate you will need to sign a consent form (a copy of the Participant Information Sheet and a copy of the signed consent form will be given to you to keep).

What happens to the data collected?
After our conversation, the information that you share with me will be typed up from the recording, word for word, and analysed alongside those of other participants in order to identify common themes as well as differences between people. Anonymised data will be encrypted and sent to supervisors in the UK by email so that they can check transcripts and interpretation. The encryption code will be sent separately. The analysed data and research findings from this study will be written up as a thesis for the degree Doctor of Philosophy. The research findings will also be published in journals, conferences, and books. You will not be identifiable in any way in any of these formats.

How is confidentiality maintained?
The researcher will ensure the anonymity of your identity. No information that identifies you will be included on the written copy of your interview. Your name and the names of other you mention will be replaced by the codes such as Patient 1, Patient 2 or Person 1, Person 2, etc.…. Your confidentiality will be respected at all times unless you reveal any information that indicates that harm will come either to yourself or others. If this is the case then I will inform the most appropriate person, for example your doctor. However please be assured that this would not take place without your having been informed.

Your personal data (name, address, contact details) and assigned code (Patient 1, Patient 2, etc) will be held in a secured (locked) place at the Faculty of Health Sciences, University of Ljubljana. After the intention to use period has passed (when you will be informed about the results), your personal data will be confidentially destroyed. All digital data carriers will be encrypted (password will be known only to the three researchers named in this sheet).

What happens if I do not want to take part or if I change my mind?
It is completely up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw up to the time when data anonymisation occurs (e.g. at the point of anonymising transcriptions or at the time of publication of findings) without giving a reason and without detriment to yourself.

Will I be paid for participating in the research?
No payment will be provided for participating in study.

What is the duration of the research?
You will be invited to take part in between two and four interviews, each of which will last between 15 and 60 minutes.

Where will the research be conducted?
I will contact you once you have indicated that you would be interested in taking part in order to arrange a time and venue for our discussion. This will be at a time and place to suit you.

The interviews can take place in one of two locations as follows:
- your home,
- in the office at the University of Ljubljana, Faculty of Health Sciences, Zdravstvena pot 5, SI – 1000 Ljubljana.

Will the outcomes of the research be published?
The findings from research will be published in nursing/medical journals with the aim of informing nurses and others interested in providing care for patient with complex wounds. However you will not be identifiable in any publications.

Who has reviewed the research project?
Project has been reviewed by the University of Manchester Research Ethics Committee (Nr: ethics/16301) and National Medical Ethics Committee of Republic of Slovenia (Nr: 0120-451/2016-2) and by two research examiners from the University of Manchester.

What if something goes wrong?

If you become upset during the interview you will be asked if you wish to take a break or end the session. Your decision will be respected. If you feel a high level of emotional distress you will be encouraged to contact your GP or a nurse and you will be assisted with this however this is very unlikely.
You are free to withdraw at any time without giving a reason and without detriment to yourself. Please note that you can no longer withdraw your data once it has been typed up as your data will no longer be identifiable.

What if I want to make a complaint?

If there are any issues regarding this research that you wish to complain about please follow procedure described bellow:

Minor complaints

If you have a minor complaint then you need to contact the researcher in the first instance.

LJUBISA PADEN, PhD student ljubisa.paden@postgrad.manchester.ac.uk, +386 1 300 11 72

If you are still not happy with the response then please contact my research supervisors named below:

PROFESSOR NICKY CULLUM, SUPERVISOR; nicky.cullum@manchester.ac.uk;

DR JANE GRIFFITHS, SUPERVISOR; jane.griffiths@manchester.ac.uk;

School of Nursing, Midwifery and Social Work
University of Manchester
Jean McFarlane Building
Oxford Road
Manchester
M13 9PL

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

or

National Medical Ethics Committee of Republic of Slovenia, Ministrstvo za zdravje, Stefanova 5, SI – 1000 Ljubljana

MR. TONE ZAKELJ; kme.mz@gov.si or by telephoning + 386 1 78 69 13

What Do I Do Now?

If you have any queries about the study or if you are interested in taking part then please contact the researcher:

LJUBISA PADEN, PhD student ljubisa.paden@postgrad.manchester.ac.uk, +386 1 300 11 72

This Project Has Been Approved by the University of Manchester's Research Ethics Committee [Nr: ethics/16301] and National Medical Ethics Committee of Republic of Slovenia [NMEC Nr: 0120-451/2016-2].

THE LIVED EXPERIENCE OF UNPLEASANT SYMPTOMS ASSOCIATED WITH OPEN SURGICAL WOUNDS

CONSENT FORM

If you are happy to participate please complete and sign the consent form below.

Please initial box

I confirm that I have read the attached information sheet on the above project and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to any treatment/service.	
I understand that the interviews will be digitally audio-recorded	
I agree to the use of anonymised quotes	
I understand that I can no longer withdraw my data once they have been anonymised.	

I agree to take part in the above project

Name of participant		Date		Signature

Name of researcher		Date		Signature

This Project Has Been Approved by the University of Manchester's Research Ethics Committee [Nr: ethics/16301] and National Medical Ethics Committee of Republic of Slovenia [NMEC Nr: 0120-451/2016-2].

ŽIVEČA IZKUŠNJA NEPRIJETNIH SIMPTOMOV POVEZANIH Z ODPRTO KIRURŠKO RANO.

Pisna pojasnila o raziskavi

Bili ste povabljeni za sodelovanje v raziskavi. Preden sprejmete odločitev ali boste sodelovali je pomembno da razumete namen raziskave. Vzemite si čas in skrbno preberite naslednje informacije in pojasnila in v kolikor želite se o tem pogovorite tudi z drugimi. Prosimo vas, da nas vprašate, če vam karkoli ni jasno oziroma bi potrebovali dodatne informacije. Vzemite si čas in razmislite ali želite sodelovati. Zahvaljujemo se, ker ste si vzeli čas in prebrali ta pojasnila.

Kdo bo izvajal raziskavo?

Ljubiša Pađen, Doktorski študent, ljubisa.paden@postgrad.manchester.ac.uk;

Profesorica Dr Nicky Cullum, mentorica; nicky.cullum@manchester.ac.uk;

Dr Jane Griffiths, mentorica; jane.griffiths@manchester.ac.uk;

School of Nursing, Midwifery and Social Work
University of Manchester
Jean McFarlane Building
Oxford Road
Manchester
M13 9PL

Kaj je namen raziskave?

Namen študije je razumeti kako je živeti z rano po kirurškem posegu. Še posebej nas zanimajo kirurške rane, ki so se razprle ali pa so ostale odprte po operaciji. Vemo, da je nekaj časa potrebnega, da se te rane zacelijo. Ugotovitve iz te raziskave bodo lahko pomagale medicinskim sestram in drugim zdravstvenim strokovnjakom da bi bolje razumeli, kako taki pacienti kot ste vi, doživljajo simptome povezane z odprtimi kirurškimi ranami, kako ti simptomi vplivajo na vsakodnevno življenje. To znanje bo pomagalo medicinskim sestram pri načrtovanju zdravstvene nege in jim pomagalo razumeti dodatne potrebe, ki jih imate.

Zakaj sem bil izbran?

Za sodelovanje v raziskavi ste bili zaprošeni, ker imate rano, ki je posledica kirurškega posega in se je razprla ali pa je ostala odprta po operaciji. Skupaj želimo govoriti z do 20 ljudmi, kot ste vi, in sicer o izkušnjah, kako je imeti takšno rano.

Kakšna bo moja vloga, če se vključim v študijo?

V okviru te študije vas bomo povabili k sodelovanju v pogovoru z menoj (Ljubiša Pađen); sem raziskovalec in diplomirani zdravstvenik. Med razgovorom, vas bom spraševal o nekaterih splošnih informacijah o vas (kot na primer če ste zaposleni,…), nato pa vas bom spraševal o tem, kako je živeti z odprto kirurško rano kot jo imate vi.

Povabljeni boste, da sodelujete pri dveh do štirih intervjujih, kateri bodo trajali med 15 in 60 minut. Intervjuje bomo z vašim dovoljenjem zvočno posneli z namenom, da bom lahko poslušal kar želite povedati brez tega, da bi moral vse zapisati.

Sodelovanje v študiji lahko predstavlja manjšo neprijetnost, in sicer zaradi časa, ki ga boste porabili za sodelovanje v intervjujih. Morda se boste počutili nekoliko neprijetno, ko boste govorili oz. razpravljali o svoji izkušnji živeti z rano. V kolikor se boste počutili nelagodno in v kolikor boste želeli, lahko intervju prekinemo kadarkoli boste želeli. Prav tako v kolikor boste menili, da intervju traja predolgo ali pa boste utrujeni, lahko intervju prav tako ustavite. Prav tako lahko zadržite katerikoli informacijo, podatek zase o katerih ne bi želeli razpravljati oziroma na vprašanje ne odgovorite.

Ni pričakovana, da bi sodelovanje v študiji kakorkoli vplivala na vaše zdravje oziroma le tega poslabšala.

V kolikor se boste odločili za sodelovanje vas bomo prosili, da podpišete izjavo o prostovoljnem informiranem pristanku za sodelovanje v raziskavi (kopija izjave o pristanku in informacij vam bomo izročili za vašo hrambo).

Kaj se bo zgodilo s pridobljenimi podatki?
Po pogovoru, bodo posneti podatki, ki jih boste delili z raziskovalcem pretipkani, in sicer beseda za besedo. Analizirani bodo poleg tistih, drugih udeležencev, da bi lahko opredelili skupne teme in razlike med ljudmi. Anonimni podatki bodo zaščiteni z geslom posredovani po elektronski pošti mentoricama v Združeno Kraljestvo, da jih bosta lahko preverili. Geslo bo posredovano po e-pošti posebej. Analizirani anonimizirani podatki in rezultati raziskave bodo uporabljeni za namen doktorskega študija. Prav tako bodo rezultati raziskave objavljeni tudi v revijah, konferencah in knjigah. Vaša identiteta ne bo prepoznavna na kateri koli način v kateri koli od the oblik (zvočno ali pisno).

Kako bo ohranjena zaupnost?
Raziskovalec bo zagotovil anonimnost vaše identitete. Noben podatek, s pomočjo katerega bi vas lahko identificirali ne bo vključen vprepis intervjuja. Vaše ime in imena drugih bodonadomeščena z oznakami kotnapromer pacient 1, pacient 2 ali oseba 1, oseba 1. Vaša zaupnost bo vedno upoštevana, razen v primeru, ko bi razkrili podatke, ki kažejo, da bi škodovali sebi ali drugim. V takem primeru bomo obvestili najprimernejšo osebo, na primer zdravnika. Vendar bodite prepričani, da česar takega ne bomo storili ne da bi vas o tem predhodno seznanili.

Vaši osebni podatki (ime, naslov in kontaktni podatki) ter pripisana koda (pacient 1, pacient 2, ipd.) bodo hranjeni v zavarovani (zaklenjeni) omari na Zdravstveni fakulteti Univerze v Ljubljani. Po preteku obdobja v katerem smo dolžni hraniti tovrstne podatke , bodo vaši osebni podatki na ustezen (zaupen) način uničeni. Vse digitalne datoteke bodo zaščitene z geslom (geslo bo znano izključno raziskovalcem,ki so navedeni zgoraj).

Kaj se zgodi, če ne želim sodelovati oziroma se premislim?

Odločitev o tem ali boste sodelovali v raziskavi je povsem vaša. V kolikor se boste odločili, da boste sodelovali v raziskavi, boste prejeli ta pojasnila in naprošeni boste, da podpišete izjavo o prostovoljnem informiranem pristanku za sodelovanje v raziskavi, katere kopijo boste prav tako prejeli. Ne glede na to, da ste se odločili za sodelovanje lahko kadar koli brez navajanja kakršnega koli razloga oziroma pojasnila odstopite oz. prekličete soglasje. Odstop in preklic ne bosta imela nikakšnih posledic za vas. Prosimo, upoštevajte, da se ne boste mogli več umakniti svojih podatkov v točki, ko bodo ti anonimizirani (torej vaša identiteta ne bo več določljiva).

Ali bom prejel denarno nadomestilo za sodelovanje v raziskavi?

Denarno nadomestilo za sodelovanje v raziskavi ni predvideno.

Koliko časa bo trajala raziskava?
Povabljeni boste, da sodelujete v dveh do štirih intervjujih, kateri vsak bo trajal med 15 in 60 minut.

Kje se bo raziskava izvajala?
Z vami bomo stopil v stik in ko boste izrazili pripravljenost na sodelovanje vas bomo prosili, da se dogovorimo o času in lokaciji intervjuja, ki bo za vas najbolj ustrezna.

Intervju lahko poteka na dveh lokacijah, in sicer:

- vašemu domu,
- in v pisarni na Univerzi v Ljubljani, Zdravstveni fakulteti, Zdravstvena pot 5, 1000 Ljubljana.

Ali bodo rezultati raziskave objavljeni?
Rezultati raziskave objavljeni tudi v medicinskih revijah oz. revijah iz področja zdravstvene nege z namenom informiranja medicinskih sester in drugih, ki jih to področje zanima. Poudariti želimo, da Vaša identiteta ne bo prepoznavna v nobeni publikaciji.

Ali je kdo ocenil etično primernost raziskave?
Etična primernost raziskave je bila ocenjena s strani Etične Komisije Univerze v Manchesteru (ethics/16301) in Komisije za medicinsko etiko Republike Slovenije (številka soglasja: 0120-451/2016-2). Prav tako sta raziskavo recenzirala (ocenila) dva ocenjevalca iz Univerze v Manchestru.

Kaj se zgodi, če gre kaj narobe?

V kolikor boste postali vznemirjeni med intervjujem vas bomo vprašali, če se želite odpočiti ali končati intervju. Upoštevana bo vaša odločitev. Če boste menili, da ste v čustveni stiski, vas bomo spodbudili, k obisku vašega osebnega zdravnika ali medicinske sestre, ki vam bo pomagal pri tem. Zelo malo verjetno je, da bi zaradi tem pogovora v intervjuju doživeli takšno čustveno stisko.

Prav tako bi vas želeli seznaniti, da lahko kadarkoli in brez navedbe razloga ter brez škode za sebe umaknete soglasje za sodelovanje v intervjuju. Prosimo, upoštevajte, da se ne boste mogli več umakniti svojih podatkov v točki, ko bodo ti pretipkani, saj bodo v tistem trenutku postali anonimni (torej vaša identiteta ne bo več določljiva).

Kaj naredim, če se želim pritožiti?

V kolikor obstaja kakršen koli problem s to raziskavo in se želite pritožiti vas prosimo, da upoštevate spodaj naveden postopek:

Manjši problem oz. pritožba:

V kolikor imate manjši problem vas prosimo, da stopite v stik z raziskovalcem, in sicer:

LJUBIŠA PAĐEN, Doktorski študent, elektronska pošta:

ljubisa.paden@postgrad.manchester.ac.uk, telefon: +386 1 300 11 72

V kolikor niste zadovoljni z odgovorom vas prosimo, da se obrnete na spodaj navedena mentorja te raziskave:

PROFESORICA DR NICKY CULLUM, MENTORICA; nicky.cullum@manchester.ac.uk;

DR JANE GRIFFITHS, MENTORICA; jane.griffiths@manchester.ac.uk;

School of Nursing, Midwifery and Social Work
University of Manchester
Jean McFarlane Building
Oxford Road
Manchester
M13 9PL

Uradna pritožba:

V kolikor želite podati uradno pritožbo ali če niste zadovoljni z odgovorom, ki ste ga prejeli s strain raziskovalcev, se obrnite na vodjo urada za raziskave po pošti: Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, UK; ali po elektronski pošti: research.complaints@manchester.ac.uk; ali po telefonu, in sicer na +44161 275 2674 ali +4461 275 2046.

ali

Komisija Republike Slovenije za medicinsko etiko, Ministrstvo za zdravje, Štefanova 5, SI – 1000 Ljubljana

Gospod TONE ŽAKELJ kme.mz@gov.si ali po telefonu +386 1 78 69 13

Kaj storim sedaj?

V kolikor imate še kakrpno koli vprašanje oziroma ste pripravljeni sodelovati, vas prosim, da stopite v stik z mano, in sicer:

LJUBIŠA PAĐEN, Doktorski študent, elektronska pošta:
ljubisa.paden@postgrad.manchester.ac.uk, telefon: +386 1 300 11 72

Ta projekt je bil odobren s strani Etične komisije Univerze v Manchestru [Soglasje s števillko ethics/16301] in Komisije Republike Slovenije za medicinsko etiko [Soglasje s števillko : 0120-451/2016-2].

ŽIVEČA IZKUŠNJA NEPRIJETNIH SIMPTOMOV POVEZANIH Z ODPRTO KIRURŠKO RANO.

PRIVOLITEV ZA SODELOVANJE V RAZISKAVI

V kolikor ste pripravljeni sodelovati vas prosimo, da preberete, izpolnite in podpišete izjavo o informiranem pristanku za sodelovanje v raziskavi.

Prosimo vas označite:

Potrjujem, da sem prebral priložena pojasnila o zgoraj omenjeni raziskavi, da sem imel možnost premisleka in postavljanja vprašanj ter da sem na njih prejel zadovoljive odgovore.	
Razumem in se strinjam, da je moje sodelovanje prostovoljno in da lahko odstopim od sodelovanja kadarkoli brez navedbe razlogov ali pojasnil za odstop, brez kakršnih koli posledic.	
Razumem in se strinjam s tem, da so intervjuji zvočno posneti.	
Strinjam se, da se uporabijo anonimizarni navedki iz intervjuja.	
Razumem in se strinjam, da ne bom mogel umakniti svojih podatkov v točki, ko bodo le ti anonimizirani.	

Strinjam se, da sodelujem v raziskavi.

Ime in priimek udeleženca	Datum	Podpis
Ime in priimek raziskovalca	Datum	Podpis

Ta projekt je bil odobren s strani Etične komisije Univerze v Manchestru [Soglasje s številko ethics/16301] in Komisije Republike Slovenije za medicinsko etiko [0120-451/2016-2].

APPENDIX 8: Interview topic guide in English and Slovene

Lived experiences of unpleasant symptoms associated with open surgical wounds

Research questions:

What is the lived experience of unpleasant symptoms associated with open surgical wounds?

Topics:

Introduction

Introduction to the interviews: presenting myself, the aims of the study, informed consent, confidentiality, timing.

Data gathered using the questionnaire: current circumstances (age, gender, education, employment, living conditions, source of income, etc.)

Topic 1: Wound, Illness, Journey

I will evoke these experiences by asking:

- Please describe your journey of having the wound.
- Please tell me, from your perspective, how you got the wound? (Examples of follow-up questions: please tell me what happened? How did you feel about it?)
- Please tell me what it was like to have this wound from the beginning to now? (Examples of follow-up questions: can you tell me more about…, how did you feel? what do you mean by that? Can you describe what happened then?)

Topic 2: Lived experience of unpleasant symptoms

I will try to evoke experiences which are related to wounds with the following questions:

- Please tell me more about your experiences having this (wound, thing, etc.)? The question will use the patient's own terminology.
- What does it mean for you to have this (wound)?
- What are the symptoms of the wound? What does it "do" and feel like?
- What is it like to live with … (symptoms)? How does it make you feel?
- Please describe a normal day.
- How has your life changed because of this wound?
- (Examples of follow up: Please tell me more about …. or you mentioned ….. could you describe…. or could you explain what have you meant with……, can you describe what happened then?)

<u>*Topic 3: Physical*</u>

Please tell me about your physical health before you had this wound and now?

- You mentioned… Can you tell me more about this?

<u>*Topic 4: Psychological*</u>

- What are your feelings about this wound?
- What do you see when you look at the wound?
- How do you see (perceive) yourself with the wound?
- (Examples of follow up: Please tell me more about …. or you mentioned ….. could you describe…. or could you explain what have you meant with……; how do you feel about this …..? Is that what you meant earlier when you said…?).

<u>*Topic 5: Social*</u>

- Can you describe your social life for me? How do you feel about it?
- What have you done in the last few days?
- What do your loved ones (partner, family, friends) say about the wound?
- How do you feel about this?
- (Examples of follow up: Please tell me more about …. or you mentioned ….. could you describe…. or could you explain what have you meant with……)

<u>*Topic 6: Financial*</u>

- You mentioned… Can you tell me more about this?

<u>Topic 7: Coping with wound</u>

- Please tell me about your everyday experience of dealing with the wound?
- (Examples of follow up question: Could you explain what did you meant by that? Is that what you meant earlier when you said…? How do you feel about….?).

<u>Topic 8: Experiences of the wound treatment</u>

- Please tell me about your experience of the wound treatment from the beginning till now? Did you experience any changes?

- Please tell me, from your perspective, how did (do) you cope (coped) with treatment?
- Did you seek for any additional information about the treatment which you have received? (Follow up: Can you tell me more about this? Why did you seek for that? Where? How?)

- (Examples of follow up question: Could you explain what did you meant by that? Is that what you meant earlier when you said…? How do you feel about….?).

Closing the interview:

I will thank the participant and answer any additional question they may have.

Words and phrases

The topic guide is flexible and it is likely that some topics may change. Furthermore in evoking experiences the terminology and phrasing of patients will be used to make them more comfortable talking about “things happening to them”.

The first interviews will be focused on patients’ current views, while second interviews will be focused on the journeys having these wounds has led them on.

Živeča izkušnja neprijetnih simptomov povezanih z odprto kirurško rano.

Raziskovalno vprašanje:

Kakšna je živeča izkušnja neprijetnih simptomov povezanih z odprto kirurško rano?

Teme:

Uvod:

Uvod v intervju: Udeležencu se predstavim. Pojasnim mu namen in cilje raziskave, kako bo zavarovana njegova anonimnost in zaupnost. Opravim pojasnilno dolžnost in prosim za pisni informirani pristanek.

Nato pridobim podatke s pomočjo vprašalnika (starost, spol, izobrazba, stanje zaposlitve).

Tema 1: Rana, bolezen in potek

- Udeleženca bom spodbudil k delitvi izkušnje s pomočjo odprtih vprašanj:
- Prosim, opišite mi kako je imeti rano?
- Prosim, opišite mi vaše videnje zakaj je rana nastala? (primeri podvprašanj mi lahko poveste kaj se je zgodilo? Kako ste se ob tem počutili?)
- Prosim, povejte mi kako je imeti rano od nastanka do danes? (primeri podvprašanj: ali mi lahko poveste nekaj več o…., kako ste se počutili?, kaj ste s tem mislili? Mi lahko pojasnite, opištete, kaj se je potem zgodilo, dogajalo?).

Tema 2: Živeča izkušnja neprijetnih simptomov

Udeleženca bom spodbudil, da govori o izkušnji, ki je povezana z rano. Pri tem bom uporabil vprašanja kot na primer:

- Prosim povejte mi nekaj o vaši izkušnji imeti rano? Poimenovanje "rane" bo sledilo predhodnemu poimenovanju, ki ga je uporabil udeleženec.
- Kaj za vas pomeni imeti to rano?
- Kateri so simptomi rane? Kaj vam povzročajo ti simptomi in kako se počutite?
- Kako je živeti z …. (simptomi)? Kakšne občutke vam povzročajo?
- Prosim, opišite mi vaš običajen dan?
- Kako se vam je življenje spremenilo zaradi rane?
- (Primeri podvprašanj: Prosim povejte mi nekaj več o… ali, omenili ste da….., ali lahko opišete…. ali lahko pojasnite kaj ste misli s tem, ko ste ….. ali lahko pojasnite, kaj se je zgodilo potem?).

Tema 3: Fizično zdravje

- Prosim povejte mi kako bi ocenili vaše fizično zdravje preden ste imeli rano in kakšno je sedaj?
- Omenili ste…., Mi lahko poveste nekaj več o tem?

Tema 4: Psihološko zdravje

- Kakšni so vaši občutki o rani?
- Kaj vidite ko pogledate rano?
- Kako doživljate sebe z rano?
- (Primeri podvprašanj: Prosim povejte mi nekaj več o… ali; omenili ste da….., ali lahko opišete…. ali lahko pojasnite kaj ste misli s tem, ko ste ….. kakšne imate občutke o ….? Je to tisto, kar ste mislili, ko ste prej omenili…?).

Tema 5: Družabno življenje

- Ali lahko opišete svoje družabno življenje? Kako se počutite glede tega?
- Kaj ste počeli v zadnjih dneh?
- Kaj pa vaše ljubljeni, bližnji (partnerjev , družina, prijatelji) menijo oziroma vam povedo o rani?
- Kako se ob tem počutite? Kakšno je vaše mnenje o tem?
- (Primeri podvprašanj: Prosim povejte mi nekaj več o… ali; omenili ste da….., ali lahko opišete…. ali lahko pojasnite kaj ste misli s tem, ko ste ….. kakšne imate občutke o ….? Je to tisto, kar ste mislili, ko ste prej omenili…?).

Tema 6: Finančno stanje

- Omenili ste…. Mi lahko poveste nekaj več o tem?

Tema 7: Soočanje z rano

- Prosim, opišite mi svojo vsakdanjeo izkušnjo, kako se soočate z rano?
- (Primeri podvprašanj: Prosim povejte mi nekaj več o… ali; omenili ste da….., ali lahko opišete…. ali lahko pojasnite kaj ste misli s tem, ko ste ….. kakšne imate občutke o ….?).

Tema 8: Izkušnja z oskrbo oziroma zdravljenjem rane

- Prosim, povejte mi kaj o svojih izkušnjah zdravljenja rane od začetka do sedaj? Ali ste opazili kakršnekoli spremembe?

- Prosim, opišite mi vaš vidik, kako se (ste) boste kosali, soočali (ste se soočili), z zdravljenjem?
- Ali ste iskali kakšne dodatne informacije v zvezi z zdravljenjem oziroma oskrbo katere ste bili deležni. (Mi lahko poveste nekaj več o tem, Zakaj vas je to zanimalo? Kje ste iskali informacije in kako?).

- (Primeri podvprašanj: Ali lahko pojasnite kaj ste misli s tem? Je to, tisto, kar ste prej povedali…? Kakšne imate občutke o ….? Kako se ob tem počutite?).

Zaključek intervjuja:

Udeležencu se bom zahvalil za sodelovanje in odgovorili na morebitna vprašanja.

Uporaba besedišča:

Potek intervjuja je gibljiv in verjetno je, da se bodo nekatere teme spremenile oziroma oblikovale.

V inetrvjuju bo uporabljeno besedišče, ki ga uporablja udeleženec. S tem bo zagotovljeno, da bodo udeleženci bolj sproščeno govorili o "tistemu, kar se dogaja njim".

Prvi intervju bo usmerjen na udeležnčeve trenutne iskušnje in poglede medtem k obo naslednji usmerjen v izkušnjo, ki traja od nastanka rane do časa intervjuja.

APPENDIX 9: Demographic questionnaire in English and Slovene

Lived experiences of unpleasant symptoms associated with open surgical wounds

NAME OF PARTICIPANT:

CONTACT DETAILS:
Phone Number:
Summary of research result to be sent to the address:

Other contact detail (email):

CODE OF PARTICIPANT:

Q1- Age: What is your age?

____

Q2 - Gender: (Please circle)

M F

Q3 - Ethnicity (or race): Please specify your ethnicity.

	White	Black	Asian	Mixed	Prefer not to say	Other:_________
Ethnicity	○	○	○	○	○	○

Q4 - Education: What is the highest degree or level of school you have completed? If currently enrolled, highest degree received. (Please circle)

a) No schooling completed
b) Primary level: Primary school
c) Secondary level: Vocational Upper Secondary School
d) Secondary level: Technical Secondary School
e) Secondary level: General Secondary School
f) Tertiary level: Non-university level post-secondary studies (technical/vocational type)
g) Tertiary level: Bachelor's degree
h) Tertiary level: Master's degree

i) Tertiary level: Doctorate degree
j) Prefer not to say

Q5 - Marital Status: What is your marital status? (Please circle)

a) Single
b) Married or domestic partnership
c) Widowed
d) Divorced
e) Separated
f) Prefer not to say

Q6 - Employment Status: What is your current employment status? (Please circle)

a) Employed
b) Self-employed
c) Out of work and looking for work
d) Out of work but not currently looking for work
e) A homemaker
f) A student
g) Military
h) Retired
i) Unable to work
j) Prefer not to say

Q7 – Household size: Please note the number of all family members living in your household. (Please circle)

a) _____________
b) Prefer not to say

Živeča izkušnja neprijetnih simptomov povezanih z odprto kirurško rano.

IME UDELEŽENCA:

KONTAKTNI PODATKI:

Telefonska številka:

Naslov, kamor lahko pošljemo povzetek raziskave:

Drugi kontaktni podatki (elektronska pošta):

KODA UDELEŽENCA:

V1- Starost: Koliko ste stari?

____

V2 - Spol: (Prosim obkrožite)

M Ž

V3 – Etnična (oz. rasna) identiteta: Prosimo, da opredelite v katero etnično skupino se uvrščate.

	Belec	Temnopolt	Azijec	Mešan	Ne želim odgovoriti	Drugo:_______
Etnična identiteta	○	○	○	○	○	○

V4 – Izobrazba: Katera je vaša dokončana najvišja stopnja izobrazbe. V primeru, da trenutno študirate, vpišite zadnjo dokončano stopnjo. (Prosim obkrožite)

a) Nedokončana osnovna šola
b) Osnovna šola
c) Srednješolski nivo: Poklicna šola (2 ali 3 letno izobraževanje)
d) Srednješolski nivo: Strokovna šola (4 letno izobraževanje)
e) Srednješolski nivo: Gimnazija
f) Višje šolski nivo: višja strokovna šola
g) Visokošolsko izobraževanje: dodiplomski študij (visokošolski strokovni in univerzitetni)

h) Visokošolsko izobraževanje: podiplomski študij – magistrski, specialistični
i) Visokošolsko izobraževanje: podiplomski študij – doktorski
j) Ne želim odgovoriti

V5 – Zakonski status: Prosimo obkrožite, kakšen je vaš trenuten zakonski stan? (Prosim obkrožite)

a) Samski
b) Poročen ali v izvenzakonski/partnerski skupnosti
c) Odovel
d) Ločen
e) Ne želim odgovoriti

V6 - Zaposlitev: Kakšen je vaš trenutni zaposlitveni status? (Prosim obkrožite)

a) Zaposlen
b) Samozaposlen
c) Brezposelen – aktiven iskalec zaposlitve
d) Brezposelen – trenutno ne iščem zaposlitve
e) Gospodinja
f) Dijak/Študent
g) Vojak, vojaški uslužbenec
h) Upokojenec
i) Nezmožen za delo
j) Ne želim odgovoriti

V7 – Gospodinjstvo: Koliko članov šteje vaše gospodinjstvo? (Prosim obkrožite)

a) _____________
b) Ne želim odgovoriti