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The Malta Journal of Health Sciences disseminates research on a broad range of allied health disciplines. It publishes original research papers, review articles, short communications, commentaries, letters to the editor and book reviews. The readership of the journal consists of academics, practitioners and trainee health professionals across the disciplines of Applied Biomedical Science, Audiology, Community Nursing, Dietetics, Environmental Health, Food Science, Health Services Management, Medical Physics, Mental Health, Midwifery, Nursing, Nutrition, Occupational Therapy, Physiotherapy, Podiatry, Radiography and Speech Language Pathology.

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Guest Editorial

The Department of Human Communication Sciences and Disorders

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Brief History

The Department of Human Communication Sciences and Disorders first opened its doors in 1991. Known as the *Communication Therapy Division* at the time, it launched the first local four–year undergraduate degree programme in Communication Therapy through the University of Malta's Institute of Health Care. This programme led to eligibility for registration as a speech language pathologist (SLP). Professor Helen Grech was then the coordinator of the programme and head of the same department. Together with the late Professor John Rizzo Naudi and Ms Helene (Jackie) Clydesdale, Professor Grech was instrumental in sowing the seeds and nurturing the programmes which were eventually offered by the department. With many years of hard work and dedication, Professor Grech skilfully developed and enriched the department, making her vision a reality.

The launching of the department in 1991, together with the first programme leading to a degree in Speech Language Pathology, had an immense impact on the service offered locally to patients/clients in various settings. Before that time, the service was sporadic due to the limited number of SLPs who could provide a service. The Maltese islands first benefited from *speech therapy* in the 1970s, when expatriate SLPs were commissioned to start the service locally. In 1977, a full–time training course *Speech Pathology and Therapeutics* was offered once, leading to an improvement in the service in 1981, as the first seven locally trained SLPs became qualified. Understandably, the service was limited because of the lack of human resources (Grech, 2002).

Today, the department includes five full–time academic members of staff and five visiting members of staff. Without their work, contribution, collaboration, support and positive attitude, we would not be able to provide the necessary structure and quality that we offer to our students. A range of programmes related to Speech Language Pathology and Audiology are offered, and in addition to the commitment to training and education, the department also aims for high–quality research on communication and communication disorders.

Rationale for the change from "Department of Communication Therapy" to "Department of Human Communication Sciences and Disorders".

When, in 2010, the Faculty of Health Sciences replaced the Institute of Health Care, the Communication Therapy Division became known as the *Department of Communication Therapy*. In March 2024, the Department of Communication Therapy made a formal request to change its name and approval was granted in May 2024. The programmes offered by the department encompass various fields of study, all falling under the overarching term 'communication,' with a specific focus on 'Human Communication'. This broad category includes diverse areas such as motor speech, language, hearing, auditory processing, and all facets of nonverbal communication.

As the training and education of SLPs and Audiologists becomes more evidence–based and reliant on scientific research, it is essential to emphasise the

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scientific nature of this broad field. In this context, scientific research investigates the causes, characteristics, assessment methods and intervention approaches for the different communication disorders (across the lifespan) of speech, voice, fluency, language, hearing, auditory processing, swallowing and more. Related sciences, such as linguistics, psychology, and neurology, are intertwined with the science of communication and are essential core areas for the understanding of typical and disordered communication. The addition of the term 'sciences' to the name of the department highlights the academic and scientific underpinnings of the disciplines, acknowledging that speech language pathology and audiology are rooted in rigorous research, evidence–based practices, and robust theoretical knowledge. This is in line with the perspective of recognised international bodies, such as the American Speech–Language–Hearing Association (ASHA) and the Royal College of Speech and Language Therapists, UK (RCSLT).

Removing the term "therapy" ensures that the name of the department reflects a broader perspective which goes beyond therapeutic intervention to heal or relieve symptoms, recognising the multifaceted nature of communication disorders. The proposed name, including the terms "communication sciences" and "disorders", encompasses both the study of typical communication processes as well as the understanding of disruptions which are addressed by the SLP and the Audiologist in clinical and research contexts.

The new term, therefore, acknowledges the evolving professional identity of SLPs and Audiologists, who are not only involved in therapeutic practice but also in prevention, advocacy, education, and research (ASHA, 2016), in collaboration with other professionals in health–related fields, social welfare and education. This terminology reflects an inclusive and collaborative approach, broadly encompassing the many possible areas which can be addressed in research and practice and is consistent with educational and healthcare approaches that push for a shared scientific interdisciplinary understanding and a holistic approach in addressing health concerns as advocated by the World Health Organisation, since 2001.

The decision to name the department "Human Communication Sciences and Disorders" was a crucial step, aligning with the current trend observed in leading international associations within the field of speech language pathology and related areas. This move ensures that our department's terminology is in sync with the latest global developments in the mentioned professions and areas of study. A notable example of this trend is the International Association of Logopedics and Phoniatrics (IALP). In 2022, after extensive deliberations, the IALP finalised a change in its name, officially registering it with the World Health Organization as the "International Association of Communication Sciences and Disorders" while retaining the acronym IALP. This decision reflects a culmination of years of discussion, prompted by the realisation that the "purpose and area of speciality (of the IALP were) not clearly understood by many potential members, including English–speaking nations and those working in the United Nations and WHO" (P. Enderby, personal communication, February 3, 2024).

The proposed change resonates with the contemporary evolution of the field, recognising the interdisciplinary nature of scientific research and practice in the field of human communication. By adopting terminology consistent with international standards, the department demonstrates its commitment to academic excellence and inclusivity, positioning itself at the forefront of global academic standards, enhancing credibility, fostering collaboration with international peers, and facilitating collaboration, research, and advancements in the ever–evolving field of human communication sciences and disorders.

Another Recent Change

The department also made a request to change the name of the undergraduate Bachelor of Science (Honours) programme from "Communication Therapy" to "Speech Language Pathology". This was approved in May 2024.

As noted above, the University of Malta started offering a B.Sc. (Hons) degree in Communication Therapy in 1991. To date, more than 260 students have obtained a Bachelor of Science (Honours) in Communication Therapy and were able to register as SLPs. This steady increase in the numbers makes it possible to offer a service in a variety of settings, using different approaches, procedures and models of service delivery. The role of SLPs has expanded during recent years as they are now established clinicians in developmental speech sound disorders, developmental language disorders (including both spoken and written disorders), voice, fluency, swallowing, acquired motor speech disorders, acquired spoken and written language disorders, and acquired cognitive communication disorders. As a result of their

intervention, SLPs ultimately aim to enhance the quality of life of individuals and the persons around them.

The name of the undergraduate 'Communication Therapy' programme has sometimes created difficulties for candidates during their studies and after graduation. The general public and professionals alike do not easily link the name of the training programme (Communication Therapy) and the role of the graduands when these join the workforce (SLP). This contrasts with other programmes within the Faculty of Health Sciences, such as B.Sc. (Hons) Physiotherapy, Occupational Therapy, Midwifery, and Radiography, which lead to the profession bearing the same nomenclature, that is, Physiotherapist, Occupational Therapist, Midwife, Radiographer, respectively. Although the term communication can serve as an umbrella term for the areas of speech, language, hearing, communication, and swallowing, it has created confusion for individuals outside the profession/department locally and abroad. There have been several episodes of confusion between the name of the programme 'Bachelor of Science (Honours) in Communication Therapy' and other programmes offered by the University of Malta, specifically the 'Bachelor of Communications (Honours)' and the 'Bachelor of Arts in Communication Studies'.

The change from B.Sc. (Hons) Communication Therapy to B.Sc. (Hons) Speech Language Pathology now ensures uniformity and consistency between the name of the course programme offered locally and the title of the profession and registration nomenclature. Locally, graduates register with the Council for the Professions Complementary to Medicine (CPCM) as SLPs and work as SLPs when they join the workforce. In addition, the speech language pathology benchmarking document of the CPCM does not mention the term 'communication therapy', but "expects that the threshold entry routes to the Speech Language Pathology Register will be a Bachelor's degree with honours in Speech and Language Pathology...." (p. 5). The local association also bears similar terms: Association of Speech Language Pathologists (ASLP).

The Royal College of Speech Language Therapists (RCSLT) in the UK celebrated its 75th anniversary in 2020 (Stansfield, 2020). Despite the consistent developments in the field, as well as the broadening of the role, the profession has retained the same name since then: Speech Language Therapy/Therapist. The use of such a term is significant in terms of professional identity for individuals working in this discipline, instilling a sense of collegiality between members of the same profession.

Terminology for the name of the profession varies in Europe and beyond. However, the name of the training programme generally matches the nomenclature of the profession in that country, e.g., 'Speech and Language Therapist' (nomenclature) and 'Speech and Language Therapy' (training programme in the UK and the Republic of Ireland); 'Speech Language Pathologist' (nomenclature) and 'Speech Language Pathology' (training programme in Canada and USA); and 'Terapeuta da fala' (nomenclature) and 'Terapia da Fala' (training programme in Portugal).

Inconsistencies in terminology must be addressed. They pose significant barriers to the development of the profession in different domains, including the profession's "advancement in research, clinical effectiveness, public image and political profile" (Walsh, 2006, p. 20). In summary, using the term "Speech Language Pathology" for a course leading to the profession of a Speech Language Pathologist is justified as it accurately represents the profession's scope, aligns with international standards, communicates academic precision, and contributes to the professional identity and recognition of graduates.

Other Highlights

Numerous opportunities for collaboration with different entities have been taken up by different members of staff within the department. Several COST (European Cooperation in Science and Technology) projects in related fields have seen the involvement of departmental members of staff, such as Dr Rachael Agius in COST action 'European Literacy Network' (ELN), and Dr May Agius in COST action 'Advancing Social Inclusion Through Technology and Empowerment' (aSTEP), and other collaborations have stemmed from past COST actions, such as the Collaboration of Aphasia Trialists (CATs, funded by the Tavistock Trust for Aphasia) with the involvement of Dr Ritienne Grima.

Other projects include Erasmus+ Cooperation partnerships in higher education (KA220–HED): "ExChange Of ExpertiSe in healthcare professionals' education" (ECHOES) (Prof. Helen Grech and Dr Rachael Agius), and a MCST–funded project "A User–Experiences Based Approach for Designing Connected Speech and Language Therapeutic Toys in a Smart City" (SALTT–

CITY), with Prof. Daniela Gatt and Prof. Helen Grech, in collaboration with the Faculty of Engineering.

More research through MSc (by research) and M.Phil/PhD is ongoing and tackles a range of areas, including "The language skills of 5–8–year–old bilingual children with a history of maltreatment: Implications for transdisciplinary trauma–informed intervention"(Estelle Zahra, supervised by Daniela Gatt) and "The Adaptation of an Aphasia Test for Maltese–English Bilingual Adults" (Lorraine Vassallo, supervised by Ritienne Grima).

Recent events hosted by the department also encouraged further collaboration, including the International Clinical Phonetics and Linguistics Association (ICPLA) conference and the Speech Language Therapy – International summer school coordinated by Dr Nadine Tabone.

Moving Ahead

The department will continue to evolve and aims to equip students with the theoretical knowledge and clinical skills required to develop into fully independent diagnostic professionals who engage in evidence–based practice. The programmes aim to stimulate intellectual development and encourage creative thinking, team building and collaborative practice. Additionally, research projects and case–based/problem–based and interactive learning opportunities allow students to develop their ability to critically appraise available literature and to foster an evidence–based approach to clinical work. The ultimate aim is to sow the seeds which lead to the development of accountable, caring and autonomous professionals, with attributes which are necessary for employability and personal growth, including collaborative practice, advocacy for the rights of people with communication and swallowing difficulties, awareness of ethical issues and of social/linguistic/cultural variations among colleagues and client/patient groups. In alignment with the best evidence base in the domains related to professional training and research, the department ultimately strives to bring about positive outcomes for the most important partners: the patients/clients and their significant others.

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Review Article

An Overview of Chitosan and Chitosan Oligosaccharides Applications in the Health Sector and the Food Industry

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Abstract

The therapeutic potential of natural compounds has piqued the interest of researchers due to their improved biocompatibility and sustainable origins. Chitosan, a derivative of chitin, has gained significant attention for its therapeutic properties and its wide–ranging applications in the food and beverage sector. Chitosan oligosaccharides (COS) are derivatives of Chitosan which often exhibit better biological properties than their parent compound, thereby amplifying interest in their potential benefits. Chitosan has a diverse set of biological properties including being an antimicrobial, antioxidant, and anti–inflammatory compound. Studies have elucidated how the specific chemical characteristics of Chitosan, such as the molecular weight and degree of deacetylation, influence these biological activities. Notably, a lower molecular weight and a higher degree of deacetylation tend to enhance the biological properties of Chitosan. Consequently, research has increasingly focused on exploring the potential of COS. Investigations into these compounds have unveiled promising applications in managing various conditions, including metabolic syndrome, diabetes mellitus (DM), hypercholesterolaemia, and obesity. Additionally, Chitosan and COS films and coatings have been developed and applied on fruits and vegetables, amongst other food products, with the aim of improving their quality, whilst increasing their shelf–life. Chitosan compounds have also been applied in the clarification process during the production of beers and wines. While substantial progress has been made, further research into Chitosan and COS is required in order to understand the mechanisms of their action and fully exploit their potential. This review highlights the gaps in research in the fields of medicine and food science regarding the use of Chitosan, providing a clearer understanding of its applications and guiding future research directions.

Keywords: Chitosan, Chitosan oligosaccharides, drug delivery, films and coatings

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1. Introduction

In recent years, there has been an increased interest in the therapeutic potential of natural compounds. The growing global concerns around sustainability are pushing major industries and corporations into considering more natural and biocompatible solutions to rising problems. Amongst various compounds researched, Chitosan, and its derivatives Chitosan oligosaccharides (COS), have been shown to be promising candidates due to their biological properties and their diverse application potential in various fields. Chitosan is a linear polysaccharide which can be derived from chitin, and is also naturally occurring in the cell walls of fungi and in the exoskeleton of insects and arthropods. COS are derivatives of Chitosan which usually exhibit better biological properties due to the increased solubility attributed to their structure (Tzeng,

Liu & Chiang, 2022). Recently, research efforts have been focused on understanding the pharmacological properties of Chitosan and COS, in an attempt to uncover their therapeutic potential against chronic diseases such as diabetes mellitus (DM), hypercholesterolaemia, and obesity, for which the traditional treatment often involves the administration of synthetic drugs (Jeong et al., 2019, Tzeng, Liu & Chiang, 2022). Such drugs, although beneficial in many ways, may bring about adverse effects to the individual and may also exhibit interactions with other medications. The natural origin of Chitosan suggests better biocompatibility compared to traditional treatment regimes. Chitosan and COS also have potential applications within the food and drink industry, particularly due to their antimicrobial properties. This review will mainly focus on the various applications of Chitosan and COS, whilst highlighting their potential as therapeutic agents and functional food additives.

2. Metabolic Syndrome and Related Conditions: Diabetes Mellitus, Hypercholesterolaemia, and Obesity

Metabolic syndrome (MetS) refers to a cluster of conditions which collectively increase the risk of several serious health conditions including cardiovascular disease, diabetes, and non–alcoholic fatty liver disease (NAFLD) (Ahima, 2024). Diagnosis of MetS can be made when at least 3 of the following conditions are present: elevated fasting glucose level (≥100 mg/dL), elevated systolic (≥130 mmHg) and/or diastolic (≥85 mmHg) blood pressure, elevated triglycerides (≥150 mg/dL), decreased high density lipoprotein (HDL) levels (<40 mg/dL in men or <50 mg/dL in women), and abdominal obesity (waist circumference ≥102 cm in men or ≥88 cm in women) (Fahed et al, 2022).

Diabetes mellitus (DM) refers to the chronic metabolic disease whereby the insufficient production and/or utilisation of insulin leads to elevated blood glucose levels (Banday, Sameer & Nissar, 2020). The International Diabetes Federation (IDF) reported that in the year 2021, an approximate 536 million individuals suffered from DM, with 6.7 million deaths being attributed to the disease (International Diabetes Federation, 2022). DM can occur as one of the following four types: Type 1 Diabetes Mellitus (T1DM), Type 2 Diabetes Mellitus (T2DM), Gestational Diabetes Mellitus, and secondary Diabetes Mellitus. T1DM is an autoimmune disorder whereby the insulin–producing pancreatic beta–cells are attacked by the immune system, thus administration of insulin is required to maintain blood glucose levels (Kahaly, Hansen, 2016). In contrast, T2DM typically arises due to acquired insulin resistance or inadequate insulin secretion; this may be caused by genetic predisposition and/or lifestyle factors including poor diet and nutrition, lack of physical activity, and smoking tobacco (Leahy, 2005). The symptoms of T1DM and T2DM are the same, but may be slightly less prominent in T2DM; these include increased feeling of thirst, more frequent urination, unintended weight loss, blurred vision, and fatigue (Banday, Sameer & Nissar, 2020). Gestational diabetes occurs in up to 14% of all pregnancies, late in the second trimester or early into the third trimester, and typically resolves itself after birth (McIntyre et al., 2019). Secondary diabetes is brought about due to onset of specific conditions or pathologies e.g., Cushing's syndrome – an endocrine disease which causes secondary diabetes (Nomiyama, Yanase, 2015). Untreated DM can lead to severe complications affecting various organs. Treatment for diabetes includes following a balanced diet and active lifestyle, and when necessary, administration of drugs such as insulin, insulin analogues, and glucose regulators (Zhao et al., 2020). Public awareness, early diagnosis, and education are crucial in addressing this global health concern.

DM is closely linked with various other conditions, including hypercholesterolaemia and obesity. The World Health Organisation (WHO) defines obesity as a medical condition characterised by excessive accumulation of body fat, typically resulting in a body mass index (BMI) of over 30 kg/m^2. This is distinct from overweight, which is defined with a BMI between 25–30 kg/m^2 (World Health Organization, Regional Office for Europe, 2022). Hypercholesterolaemia occurs when cholesterol levels in the blood rise above 190 mg/dL (World Health Organisation, 2012). The occurrence of diabetes mellitus, hypercholesterolaemia, and obesity increases the risk of developing cardiovascular diseases, such as ischemic heart disease, which is the leading cause of death in the Maltese Islands (European Observatory on Health Systems and Policies, 2023). Trends exhibit a rise in the number of obese individuals in recent decades, accompanied by an increase in the prevalence of T2DM. This phenomenon can be attributed to the adverse impact of obesity on insulin resistance and pancreatic beta–cell function (World Health Organization, Regional Office for Europe, 2022). Decreasing body fat through dieting

may enhance overall beta–cell function and potentially induce diabetes remission. Furthermore, reducing body fat could also lower blood cholesterol levels, thereby decreasing the risk of cardiovascular disease.

3. Chitin, Chitosan, and Chitosan Oligosaccharides

Chitin is a natural polymer found in the exoskeleton of insects and arthropods, and in the cell walls of fungi. It is a linear polymer consisting of repeat β–(1,4)–2–acetamido–D–glucose units (Tzeng, Liu & Chiang, 2022). Chitosan is a derivative of chitin having at least 50% degree of deacetylation (Rinaudo, 2006). Chitosan consists of a random assembly of β–(1,4)–2–amino–D–glucose and β–(1,4)–2–acetamido–D–glucose units connected via β–(1,4) glycosidic bonds (Nicolle, Journot & Gerber–Lemaire, 2021). The deacetylated units in Chitosan allow the primary amine functional group to be protonated, thus increasing its solubility in aqueous acidic conditions.

As the molecular weight of Chitosan increases, its solubility decreases due to the formation of intermolecular and intramolecular hydrogen bonds (Cheung et al., 2015). In contrast, chitin cannot be protonated due to the N–acetyl functional group, and is thus insoluble in aqueous conditions (Aranaz et al., 2021). The term Chitosan oligosaccharide (COS) refers to Chitosan having a degree of deacetylation higher than 90% and a degree of polymerisation lower than 20%, with a molecular weight less than 3.9 kDa. It is the result of enzymatic or chemical hydrolysis of Chitosan or chitin (Naveed et al., 2019). The higher degree of deacetylation of COS renders these compounds more soluble in aqueous conditions than Chitosan.

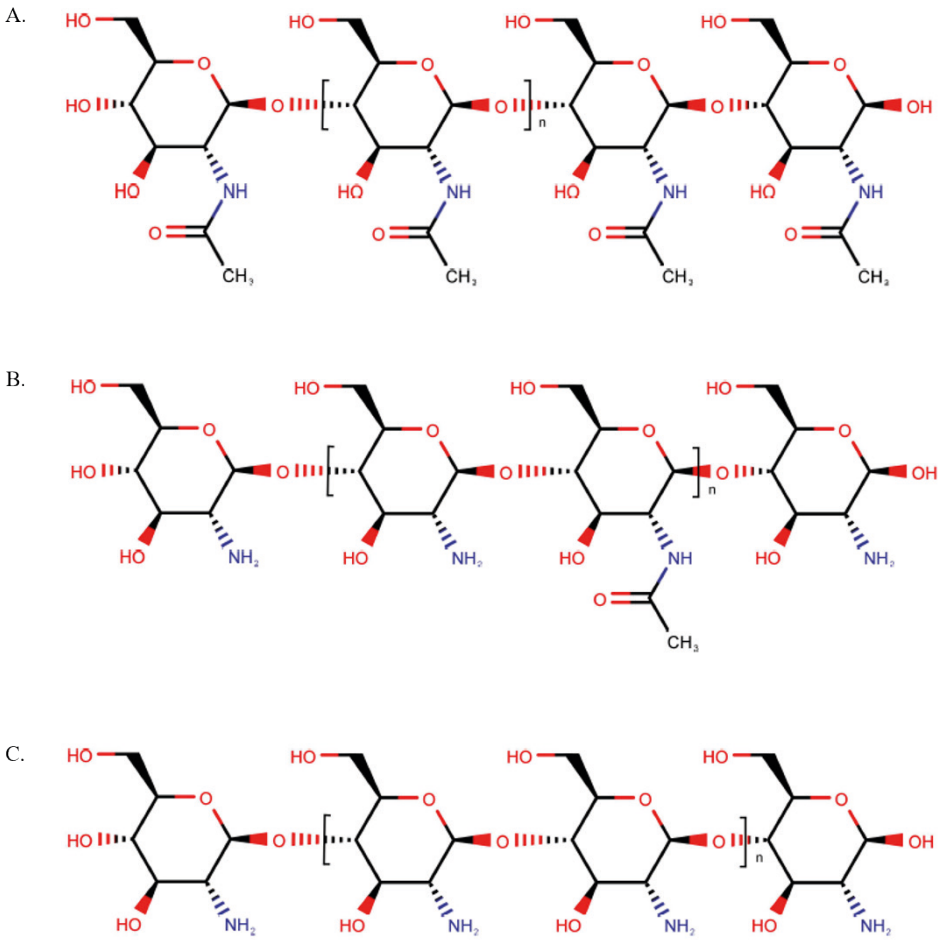

Figure 1: Chemical structures of (A) Chitin, (B) Chitosan, and (C) Chitosan oligosaccharides. Diagram was created using MarvinSketch version 19.3.0, 2019, ChemAxon (http://www.chemaxon.com).

The chemical and biological properties of Chitosan depend on its molecular weight, the degree of deacetylation, the degree of polymerisation, and the distribution of charges (Tzeng, Liu & Chiang, 2022). It is believed that Chitosan having a lower molecular weight (e.g., COS) has higher bioactive potential than its higher molecular weight relatives. An increase in the degree of deacetylation influences the distribution of the positive charge on Chitosan. Commercially available Chitosan typically has a degree of deacetylation between 70–90% as it exhibits more ideal biological properties (Chatelet, Damour & Domard, 2001).

4. Biological Properties of Chitosan and Chitosan Oligosaccharides

Chitosan and COS have an array of biological functions such as antimicrobial and antioxidant activities, as well as anti–inflammatory properties, rendering them good candidates for further research.

4.1. Antimicrobial Properties

The antimicrobial properties of Chitosan and COS depend on both the molecular weight of the polymers as well as the overall structure. Chitosan has the ability to disrupt bacterial cells through the interaction of the $-NH_2$ group on the β–(1,4)–2–amino–D–glucose subunit with the overall negatively charged groups on the outer cell membrane (Ke et al., 2021). Gram–positive bacteria have negatively charged lipoteichoic and teichoic acids protruding through the peptidoglycan layer covering the plasma membrane (Rohde, 2019). Gram–negative bacteria have a lipopolysaccharide layer encasing the outer cell membrane which contains negatively charged phosphorylated groups (Raetz et al., 2007). Both Gram–positive and Gram–negative bacteria are affected by both high and low molecular weight Chitosan and COS, as they disrupt the outer layers of the cell. Consequently, low molecular weight Chitosan and COS can penetrate the cell, directly impacting the synthesis of proteins and nucleic acids (Ke et al., 2021). Similarly, in fungi, low molecular weight Chitosan and COS are able to migrate into the cell and alter the synthesis of proteins and nucleic acids, as well as the activity of the mitochondria. Besides the mentioned mechanisms of disruption which Chitosan and COS exhibit on bacteria and fungi, these polymers are also capable of chelating to metal ions, thus preventing them from being absorbed into the cells, leading in nutrient deprivation (Rabea et al., 2003). The degree of deacetylation significantly effects the antimicrobial properties of Chitosan and COS. A higher degree of deacetylation implies a more positive charge on the overall polymer leading to a stronger interaction with the outer layers of the cell membrane of bacteria and fungi (Aranaz et al., 2021).

4.2. Antioxidant Properties

Exposure to an abundance of free radicals and reactive oxygen species (ROS) brings about oxidative cellular stress which may result in a number of complications by inflicting damage to cellular membranes, DNA, and proteins. Oxidative stress is considered to be involved in a number of conditions and diseases including neurodegenerative diseases such as Parkinson's disease and Alzheimer's disease (Jaffe, Mani, 2014). Some studies have suggested that Chitosan, as well as COS, may exhibit antioxidative properties due to the possession of an amino group and two hydroxyl groups which are capable of reacting with free radicals (Abd El–Hack et al., 2020; Pu et al., 2019). This gives Chitosan and COS a scavenging ability, meaning that they are able to neutralise free radicals and ROS present in biological systems. This occurs through the Chitosan or COS donating hydrogen atoms to the unstable free radicals, resulting in conjugated molecules (Abd El–Hack et al., 2020). It was found that lower molecular weight Chitosan and COS exhibit increased antioxidant activity, likely due to the inability of the short chains to form intramolecular hydroxyl bonds (Sun et al., 2007). This frees up more hydroxyl and amino groups which are in turn more readily available for radical scavenging. It was also found that an increase in the degree of deacetylation results in an increase in the antioxidant properties exhibited, therefore confirming that COS have stronger antioxidant capabilities compared to higher MW and more acetylated Chitosan (Pu et al., 2019).

Alzheimer's disease is a progressive neurodegenerative disorder involving neuronal cell dysfunction and death, and is characterised by cognitive decline, memory loss, and behavioural changes (Manohoran et al., 2016). Parkinson's disease is a progressive disorder involving the degeneration of neurons and the deficiency of dopamine, and is characterised by muscle rigidity and tremor (Tolosa et al., 2021). Glutamate–induced neuronal cell death is observed in both Alzheimer's disease and Parkinson's disease (Hao et al., 2017). Glutamate is an integral excitatory neurotransmitter in the central nervous system; however, accumulation of glutamate may result

in increased formation of ROS, neuronal injury and cell death (Hao et al., 2015). A study by Hao et al. (2015) demonstrated that the treatment of PC12 cells (neuronal cell line) with peracetylated Chitosan oligosaccharides (PACO) resulted in decreased ROS production, decreased lactate dehydrogenase (LDH) release, and reduced glutamate–induced cell death, in a dose dependent manner. This suggests an innate property of PACOs to reduce oxidative stress, thereby potentially slowing down the progression of neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease.

4.3. Anti–inflammatory Properties

The term inflammation refers to the changes resulting from the detection of a foreign species or injury to a particular site in the body. The physiological response of increased blood flow, release of inflammatory mediators, and recruitment of immune cells, contribute to the body's defence against the injury/infection (Lordan, Tsoupras & Zabetakis, 2019). The inflammatory modulating responses brought about by the administration of Chitosan are dependent on the structural properties of Chitosan (i.e., the degree of deacetylation and the molecular weight), as well as the dose administered, the model on which the data is recorded, and the presence of other pro–/anti–inflammatory co–stimulating agents (Hoemann & Fong, 2017). One of the molecules which is involved in the enhancement of inflammation is nitric oxide (NO) which is released in high amounts by activated macrophages (Chang et al., 2019). There have been conflicting results concerning the effect of Chitosan on NO production regardless of the molecular weight of the polymer (Oliveira Junior et al., 2012, Brodaczewska, Doligalska, 2013). Some studies have shown that the COS have a direct effect on the NO produced whilst others negate this statement (Ma et al., 2011, Wu, Tsai, 2007). In the study by Chang et al. (2019), the anti–inflammatory activity of various molecular weights of Chitosan and COS were assessed in terms of NO production. Results indicated that the use of higher molecular weight Chitosan inhibited the production of NO, whilst lower molecular weight Chitosan and COS promoted it (Chang et al., 2019).

The activation state of immune cells prior to the introduction of Chitosan also has an effect on the inflammatory response produced (Hoemann & Fong, 2017). Macrophages are polarised differently depending on their environment giving rise to various subtypes e.g., microbial lipopolysaccharides (LPS) trigger macrophage polarisation to the M1 subtype whilst the presence of interleukin 4 (IL–4) triggers macrophage polarisation to the M2 subtype. M1 macrophages trigger pro–inflammatory responses whereas M2 macrophages trigger anti–inflammatory responses (Yunna et al., 2020). The administration of Chitosan is thought to enhance the natural inflammatory response produced. Chitosan enhances the release of pro–inflammatory cytokines when macrophages are in the M1 state whereas when macrophages are in the M2 state, the release of anti–inflammatory cytokines is enhanced instead (Fong & Hoemann, 2018).

5. Applications of Chitosan and COS in Medicine

Chitosan and COS have a number of applications within the field of medicine. For the purpose of this review, a selected number of applications shall be discussed.

5.1. Medicinal Properties of Chitosan and COS

A number of studies have been conducted in animal models as well as clinical trials in humans, to assess the medicinal properties of Chitosan and COS in terms of treatment and management of various conditions including DM, hypercholesterolaemia, and obesity (Hayashi, Ito, 2002; Gautier et al., 2008; J.G. Kim et al., 2014; H. J. Kim et al., 2014; Chiu et al., 2015; Trivedi et al., 2016; Escárcega–Galaz et al., 2018; Huang et al., 2018; Totsuka Sutto et al., 2018; Jeong et al., 2019; Guo et al., 2020; Huang et al., 2020; Sheir, Nasra & Abdallah, 2021; Fatahi et al., 2022). The chemical properties of Chitosan, specifically the molecular weight and the degree of deacetylation, have a notable impact on the therapeutic effect produced.

Chitosan is thought to regulate lipid absorption and excretion by interacting with fatty acids through its amino group. Upon ingestion, Chitosan expands in the highly acidic conditions of the stomach and becomes more positively charged due to the amino groups taking on a H^+ ion. This positive charge on the amino group is then able to interact with the negatively charged fatty acids via hydrophobic bond formation, resulting in an interruption of the emulsification process (Ylitalo et al., 2002). The interaction of Chitosan with fatty acids inhibits their absorption through small intestinal microvilli, thereby increasing faecal excretion of lipids.

Administration of 500 mg of Chitosan five–times a day was reported to reduce the mean body weight of the overweight and obese participants by 3 kg without changes in their dietary habits (Trivedi et al., 2016). Administration of high molecular weight Chitosan showed resistance to the effects of high–fat diet induced obesity and supported the activation of AMPK which is involved in the downregulation of lipogenesis associated genes (Chiu et al., 2015). Supplementation with Chitosan was shown to successfully improve the total cholesterol levels and LDL–C levels thereby indicating a potential in ameliorating hypercholesterolaemia (Huang et al., 2018).

Low molecular weight Chitosan was shown to significantly delay the rise of blood glucose levels in genetically obese, diabetic mice (Hayashi, Ito, 2002). Similarly, administration of Chitosan oligosaccharide GO2KA1 supplement to db/db mice showed a significant reduction in blood glucose which is similar to that observed upon administration of acarbose (J.G. Kim et al., 2014). Acarbose is an anti–diabetic drug which functions in the gastrointestinal system, and thus is associated with the common adverse effect of gastrointestinal upset (McIver, Preuss & Tripp, 2024). Similarly to the findings of Kim et al. (2014), a clinical trial observed significantly lower blood glucose levels at 60 minutes of the test group of individuals having impaired glucose tolerance and fasting glucose, compared to the control group, when administering GO2KA1 (Jeong et al., 2019).

A clinical trial on individuals with prediabetes concluded that the supplementation of 1.5 g of GO2KA1 per day brought about a reduction in TNF–α, IL–6, and HbA1c (H. J. Kim et al., 2014). TNF–α and IL–6 are cytokines which contribute to the onset of inflammation and are known to have effects on the development of obesity and T2DM (Popko et al., 2010). HbA1c is a glycated haemoglobin which is chemically associated to blood glucose. Measurement of HbA1c gives an indication of the average blood glucose over a period of about 3 months, and is thus used to diagnose diabetes and prediabetes (Eyth, Naik, 2024). The results reported by Kim et al. (2014) support the anti–inflammatory properties of COS. An investigation into the effect of Chitosan on obesity in adolescents also found positive correlations between the administration of Chitosan and a decrease in body weight. The same clinical trial also recorded an improvement in glycaemic markers, indicators of obesity, and appetite related hormones following administration of 3 g/day Chitosan over 12 weeks (Fatahi et al., 2022). A meta–analysis of various clinical trials concluded that the administration of Chitosan has a positive effect on weight loss in overweight and obese patients (Moraru et al., 2018).

Additionally to the therapeutic properties of Chitosan mentioned above, some studies have also reported that the topical application of Chitosan may be beneficial for treatment of diabetic skin ulcers. The application of Chitosan–alginate nanoparticles on pressure induced skin ulcers in mice, once daily, was observed to improve the healing process (Sheir, Nasra & Abdallah, 2021). These Chitosan–alginate nanoparticles are small spherical particles composed of a combination of the two polymers. A human trial investigating the effects of Chitosan gels and films on DM–associated skin ulcers reported a significant improvement in the injury of all patients (Escárcega–Galaz et al., 2018). Another study which assessed the effects of a combination treatment of Chitosan and isosorbide dinitrate on diabetic ulcers reported an increase in the number of individuals who experienced complete wound closure following treatment, compared to the placebo group (Totsuka Sutto et al., 2018). Isosorbide dinitrate is a vasodilator, whilst Chitosan has anti–inflammatory properties. When combined, isosorbide dinitrate and Chitosan are able to shorten the inflammatory period such that the wound healing phase is initiated earlier on.

Other chitin derivatives have also been studied for their medicinal properties. Chitin–glucan is an insoluble natural polymer found in the cell wall of fungi. Research has indicated that the application of chitin–glucan as a component in creams and moisturisers increases the moisturisation process due to its water–binding capabilities (Gautier et al., 2008). Glucosamine is a compound present in cartilage; however, it can also be derived from chitin from the exoskeleton of crustaceans (Murray, 2021). Research has revealed that glucosamine was effective at reducing pain in osteoarthritis patients. A meta–analysis into this topic revealed that treatment with glucosamine did not raise any significant adverse effects or exhibit interactions with other medications (Vo et al., 2023). Studies related to the medicinal properties of Chitosan and other chitin–derivatives are summarised in Table 1.

Table 1: Research articles related to the medicinal properties of Chitosan and other chitin–derivatives

Sample size and Participants	Type of Study	Type of Compound	Dosage	Summary of Findings	Reference
6 male ICR mice and 24 male KK–A^y mice	Animal study	Low molecular weight Chitosan	0.05%, 0.2% or 0.8% water solution (as drinking water)	–Prevention of total cholesterol level increase in normal ICR mice fed a cholesterol–rich diet upon daily administration of Chitosan –Slight dose dependent anti–obesity action –Reduction in serum glucose and triglyceride levels	Hayashi, Ito, 2002
20 male patients	Clinical trial	1.5% chitin–glucan formulation	Topical application twice daily	–Formulation limits water loss – Beneficial for moisturisation and correcting functional maturation changes in skin	Gautier et al., 2008
30 C57BL/ksj–db/db(db/db) mice	Animal study	GO2KA1 Chitosan oligosaccharide	40 g/kg	–Reduction in body weight, fasting glucose and hba1c levels compared to control group	J.G. Kim et al., 2014
51 subjects with impaired fasting glucose or impaired glucose tolerance	Clinical trial	GO2KA1 Chitosan oligosaccharide	1500 mg per day	–Improved control of postprandial glycaemic response in prediabetic individuals –Decrease in pro–inflammatory cytokines	H. J. Kim et al., 2014
40 male Sprague–Dawley high fat diet induced obese rats	Animal study	Chitosan (MW: 560 kDa)	3%/5%/7% composition of diet	–Decreased plasma triglyceride levels –Down–regulation of Angptl4, MTTP, and apoe. –Indication that Chitosan supplementation may alter lipid homeostasis in high fat diet	Chiu et al., 2015
96 obese and overweight human participants	Clinical trial	Chitosan capsules	500 mg five/day	–Mean weight loss of 3 kg after 90 days –Improvements in anthropometric parameters, hba1c levels, and body composition –Improvement in Quality–of–Life score –No effect on lipid levels	Trivedi et al., 2016

Table 1: Research articles related to the medicinal properties of Chitosan and other chitin–derivatives

Sample size and Participants	Type of Study	Type of Compound	Dosage	Summary of Findings	Reference
8 diabetic patients	Clinical trial	2% Chitosan gel	Topical application every 48 hours	–All patients showed significant improvement –One patient showed complete healing of the lesion	Escárcega–Galaz et al., 2018
1108 participants	Meta–analysis	Chitosan	Various	–No adverse effect difference between placebo and Chitosan –Reduction of total cholesterol and low–density lipoprotein cholesterol levels	Huang et al., 2018
68 patients	Clinical trial	10% Chitosan gel	Topical application every 24 hours	–Increase in the total number of individuals who achieved total wound healing –Combination therapy showed better healing progression	Totsuka Sutto et al., 2018
37 subjects with either impaired glucose tolerance and impaired fasting glucose or healthy subjects	Clinical trial	GO2KA1 Chitosan oligosaccharide	500 mg daily	–Test group exhibited lower blood glucose levels and postprandial blood glucose levels compared to placebo group	Jeong et al., 2019
1473 participants	Meta–analysis	Chitosan	Various	–Improvement in glucose levels of diabetic and obese/overweight participants upon 1.6–3 g Chitosan supplementation per day for a minimum of 13 weeks	Guo et al., 2020
1130 participants	Meta analysis	Chitosan	Various	–Significant reduction in body weight and body fat –No major drug–related adverse effects –Improvement in body composition upon administration of dose >2.4 g/d for less than 12 weeks	Huang et al., 2020
24 male Sprague–Dawley rats	Animal study	Chitosan alginate nanoparticles	Topical application of 2 or 4.8 mg/day	–Improvement in the rate of skin healing rates with higher concentrations of Chitosan	Sheir, Nasra & Abdallah, 2021

Table 1: Research articles related to the medicinal properties of Chitosan and other chitin–derivatives					
Sample size and Participants	**Type of Study**	**Type of Compound**	**Dosage**	**Summary of Findings**	**Reference**
61 adolescents with overweight and obesity	Clinical trial	Chitosan	1.5 g twice/ day	–Improvement in lipid and glycaemic markers –Improvement in anthropometric indicators of obesity –Reduction in appetite–related hormones	Fatahi et al., 2022

Despite the diverse advantages of Chitosan, some adverse effects and safety concerns have been reported. The primary adverse effect to be reported in association with Chitosan is gastrointestinal symptoms including constipation, nausea, and flatulence (Ho et al., 2001; Pittler et al., 1999; Wuolijoki, Hirvelä, & Ylitalo, 1999). Another concern is allergic reactions, especially to individuals with shellfish or mushroom allergies. A study by Waibel et al., (2011) investigated the safety of Chitosan bandages in patients with shellfish allergies. This study found that none of the participants reported any symptoms after 24 hours and that 70% of participants were unbothered by the bandage (Waibel et al., 2011). Another study by Amaral et al. (2016) investigated the safety of Chitosan processed wine and reported that out of 13 participants with anaphylaxis to shrimp, only one individual had a positive skin prick test. Finally, although very rarely, Chitosan may exhibit moderate interactions with other drugs, particularly anticoagulants (Lorkowska–Zawicka et al, 2014; Huang, Sung, & Chiang, 2007).

5.2. The Role of Chitosan in Drug Delivery

The non–toxic and biocompatible properties of Chitosan make it an excellent candidate for drug delivery, ensuring minimal adverse effects when administered to patients. The biodegradability of Chitosan further contributes to this, since it is broken down by the body into harmless byproducts. An additional property of Chitosan which further implicates it as a drug delivery candidate is its mucoadhesive properties i.e., its ability to bind to mucosal surfaces throughout the body e.g., in the gastrointestinal tract. This enables for prolonged contact with the tissue, thus allowing adequate amount of time for drug release and absorption into the body.

Chitosan has been extensively utilised by the pharmaceutical industry as an excipient, particularly as a binder, a disintegrant and a granulating agent (Kumar et al., 2004). Another method by which Chitosan can be used as a drug deliverable is through the formation of films, hydrogels, and nanoparticles. This allows for prolonged release of the drug from the Chitosan–based delivery system, making such particularly important for drugs with narrow therapeutic windows. Hydrogels consist of large amounts of water trapped within a polymeric three–dimensional network; hydrogels can either be chemical or physical (Montembault, Viton & Domard, 2005).

Zhang et al. (2018) developed a hydrogel composed of Chitosan and hyaluronic acid, and loaded with β–glycerophosphate. When injected, this solution will turn into a gel upon reaching body temperature and is triggered to release the anticancer drug when in the presence of the acidic tumour environment. The hydrogel also demonstrated good affinity to the cancer cells (Zhang et al., 2018). Another promising strategy for cancer therapy is the use of Tamoxifen–loaded Chitosan nanoparticles for the treatment of breast cancer (Vivek et al., 2013). These nanoparticles are produced in such a way that the drug is released from the Chitosan in a pH responsive manner i.e., when the nanoparticles are near the acidic conditions of the tumour, the Tamoxifen will be released from the Chitosan and allowed to carry out its anticancer activity. A similar concept was applied in a study by Nokhodi, Nekoei & Goodarzi (2022) where, the use of hyaluronic acid coated Chitosan nanoparticles carrying Tamoxifen was able to have a more significant suppressive impact on cancer cells compared to the free drug at a higher dosage.

Cisplatin loaded Chitosan microspheres have also been developed as an administration method for the chemotherapeutic drug. The delivery of Cisplatin via Chitosan microspheres allows for the drug to be released

in a more prolonged manner compared to the free drug. In the study by Singh et al. (2012), the microspheres were inhaled, and drug release was initiated when the particles make contact with the tissue. In another study, injected Cisplatin–coated Chitosan nanoparticles were shown to produce a cytotoxic effect on human breast cancer cells (Sultan et al., 2022). Studies related to the use of Chitosan for drug delivery are summarised in Table 2.

Table 2: Research articles related to the use of Chitosan and its derivatives for drug delivery.

Drug Delivery Method	Summary of Findings	Reference
Injected Chitosan and hyaluronic acid hydrogel loaded with β–glycerophosphate	Release of drug in a temperature and pH dependent manner	Zhang et al., 2018
Injected Tamoxifen–loaded Chitosan nanoparticles	Release of the drug in a pH dependent manner	Vivek et al., 2013
Injected Tamoxifen–carrying, hyaluronic acid–coated Chitosan nanoparticles	Better cytotoxicity compared to free drug	Nokhodi, Nekoei & Goodarzi, 2022
Inhaled Cisplatin loaded Chitosan microspheres	Prolonged drug release	Singh et al., 2012
Injectable Cisplatin–coated Chitosan nanoparticles	Increase in cytotoxic effect on human breast cancer cells	Sultan et al., 2022

Although Chitosan holds significant promise for applications in drug delivery, several challenges hinder its full potential. The major issue of Chitosan is the variability in its quality and purity. The natural origin of Chitosan makes it difficult to control its degree of deacetylation and molecular weight, thus affecting reproducibility of drug delivery systems. The development of sustainable and reproducible production methods for Chitosan is essential to ensure consistent quality for medicinal applications.

6. Applications of Chitosan and COS in the Food Industry

The biological properties of Chitosan and COS allow for their extensive use in various industries, particularly in the food sector. Their natural composition and antimicrobial properties make them ideal candidates as food preservation agents. Numerous studies have been conducted to assess the effects of using chitin derivatives to produce films and coatings for covering various types of foods, including fruits, vegetables, meats, and cheeses (Zhang et al., 2023). The effectiveness of such films and coatings has been tested against a wide range of microbial organisms, including yeasts, moulds, *Staphylococcus aureus*, *Listeria monocytogenes*, and *Escherichia coli*, amongst others. A study by Coma et al. (2006) demonstrated that the use of Chitosan films as cheese slice separators was able to inhibit the growth of *L. monocytogenes* for at least 8 days. Another study showed that applying Chitosan as a coating for fresh strawberries protected the fruit from fungal attacks while preserving its characteristic attributes, including aroma, texture, and appearance (Pavinatto et al., 2020). Similar results were observed when coating Ricotta cheese surface with a Chitosan–whey protein edible film; in this case the coating was successful in delaying the acidification of the cheese and reduced the growth of microbial organisms, thereby improving its shelf life (Di Pierro et al., 2011).

The combination of the biological properties of Chitosan with other antimicrobial agents has also been looked into extensively, with essential oils being one of the most commonly explored compounds. One study found that the application of thyme essential oil–infused Chitosan coating on Karish cheese decreased both the total aerobic and total psychrotrophic bacterial counts as well as total yeast and mould counts (Al–Moghazy et al., 2021). Similarly, Sakr et al. (2022) observed that the combination of Chitosan and thyme essential oil was able to improve the shelf life of soft white cheese up to 4 weeks while maintaining the characteristic attributes of the product. Oregano essential oil–enriched Chitosan–casein edible films were able to increase the cold storage shelf life of cherry tomatoes whilst delaying shrinkage

and weight loss of the fruit (Roshandel–hesari et al., 2022).

Chitosan and COS also serve as functional ingredients and additives in the beverage industry. A study by Gassara et al. (2015) found that the addition of chitin and Chitosan to beer samples resulted in a significantly decreased turbidity both at a laboratory scale and an industrial scale. This research solidifies the use of Chitosan and chitin as flocculants or clarification agents, in the beer manufacturing industry. A similar concept is employed in the wine production industry where Chitosan has been found to improve the clarification and removal of undesired substances such as residual pesticides (Bornet, Teissedre, 2010). Chitosan is also considered to be an effective emulsifier due to its amphiphilic nature; it is often utilised in the production of ice creams and sauces (Thambiliyagodage et al., 2023). Another application of Chitosan is in the controlled release of fertilisers. Research has suggested that slow–release potassium by Chitosan nanoparticles may improve the soil properties including increased water conductivity and porosity (Kubavat et al., 2020). A summary of some studies using Chitosan in various ways in foods are presented in Table 3.

Table 3: Research articles related to the use of Chitosan in food applications

Type of Compound	Type of Product	Additives	Summary of Findings	Reference
Chitosan	Emmental cheese	–	–Complete inhibition of *Listeria monocytogenes* for at least 8 days –Decreasing bactericidal effect with time	Coma et al., 2006
Chitosan and whey protein	Ricotta cheese	–	–No modification of sensory characteristics –Delayed acidification of cheese –Reduction in microbial growth	Di Pierro et al., 2011
Chitosan	Karish cheese	Thyme essential oil	–Decrease in total aerobic bacteria, total psychrotrophic bacteria, total yeast and mould counts	Di Pierro et al., 2011
Chitin and Chitosan	Beer	–	–Higher turbidity reduction compared to stabifix and bentonite	Gassara et al., 2015
Chitosan	Strawberries	–	–No alteration in aroma, taste, texture or appearance of fruit –Good bactericidal and fungicidal activity for 1 week	Pavinatto et al., 2020
Chitosan	Sausages	Radish powder	–Inhibition of Gram–negative bacteria –0.25% Chitosan did not have an effect on the aroma of the food –Chitosan did not have an effect on pH during ripening	Ozaki et al., 2020
Chitosan	Ham	Basil essential oil	–Inhibition of changes in pH over storage –Decrease in growth of aerobic mesophilic bacteria	Amor et al., 2021

Table 3: Research articles related to the use of Chitosan in food applications

Type of Compound	Type of Product	Additives	Summary of Findings	Reference
Chitosan, sodium alginate, and carboxymethyl cellulose	UF soft cheese	Antimicrobial microcrystalline cellulose (AMCC) and probiotic strains	–Good antimicrobial properties against *Staphylococcus aureus*, *Salmonella* Typhimurium, *Listeria monocytogenes*, *Escherichia coli*, *Bacillus cereus*, *Aspergillus niger*, and *Aspergillus flavus*	El–Sayed et al., 2021
Chitosan and procyanidin	Cheese	–	–Improvement in cheese preservation –Improved characteristics of cheese compared to control group	Zhang et al., 2021
Chitosan and casein	Cherry tomatoes	Oregano essential oil	–Improvement in antifungal activity of film –Preservation of cherry tomatoes for up to 32 days –Potent antioxidant and antimicrobial properties	Roshandel–hesari et al., 2022
Chitosan	Soft white cheese	Thyme essential oil	–Acceptable taste and aroma –Extension of shelf life over 4 weeks of storage	Sakr et al., 2022

7. Regulations of Chitosan and COS in the Food Industry

The European Food Safety Authority (EFSA) considers Chitosan to be a novel food ingredient, meaning it is not consumed in significant amounts, and defines it as an exoskeletal component of crustaceans and a cell wall component of fungi, having a degree of deacetylation ranging between 60–100% and a molecular weight ranging between 3.8–20 kDa. The EFSA has assessed and published opinions on multiple research studies which investigate the characterisation and safety of Chitosan and other chitin derivatives. It is recommended that the daily intake of Chitosan does not exceed 3 g/day (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011). Other chitin–derived compounds, such as glucosamine, have different regulatory dosages. The daily recommended intake of glucosamine hydrochloride obtained from *Aspergillus niger* should not exceed 750 mg/day, whilst the daily intake of chitin–glucan obtained from the same fungi, should not exceed 5 g/day (European Commission, 2023).

8. Future Outlook and Concluding Remarks

The properties demonstrated by Chitosan and its derivatives, such as their antimicrobial and antioxidant properties, have been proven to have various effects on human life. Recent clinical trials have highlighted the efficacy of Chitosan in weight management, specifically in the treatment of overweight and obese individuals. These encouraging findings serve as an indication of the yet undiscovered properties and potential applications of Chitosan and COS. It is expected that future research will continue to explore such avenues, particularly in the treatment of lipid management disorders and the involvement of Chitosan in combination therapies for disease management. The information on long–term safety of Chitosan in humans is very limited, and thus more comprehensive studies are required in order to fully evaluate any potential chronic and toxicity effects which may develop over extended periods.

The integration of Chitosan and COS into the food industry is another ongoing area of exploration, with

researchers actively seeking new combinations of antimicrobials to incorporate into and improve Chitosan and COS films and coatings. Innovations in Chitosan–based antimicrobial agents and bioactive packaging technologies have the potential to transform food preservation practices and improve the overall quality of food products. It is possible that research in the area of Chitosan edible films and coatings for food products will expand further on the inclusion of other newly characterised natural antimicrobial compounds, as well as the incorporation of beneficial bacteria (i.e. probiotics) as a method of bioprotection and biopreservation. In order for such research to be carried out, it is necessary that standardised production and characterisation protocols are established such that experimental findings are consistent and reproducible.

In conclusion, the future of Chitosan in both medicine and the food industry looks promising. With the increasing emphasis on sustainability and environmental responsibility, biodegradability, and biocompatibility, Chitosan and its derivatives seem to be very promising for the food industry. Ongoing research and innovation are expected to unlock new therapeutic applications, enhance existing technologies, and address emerging challenges, contributing to improved health outcomes and sustainable food production and preservation practices.

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Conflicts of interest

The authors report no conflicts of interest.

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Research Paper

A Multicultural Force: The socio–professional experiences of migrant nurses in western countries

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Abstract

Nurses' globalisation and migration are not new trends. However, the retainment of foreign–educated recruited nurses seems challenging, in part due to socio–cultural differences, values and adaptation processes. These challenges often cause foreign–educated nurses to seek alternative resettlements to find a more adaptable place of work, which is socially, emotionally, and professionally more accommodating. Maltese healthcare is currently experiencing challenges in retaining foreign–educated nurses. This research aimed to explore the lived professional experiences of foreign–educated nurses in their new country of settlement and employment. For instance, their day–to–day adaptation and integration. This research has employed a qualitative approach, with the design methodology of a scoping review. A road mapping approach was used to develop emergent themes comprehensively. Five themes emerged: Language and Communication, Nursing Knowledge and Experience, Visible Minority, The Transition and Improved Working Environment. The themes were the result of the analysis of the professional, social, cultural and environmental factors which contribute to the experience of foreign–educated nurses. Cultural differences, awareness, adaptability, social–cultural expectations, relationships with colleagues and management support were determinants which influenced the experiences of foreign–educated nurses and, moreover, impacted their intent to continue working in a country or decide to search further. Nursing implications such as low retention and higher resignation, burn–out and patient risk were identified. For prospective nursing inquiry, exploration is recommended in areas of cultural awareness, team building, and managerial support, which may enable resilience and the propagation of global nursing values. This research brings a fresh, broad and diverse perspective to the topic of multicultural nursing.

Keywords: Foreign–educated nurses (FeNs), multicultural nursing–force, acculturation, nursing globalisation, patient safety, cultural awareness.

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Introduction

The world is ageing. In 2019, 703 million individuals were sixty–five years old or above (United Nations, 2019). Also, humans in the Western world live longer, whereby half of Europe is above 65 years old (United Nations, 2019). At the same time, the baby boomers have aged and continue to retire daily (McGreevy, 2012; Caulfield, 2020). Furthermore, chronic conditions and comorbidities are rising; this has caused a severe shortage and desperate need for healthcare professionals (HCP), especially nurses (Schilgen et al., 2017; United Nations, 2019; Stokes and Iskander, 2021). A remedy for Western countries has been recruiting foreign–educated nurses (FeNs).

However, there are financial burdens associated with international recruitment (Leone et al., 2016; Elliott, 2019). As a reference, the healthcare workforce accounts for five per cent of the global economic workforce, making it the highest share of cost in a single employment sector (Elliott, 2019). Similarly, in Norway, a high–income European union (EU) country, healthcare employment accounts for 20% of its total employment (Organisation for Economic Co–operation and Development, 2017). Moreover, the Maltese healthcare expense in 2014 was recorded at 9.75%, which was higher than the EU average of 9.45% (Azzopardi–Muscat et al., 2017). Hence, this denotes that only economically stable countries can afford to manage nurse shortages. The EU, consisting of economically stable countries, has massive recruitment of FeNs (United Nations, 2014; Braw, 2021). Examples of the countries include the United Kingdom (UK), Germany, Norway and the local (Malta) healthcare system. Unfortunately, however, no statistics show the total number of migrant nurses employed within the EU. The lack of statistics on FeNs also applies within the Maltese nursing workforce. Although a local journalist Sansone (2016), reported that one in ten nurses locally (Malta) were foreigners.

However, studies have identified that successful integration of FeNs into a country's workforce is complex (Leone *et al.,* 2016; Roth *et al.,* 2021). Common challenges include adaptation, communication, discrimination, and cultural differences (Stokes and Iskander, 2020; Roth *et al.,* 2021). Maltese healthcare struggles in retaining FeNs. In 2021, 140 foreign nurses left Malta for other destinations (Xuereb, 2021). This trend continued, whereby up to January 2022, the local nursing workforce had lost 600 FeNs (Meilak, 2022).

Achieving universal health coverage is dependent on the workforce's capabilities to meet the population's needs (Drennan and Ross, 2019; Sanner–Stiehr *et al.,* 2021). Workforce capability here refers to the nursing staff's cooperation, quality of patient care and improved outcomes. These capabilities are directly or indirectly influenced by factors such as working conditions and environment, social and emotional status, professional support, and colleague interaction (Kieft *et al.,* 2014; Drennan and Ross, 2019).

Evidence suggests nurses' experiences positively or adversely influence both the quality of care provided and patient outcomes (Iheduru–Anderson and Wahi, 2018; Balante, Broek and White, 2021). Although the above fact pertains to nurses generally, studies have demonstrated that foreign–educated and migrant nurses experience significantly more hostile working environments than their colleagues (Moyce, Lash and de Leon Siantz, 2015; Schilgen, Nienhaus and Mösko, 2020). Likewise, research suggests migrant nurses face unfriendly treatment from colleagues, patients, and organisations (Moyce, Lash and de Leon Siantz, 2015; Mitchel, 2022). Therefore, this research asks: What are the professional experiences of FeNs? What aids the socio–professional acculturation of FeNs?

Methodology

A scoping literature review was undertaken, because it allowed simultaneous exploration, summary, and dissemination of findings across bodies of existing evidence (Tricco, 2016). Inclusion and exclusion criteria established that the identified studies addressed the research questions. Therefore, only studies on migrant and FeN nurses who practice in countries other than where they were educated were included. Parahoo (2014) suggested that qualitative inquiry studies are best able to answer questions concerning human feelings. For this review, quantitative studies were excluded since this research aimed to explore human emotions rather than statistical or numerical data.

Diverse search terms were used to ensure that all relevant studies were appraised and included 'migrant nurses', 'foreign nurses', 'acculturation', 'socio–cultural' and 'experiences'. The search terms used in conjunction with Boolean Operators produced a plethora of articles, so filtering tools were applied to filter studies unsuitable for answering the research questions.

Results were limited to papers not more than ten years old, published in peer–reviewed journals, written in the English language, and search engine generated filters: ‘nurses’, ‘immigration’, and ‘foreign–educated’ were applied.

This produced six articles directly relevant to the research questions. The locations of which studies were carried out include, Malta, Netherland, Norway UK, Australia, and New Zealand h. A brief summary of the articles is found in appendix 2. All the reviewed articles were critically assessed for quality using the 'Critical Appraisal Skills Programme' (CASP) tool. A Prisma diagram was used to demonstrate a clear depiction of the inclusion and exclusion criteria of the research strategy (appendix 1). Each of the articles was read and

reread multiple times to become immersed in the data. After data immersion, Then the six steps road mapping approach was selected from multiple bodies of work to develop themes. (appendix 3). These six steps were applied to create, navigate, and maintain objectivity throughout the development of themes. Five themes were identified as collectively representing the findings of the selected literature.

Findings

1. Theme 1: Language and Communication

Language and communication were the main predictors of interactive experiences across all six articles. Although experiences varied distinctively, they were still interconnected. Whilst knowledge and command of the official language in recruiting countries were a standard requirement, communication challenges remained a significant obstacle in achieving team cohesion. Likewise, understanding cultural nuances, subtlety and response appropriateness determined communication experiences.

Dahl et al.'s (2017) study conducted amongst 144 FeN participants of 18 nationalities in Norway reported a juxtaposition involving communication and culture. In their study, two participants, a European FeN and an Asian FeN, addressed an impolite patient with contradictory cultural approaches. The European FeN with seriousness and irritation, whereas the Asian counterpart tackled the situation with a smile and humility. The example is open to interpretation. One could suggest that this emanates from a cultural perspective because perhaps Asian people are not confrontational, or even that this specific nurse is not confrontational. Alternatively, a biased perspective would assume that the Asian nurse is simply a non–assertive professional. Interestingly, all the six studies reviewed showed that FeN, especially those from third–world countries, were automatically considered non–assertive and as a result were treated as insignificant in their organisations. Similarly, Chok et al. (2018) outlined that social acceptance in the workplace is essential for FeN. Therefore, the nurse's communication choice of humility over assertiveness could reasonably be perceived to be a means to facilitate social acceptance.

Other determinants of communication outcome which echoed through all the reviewed studies included fluency, accent and understanding of the context of a given language. A FeN participant in the Brunton et al. (2019) study described how he was afraid to respond to a telephone call because he might not fully understand the callers' accent or terminology. Buttigieg et al. *(2017)* identified that the two–way communication process is a culturally diverse exchange, allowing learning to occur within a distinct group of individuals. However, as seen in Ham's (2020) study, assumptions hindered interactions from knowing each other. For example, in Ham's (2020) study, the FeNs did not participate in group conversation because they feared their language skills were insufficient to communicate fluently. On the other hand, Local Nurses (LcNs) felt that the FeNs showed a lack of interest, implying they were not ready to learn. The finding of Buttigieg et al. *(2017)*, conveyed a clear perspective of the FeNs fear of participating in conversations. The FeNs were disregarded if they made mistakes or did not fully understand a conversation or the context of a discussion.

Obrey's (2013) research sought to understand the experiences of FeNs in the national health service in England. Obrey's findings also highlighted communication challenges. However, he took the position that the fear of participation on the part of the FeNs was not because they lacked basic knowledge of the language. Rather, they required social integration, enhancing confidence and acculturation.

2. Theme 2. Nursing Knowledge and Experience

In the previous theme, fluency was assumed to quantify language knowledge. A parallel trend was observed in this theme, by which the nursing approach of the FeNs was postulated to classify nursing skills and knowledge.

Variations in nursing roles in the previous country of practice compared to the new places of practice affected the perceptions of both FeNs and LcNs. For example, drawing inference from Buttigieg et al. (2017), some FeNs thought certain roles, such as bathing patients, were beneath a qualified nurse's role. Such remarks caused disagreements between FeNs and LcNs, causing both nurses to fight to keep their own beliefs and norms. Dahl et al. (2017) also found differences in how patients' needs are met. For instance, a FeN believed that patients' families were in the best position to provide their relatives emotional comfort and that relatives could help her by feeding the patients. Such beliefs are rooted in cultural

values (Dahl et al., 2017). However, the FeN assertion dumbfounded LcNs, who argued that such roles are expected to be met by nurses.

In Brunton et al. (2018), a FeN discussed how she remained silent because her professional expertise and experience were never appreciated, and she risked losing her job if she argued with the ward manager. This was mirrored in Chok et al. (2017), whereby nurses felt disempowered, resulting from the negation of skill and lack of acknowledgement of nursing expertise. An example of skill repudiation was illustrated by Ham (2020) when a LcN asked a FeN if they knew how to insert a catheter. The LcNs assumed that FeNs nursing knowledge was primitive and not adequate for Western standards.

3. Theme 3: Visible Minority

Summation of the six articles has helped define discrimination as behaviour or manner of approach influenced by the physical appearance or perceived worthiness of an individual's position (Dahl et al., 2017; Chok et al., 2018). Also, cultural clashes, the need to prove and show superiority, be it culturally, economically, by religion, skin tone, or Western culture, influenced moral degradation (Buttigieg et al., 2017; Brunton et al., 2018; Ham, 2020).

3.1. *Team support and collaboration*

Buttigieg et al. (2017) found that FeNs are often chastised for minor misdemeanours by their colleagues and manager, as opposed to how LcNs are educated about appropriate approaches. A FeN explained a similar account in Obrey (2013). The FeN felt disillusioned by the amount of courtesy that most LcNs enjoyed whereas FeNs were always treated as inferior. Examples of favouritism included the amount of workload and peer support.

Chok et al. (2018) noted how a FeN was berated for allegedly not knowing the Western way of seeking help and learning. Ham (2020) also indicated inadequate peer support. FeNs were confident that service users would have been more trusting if their colleagues actively supported them. Hence, integration and building relationships with patients would have been more straightforward. Indeed, discrimination towards FeNs by the patient was consistent across all six articles.

3.2. *What should a nurse look like?*

A patient in Brunton et al. (2018) reportedly questioned the qualifications of a FeN because of their social–cultural background. Moreover, the patient claimed they had never seen an Asian nurse, only had servants with a similar physical appearance. Here the patient attributed being a non–Caucasian with menial jobs and a white individual worthy of being a qualified nurse. Likewise, LcNs in Buttigieg et al. (2017) discussed how some patients feared nurses of colour, predominantly dark–skinned FeNs. It is notable that FeNs who are Caucasian, thus white–skin tone, do not experience the same amount of discrimination and marginalisation endured by black FeNs. Three out of the six articles reviewed in this study, Buttigieg et al. (2017), Dahl et al. (2017) and Chok et al. (2018), had both Caucasian and dark–skinned or black FeNs study participants. Interestingly, the narratives of their experiences seemed to have varied depending on their skin tone and nationalities. The variations in their experiences included the quality and extent of professional satisfaction and autonomy, happiness, and social interaction. Overwhelmingly, the Caucasian FeNs experiences were more favourable than those of third–world and dark–skinned FeNs (Buttigieg et al., 2017; Dahl et al., 2017; Chok et al., 2018).

3.3. *Systematic organisational discrimination*

The Western FeNs in Brunton et al. (2018) argued the importance of nurses' ability to advocate for patients and form a therapeutic bond. However, patient advocacy was hardly an option for third–world FeNs because they lacked professional autonomy. More so, they could hardly advocate for themselves. Indeed, third–world FeNs were scared to report challenges to the management due to fear of deportation, reprimand, or being ignored altogether. Managerial fear was a shared experience across all the reviewed articles.

It could be postulated that systematic organisational discrimination is the foundation of third–world FeNs lack of assertiveness, autonomy, and feelings of inadequacy to take on patient advocacy roles (Obrey, 2013; Chok et al., 2018). For instance, in Buttigieg et al. (2017), the third–world FeNs were made to sign employment contracts that differed markedly from the terms and conditions of the LcNs. These contracts stipulated and legally asserted a stagnant career advancement (no professional progression), nor would they get paid beyond a fixed wage scale. These adverse experiences are argued to cause

physical, emotional, and social burdens in the personal and professional lives of the involved professional (Obrey, 2013; Dahl et al., 2017)

4. Theme 4: The Transition

Previous themes discussed the challenges experienced by the FeNs. This theme reflects the adaptation, creation of new reality, acculturation and process that guide a successful transition into a new working environment. In addition, this phase depicts coping strategies, role appreciation, being valued and multicultural team inclusiveness.

4.1. *Towards the new culture*

The study by Chok et al. (2018) was an integrative review, summarising past evidence of FeNs experiences to provide a clear and comprehensive interpretation of the phenomenon. Thus, it captured the migration story of the FeNs extensively. showing that FeNs knew the potential challenges yet proceeded with the migration journey with a positive mindset of overcoming future obstacles. Acceptance of diversity was stressed as the first integration process into a new culture (Buttigieg et al., 2018). However, FeNs seemed poorly prepared for cultural and environmental change across all the reviewed studies.

A FeN in Brunton et al. (2018) discussed her acculturation process as trying to adapt to different colleagues' points of view, stating that everyone is different. Another approach is a FeN who felt prepared to take the next step toward positive social and clinical experience after learning about the British culture from several unpleasant experiences (Obrey, 2013). These approaches seem practical compared to the avoidance and silence approach used by both FeNs and LcNs in Ham's (2020), which created unintended assumptions and prejudice. For instance, the FeNs and LcNs claimed separate tables during breaktimes, reducing the possibility to create team bonding. Additionally, their assumptions and prejudice included a superiority argument between Western and non–Western caregiving capabilities and professionalism.

4.2. *Feeling appreciated*

Feeling appreciated suggests a positive cultural and social integration, especially from patients. Obrey's (2013) exploration captured the emotional extent of patient appreciation when a FeN mentioned being thanked for their care. Buttigieg et al. (2018) also identified and highlighted appreciation factors, they indicated that foreign patients claimed feeling more at ease when cared for by FeNs.

Also, while support from fellow nurses and teammates could be an excellent means of acculturation and social integration, however scantly reported. Only three of the six reviewed articles, Buttigieg et al. (2018), Dahl et al. (2017) and Brunton et al. (2018), reflected team support. However, regardless of the differences between the FeNs and LcNs, they seemed to want the same thing, a safe, peaceful working environment.

5. Theme 5: Improved Working Environment

Factors contributing to an improved working environment could be divided into two groups. The first is Western advancement, and the second is acceptance of the new cultural environment. The attributes included quality equipment, continuing education, advanced nursing training opportunities and finding common ground with colleagues.

Dahl et al.'s (2017) research inquired about the perception of FeNs about their work environment. In their findings, FeNs accented to patient–centred care as a Western approach that aided a positive nurse–patient collaboration. Also, the possibility for continuous professional development was identified as a positive experience facilitator for FeNs (Dahl et al., 2017; Chok et al., 2018). Furthermore, positive social interaction was stated to enable a peaceful working environment. Nevertheless, some potentially significant limitations were noted in studies that were reviewed in this study. For example, a limitation to this scoping review was the minimal availability of local studies. It is thought that local studies might have provided more insight into the situation of FeNs in the Maltese context, which might have enabled tailored recommendations for Maltese healthcare.

Discussion

Nurses' globalisation and settlement of FeNs are currently bolstering the understaffed and ageing nursing population in the western world (OECD, 2019). Locally retention of FeNs is low compared to the resignation and outwards migration (Amaira, 2022). To exacerbate this,

locally educated migrant nurses seemed to have joined the trend of not working in Malta due to restrictions on the local employment conditions (Amaira, 2022).

Although adapting to a new culture is undoubtedly complex, the finding of this literature review has suggested that social acceptance into a new culture mediates positive experiences in FeNs, professionally and emotionally. Whereas, acculturation challenges seemed highly attributable to management, lack of structured adaptation processes and organisation culture inadequacies.

Education

Language education for FeNs merits significant attention because differences in terminology and pronunciation affect the comprehensibility of a conversation (Neff and Harman, 2013). At the same time, cultural education is emphasised as a core component of communication (Philip, Woodward–Kron and Manias, 2019; Gradellini et al., 2021). After all, cultural interaction includes nuances like the use of hand, colloquialism, and facial expression. Such cultural nuances are crucial for nurses, particularly if they need to interpret unspoken communication, including appreciation, concern, safeguarding issues, discomfort, or the need for immediate intervention (Neff and Harman, 2013; Azam and Roger, 2018).

On this note, the one–time language proficiency test during the recruitment phase of FeNs (as required locally) is questioned as to its sufficiency in addressing language challenges. Perhaps ongoing continuous language education and evaluation would enable new ways of using, relating and adapting to the Maltese cultural ways and norms. Additionally, targeting written and spoken language use in clinical and social contexts may help to overcome communication barriers (Muller, 2016; Séguis and Lim, 2020).

Continuous education of cultural competency

Culture is not static but constantly changing through interaction of individuals with different perspectives, values, skill sets, media, technology or organisation (Kaihlanen, Hietapakka and Heponiemi, 2019). Cultural competence (CC) is the accommodation, knowledge and application of multicultural flexibility and diversity (Cruz et al., 2018). CC taught in isolation is claimed to engender social stereotypes because it depicts traits of a specific group of people as stagnant (Lekas, Pahl and Fuller, 2020). For instance, associating poor infection control practices to third–world FeNs without considering the availability of resources, would be stereotypical until their practice is observed in a well–equipped working environment. Therefore, teaching cultural awareness to undergraduate nurses could be a way to achieve a comprehensive CC. Cultural awareness is the understanding that attitude, behaviour, and values are cultural attributes, however dependent on the consciousness of own culture (Jongen, McCalman and Bainbridge, 2018).

First, it is necessary to emphasise teaching cultural humility to nurses, possibly as part of graduate competencies (Foronda et al., 2022). For instance, a cultural module could be implemented within the undergraduate nursing course, starting with this group since nurses who have qualified for several years are less amenable to change. Although Hader (2013) noted that older generation nurses perceive change as hostile to their confidence and comfort, making them difficult to convince and teach, Vinkenburg (2017) argued that although diversity resistance is not unusual, such resistance can be mitigated through behavioural diversity interventions. The United Kingdom NHS has a workforce, training and education toolkit consisting of activities to enhance team collaboration, and creating acquaintances, published in 2009, however remined relevant till date (NHS, 2009). A similar approach could be employed to facilitate team acquaintance, staff collaboration, and team efficiency locally. For example, group coaching sessions about differences in working styles, problem–solving approaches, task comprehension and socio–cultural values. Finally, cultural education cannot stop at healthcare professional levels, but must include the patient and public, owing to the reported extent of discrimination endured by the FeNs from the patient.

Educating the public

Mass media could be utilised for public education by promoting appreciation of cultural diversity and inclusion of FeNs. Television, billboards and social media are examples of media employed for public education (Ventola, 2014). After all, media use is considered an influential correspondence of public information flow and engagement (Utengen et al., 2017).

The presentation of facts to correct misinformation about FeNs would be desirable. Factual evidence could be presented as a public campaign to counteract myth and assumptions that promote discrimination, prejudice, and stereotypes.

Management Institutionalised healthcare

Healthcare management provides leadership directions that include human resource management, recruitment and staff development (Thompson, Buchbinder and Shanks, 2012). Ideally, management would ensure staff and patient satisfaction, making managerial decisions vital in shaping organisational culture and performances (Thompson, Buchbinder and Shanks, 2012; Cox, 2019). However, because EU healthcare is institutionalised, social and cultural forces determine organisational cultures, thus provoking questionable equality (Darity, Hamilton and Stewart, 2015). Both Roux (2017) and Elias and Paradies (2021) postulated that EU healthcare institutionalisation is due to preserving the Western world's historical legacies. The Western world's historical legacies are deeply rooted in nation–building and discrimination through socio–cultural standardisation, classifying individuals using wealth, education, and race (Roux, 2017; Elias and Paradies, 2021). Nonetheless, diversity in healthcare is now a global phenomenon. Therefore, institutional management must recognise and act on improving nurses' workplace diversity (Stenhouse, 2021).

The ward manager's ethical and humanitarian role

The management closest to the nurses can champion diversity in healthcare, such as the ward managers (WMs). Acknowledging and acting on reported challenges faced by the FeNs could be an essential step toward achieving a healthy working experience (Moss and Sims, 2016; Archibong et al., 2019). Also, the adoption of a relational leadership style by WMs could promote a positive professional environment and emotional empowerment (Cowden and Cummings, 2015; Cardiff, McCormack and McCance, 2018). Furthermore, educational sessions, such as coaching, workshops and seminars organised by higher management could help the WMs to strategise their leadership style and skills. Nurses who receive managerial support have higher job satisfaction and emotional resilience, promoting nurse retention and improved quality of care (Chamberlain et al., 2016; Senek et al., 2020).

Since WMs are the closest management to nurses, they could adopt a humanitarian and ethical role of advocating for FeNs (Tuckett et al., 2015; Henriksen, 2016; Roger, 2019). The WMs advocacy role could include reporting the challenges and obstacles that hinder the FeNs professional actualisation, psycho–social harmony, and acculturation. The report should be directed to higher management to ameliorate the experiences of the FeNs, retention, and ultimately safe and improved quality of care.

Research

Evidence–based research ensures that the right questions are being inquired, explored, and demonstrate benefits to the field of practice (Schmucker et al., 2013; Robinson et al., 2021). Research recommendations on FeNs acculturation have encompassed analysis of cultural differences, mediators of racial relationships, and adaptation inquiries (Canales, 2000; Hurtado et al., 2012; Likupe, 2015).

Nevertheless, studies consistently identify the same disparities despite research into these recommendations. Consequently, the same recommendations were repeated in different forms in recent studies, such as communication mediation, cultural nuances, social integration, and emotional support (Viken, Solum and Lyberg, 2018; Balante, Broek and White, 2021).

Investigations into how multicultural education and racial equality can be implemented in varying levels of education might provide a means of efficient multicultural exposure. For example, introducing diversity in extra–curricular and social activities in the foundation stages of school (four to five years). Perhaps by researching and identifying the approaches to diversity education at a young age, the same approach could be replicated in teaching older students. Furthermore, teaching diversity to the general population could be a priming approach. For example, a dark–skinned FeN could represent a 'good' nurse in television or billboard advertisements. Furthermore, a population–specific inquiry is suggested to identify if any particular group of FeNs is more or less discriminated against or finds it harder or easier to integrate locally. Identifying FeNs ease

or difficulties of integrating might help create tailored acculturation programmes.

Practice

A nurse is an instrument of change who practises the art of therapy by forming positive relationships with individuals (Henderson, 2006). Likewise, nursing values encompass the salience of embracing individual uniqueness (Lim and Marsaglia, 2018). Nevertheless, social norm and conformation, in areas such as sexual orientation, gender, age, race, or religion, places the integrity of the nursing value under scrutiny (Levett–Jones and Lathlean, 2009; Schmidt, 2016; Markey and Okantey, 2019). Moreover, social conformation creates division as to who is considered socially appropriate as a colleague and a nurse. Therefore, it is appropriate to acknowledge that nursing education and ethics stress empathy and compassion as fundamental values (Nijboer and Van der Cingel, 2019; Council for Nurses and Midwives, 2020). Because the findings of this research call into question the actuality of much–touted nursing values, a desirable recommendation is to teach empathy and compassion. However, the reality is that maybe it cannot be taught (Hofmeyer et al., 2016: Walker, Quinn and Corder, 2016; Durkin, Gurbutt and Carson, 2018).

Challenges in nurses transitioning from one nursing environment to another or from new–graduate to registered nurses have received considerable research attention (Gordon et al., 2014; Powers, Herron and Pagel, 2019; Ohr, Holm and Giles, 2020). The often–reported challenges include burnout, socialisation issues, and lack of confidence in making clinical decisions. These obstacles are argued to cause transition shock, fear and feelings of incompetency (Clipper and Cherry, 2015). Consequently, strategies frequently employed to reduce the transition challenges include preceptorship, case scenario simulations, and orientation programmes (Edwards et al., 2015; Powers, Herron and Pagel, 2019). Hence, it is suggested that FeNs in the local healthcare are provided with preceptorship programmes.

Preceptorship programmes are recommended to last for three to twelve months, depending on the adaptation needs of FeNs (Lalonde and McGillis, 2017; Shinners et al., 2021). Nurses tasked with being preceptors must have cultural competency training to recognise cultural challenges and barriers. FeNs are disadvantaged due to their need to acculturate, apart from needing to adapt to a new working environment. Thus, shared ethical and moral nursing values should be practised through openness, tolerance, and respect to help realise a peaceful day to day working experience between LcNs and FeNs. Ultimately, nurses should strive to learn, accept and appreciate the diversity of their colleagues to create a prejudiced free interpersonal relationship (Maltese Nurses and Midwives Code of Ethics, 2020). A prejudiced free interpersonal relationship could be built by taking small steps, such as referring to colleagues' actual names; this signifies respect for individual uniqueness.

Conclusion

The determinants of FeNs acculturation are multifaceted, thus requiring determination, tolerance, and patience both from LcNs and FeNs. Significantly, it is found that the value given to individual uniqueness, be it cultural or just as a person, plays a vital role in creating positive or negative social and professional experiences.

Conclusively, there is every indication that for the foreseeable future, nursing will be dependent upon the migration of FeNs. Therefore, it is of crucial importance to prioritise the integration of FeNs.

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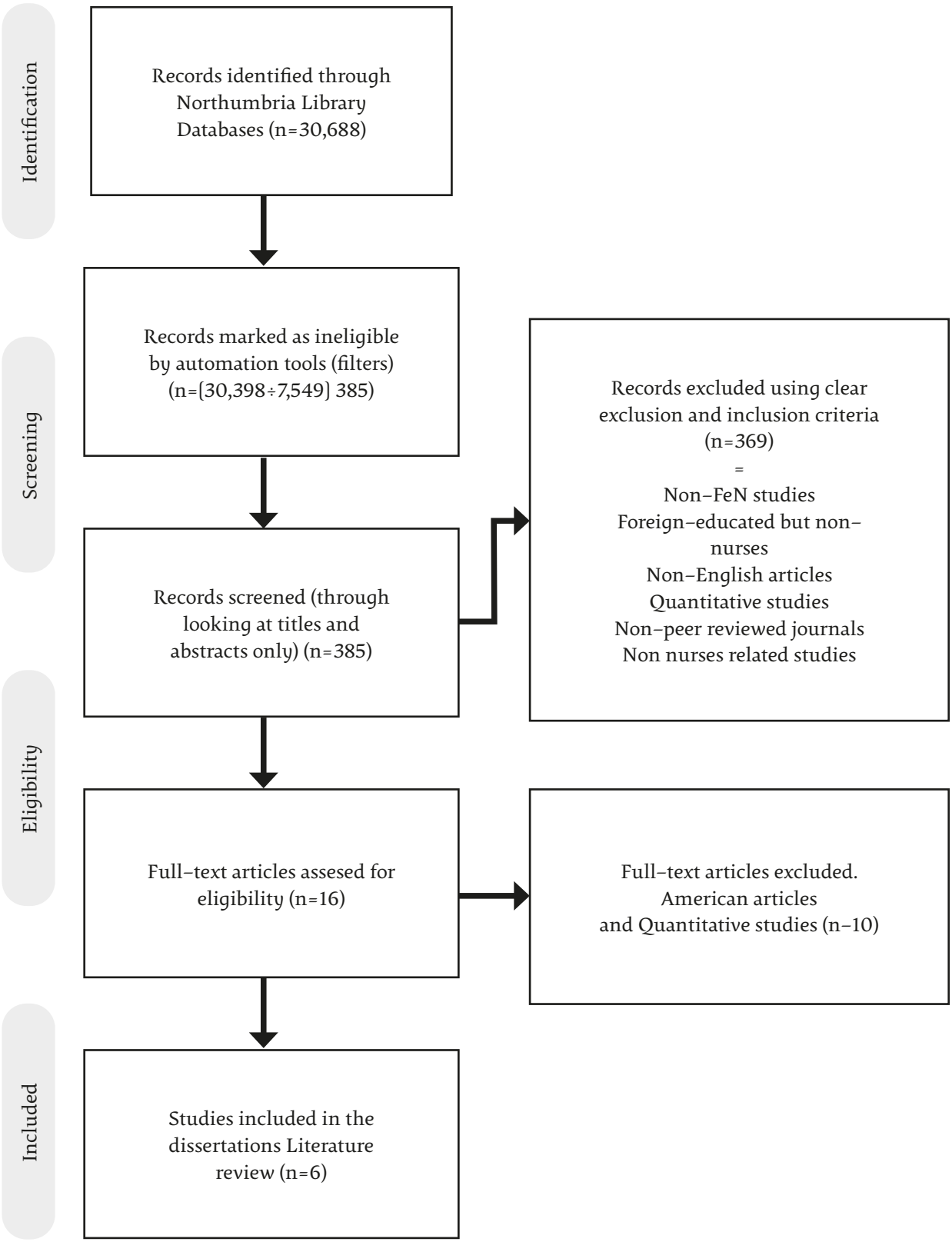
Conflicts of interest

The authors report no conflicts of interest.

Appendix 1: Prisma Diagram

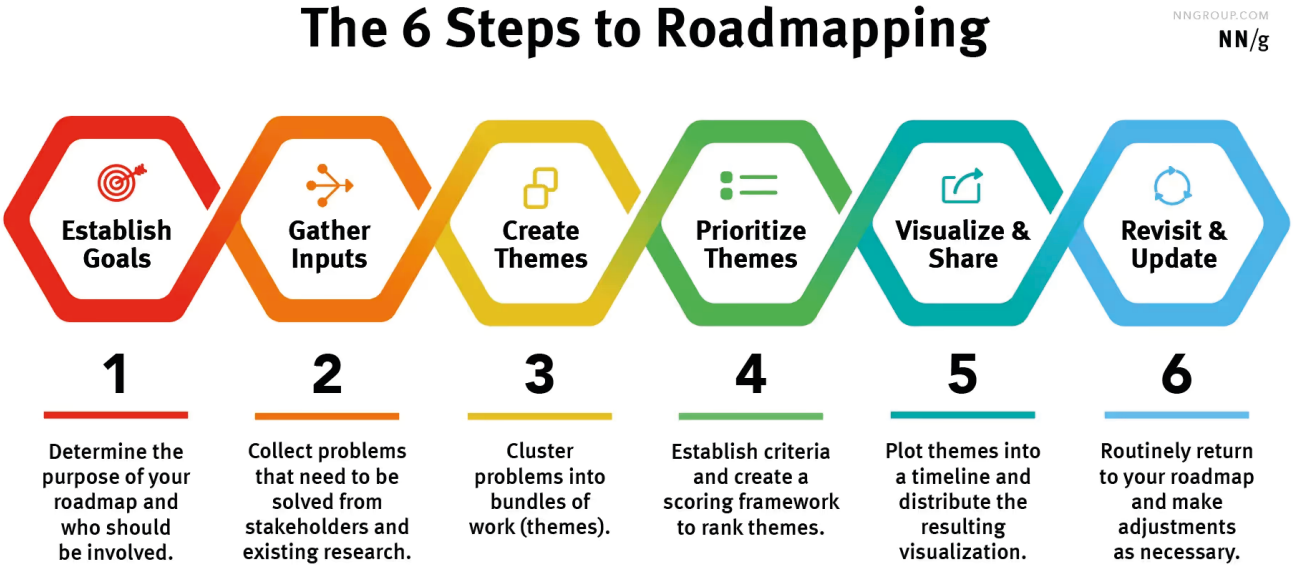


Appendix 2: Summary of articles

No.	Author and Year	Methodology	Aim	Findings
1.	Brunton *et al.* (2019)	Exploratory qualitative study	To compare the communication and practice experiences of migrant nurses in geographically distant, culturally dissimilar countries in Eastern and Western contexts.	• Language issues were dominant; respondents expressed disquiet about the exclusionary nature of using other languages both on and off the wards. • Cultural assumptions impacted power hierarchy, nurses' ability to advocate for their patients and practice independently • Cultural value clashes threaded through many of the critical incidents expressed by nurses • Challenges to professionalism; patients attitudes based on the expected socio–cultural backgrounds and roles of certain nationalities • Gender roles in each culture and how they create tension and nurses' ability to advocate for their patient
2.	Buttigieg *et al.* (2017)	Qualitative case study approach	To identify the extent to which immigrant nurses have integrated within the Maltese healthcare system.	• Immigrant nurses have helped relieve the reported shortage of nurses in the country. • The language barrier was a significant concern for all the stakeholders, hospital managers, the Maltese nurses, and the immigrant nurses. • Cultural differences may lead to both positive and negative outcomes. • Discrimination such as reprimanding for a minor misdemeanour, racism, lack of equal opportunities was evident towards the immigrant nurse.
3.	Chok *et al.* (2018)	Integrative review	An exploration of the literature on the factors that impact on internationally educated nurses' personal and professional experiences during their journey into the Australian health workforce.	• Adapting to a new culture, cultural shock, and the need to develop a new identity • Poor competencies in the English language created barriers and hindered transition resettlement • Discrimination and bullying at work caused loneliness hindered workplace interaction and professional advancement. • Personal support system, social support maximises the experience of integration • Improved working environment, workloads, better resources, and autonomy were identified as motivating factors.

No.	Author and Year	Methodology	Aim	Findings
4.	Dahl *et al.* (2017)	Qualitative design (social constructive perspective)	To explore how immigrant nurses, all educated as nurses in their home countries, experience working as a nurse in Norway	• the understanding of nurses' role as an independent professional, task orientation, efficiency, knowledge of skills and hierarchical • position as a healthcare professional (nurses being doctors assistants). • linguistic challenges • Discrimination • Collaboration using diverse professional experience and expertise promote integration and patient safety • Diverse approach to addressing challenges • possibility for professional development, nurses' autonomy, good working environment and availability of resources contributed to positive working experience
5.	Ham (2020)	Ethnographic method	To examine social processes affecting workforce integration of first–generation immigrant health care professionals in ageing citizens in a Dutch health institution in the Netherlands.	• presumptions about immigrant nurses professional capabilities caused tensions between immigrant nurses and the local nurses • Language barriers impact the inability to form a relation and function adequately as a team • discrimination and prejudice • the local nurses felt they needed to protect their territory • Lack of organisational support negatively impact the collaboration between local and foreign nurses
6.	Obrey (2013)	Phenomenology approach (Heidegger)	To gain an understanding of Internally Educated Nurses' experiences of working in the NHS in England.	• the fear of the unknown (moving to a new environment) • Language barrier • Cultural differences • Discrimination; loneliness, inequities, and marginalisation • Seeking support networks and coping strategies

Appendix 3: The Six Steps Road Mapping Approach



6 Steps to Roadmapping (from Gibbons, S. 2022)

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Research Paper

Maltese and Gozitan Parents Request more Professional Support during their Children's Autism Diagnosis Process

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Abstract

Services for children within the Autism Spectrum in Malta have been improving. One recent new development has been the screening for autism of all 18–month–olds. However, there is a continuing need for monitoring how families are being served. This study explored Maltese and Gozitan parents' experiences of the journey toward and following their child's diagnosis within the autism spectrum. The study adopted a qualitative approach. Semi–structured interviews were conducted with three Maltese and three Gozitan families whose children had been diagnosed in the previous five years. Three main themes were identified through reflexive thematic analysis of the data: Firstly, it was found that the parents had a hard time struggling to understand and accept their child's diagnosis, all being shocked and saddened by the diagnosis, although the experience was extenuated by the different parents' expectations and how the diagnosis was delivered. Secondly, parents felt a lack of emotional support during and after the diagnosis which they mainly found in sharing the challenge with other parents of children with autism. And finally, while all parents called for improvement of services and societal acceptance, Gozitan parents reported specific difficulties in obtaining support and suffered from stigma. The study highlights the importance of early screening and intervention together with more professional guidance and support for parents.

Keywords: autism spectrum condition, diagnosis, parents' experiences, support, services

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1. Introduction

A diagnosis of an Autism Spectrum Condition (ASC) is a complex process for both parents and professionals (Rabba, Dissanayake & Barbaro, 2019). This study is an attempt to understand the way parents experience the journey from concerns about the child's development to diagnosis and support. Despite improvements, parents still experience delays in receiving a diagnosis, causing frustration and delaying support for children on the spectrum (Zablotsky et al., 2017). Parents tend to opt for government or private routes depending on which has the shortest waiting time (Saggu, 2015). They express satisfaction when professionals exhibit expertise and empathy (Crane et al., 2016). However, professionals sometimes have difficulty communicating the difficult news to the parents (Bartolo, 2002).

In the last ten years, there has been a substantial increase in global rates of ASC diagnoses reaching an overall prevalence of 1 in 36 children aged 8 years (Maenner et al., 2023) (Here we use the term ASC because autistic adults feel the term 'autism spectrum disorder' is stigmatising – Baron–Cohen, 2017; Monk, Whitehouse & Waddington, 2022). Despite the presence of public services and several private services in Malta, there is

currently no official data available on the prevalence of autism in the local context (Azzopardi et al., 2023; Mubashir et al., 2020). Tanti Burlo' (2016) calculated a prevalence of autism of 1 in 52 births, while Prisms Malta (2020a) report a total of 7,700 people with autism in Malta. Screening programmes facilitate early detection of developmental difficulties, crucial for enhanced developmental outcomes through timely intervention (Delgado et al., 2023; Eisenhower et al., 2021; Thomas et al., 2016). Recently, a nationwide autism screening programme called *Lenti* was set up for 18–month–olds (Government of Malta, 2020). *Lenti* stemmed from a pilot project across Malta's health clinics, where 1500 infants were screened for autism, with 200 of them requiring subsequent follow–ups with professionals (Grech, 2017). The screening process involves asking parents a set of questions from the Modified Checklist for Autism in Toddlers (M–CHAT–R) (Robins, Fein & Barton, 2009). The geographical location of the family (urban versus rural), particularly the distance between the home and the available services may influence ASC screening and diagnosis (Antezana et al., 2017; Ashburner et al., 2016; Gona et al., 2016). Tightly knit rural communities may be reluctant to seek professional advice which is also scarcer in such areas (Mello et al., 2016; Strasser, 2003).

Parents experience stigma, shame and loneliness during the diagnostic process (Sakai et al., 2019; Tait et al., 2016). They also experience uncertainty and grief which could be linked to Kubler–Ross's (1969) stages of grief (Wayment & Brookshire, 2017). Most parents struggle with acceptance and may be driven by anger and frustration into helping their child (Mansell & Morris, 2004; Rabba, Dissanayake & Barbaro, 2019). Hence, parents may feel chronically tired (Burrell, Ives & Unwin, 2017; Camilleri, 2022).

Parents also consider whether to disclose the diagnosis and the consequences of doing so (Rabba, Dissanayake & Barbaro, 2019). For Maltese fathers, society's reaction to their child's atypical behaviours is a cause of concern and distress (Camilleri, 2022). Other major parental concerns revolve around the child's future and the financial burden of their child's autism diagnosis (Caruana, 2020; Shave & Lashewicz, 2016).

On the other hand, some parents feel relieved to have a reason for their child's atypical behaviour and to access support services (Rasmussen, Pedersen & Pagsberg, 2020; Russell & Norwich, 2012). Moreover, the diagnosis might shift the blame away from the parents and change perceptions of the child's behaviour (Jacobs et al., 2020).

Multidisciplinary diagnostic services have for long been offered in Malta by the Child Development and Assessment Unit (CDAU), but always with rather long waiting lists and with limited intervention. On the other hand, an autism specific assessment and education service has been provided by a non–governmental organisation (NGO) for the past three decades which is accredited for quality by the National Autistic Society of the UK, namely the Step programme of the Eden – now Inspire – Foundation (Borg & Bartolo, 2000). There are now also other NGO autism services such as Equal Partners, Hand–in–Hand, and the Malta Autism Centre though stakeholders still report a severe lack of resources and support services post–diagnosis (Azzopardi et al., 2023; Saliba, 2023). It has been found that the degree of tailored support received post–diagnosis strongly predicts parents' degree of satisfaction (Crane et al., 2016). This is often available only from alternative sources, including schools and support groups (Mansell & Morris, 2004).

Local studies indicate that support groups empower parents to participate in the community, despite the prevalent stigma in Maltese society (Bartolo, 2017; Camilleri, 2022; Spiteri & Borg, 2019). Ensuring adequate support and communication between parents and government service agencies remains a priority (Caruana, 2020). There is also a crucial need for the general public to embrace individuals with ASC as regular members of society (Bonnici & Bartolo, 2021). Recently, the St Jeanne Antide Foundation (SJAF, 2021) together with the Autism Parents Association – Malta (APA–M, 2019) provided a Social Integration Programme for Teens (SIPT) with autism. Other local NGOs such as Prisms Malta (2020b) also launched an Autism Friendly Spaces project aimed at empowering individuals with autism and promoting their participation in society.

Previous studies have mainly considered the perspectives of mothers or other actors, such as healthcare providers and society (e.g. Bonnici & Bartolo, 2021; Ciantar, 2018; Spiteri & Borg, 2019). The father's point of view and the experience of Gozitan parents has received little attention. Gozo is here regarded as a rural area given its comparatively lower population density – 1,948 vs 572 persons per square kilometre (National Statistics Office, 2022).

The present study attempts to answer the following research question: How do Maltese and Gozitan parents perceive their journey toward and following the diagnosis of their child within the autism spectrum? A better understanding of parents' experiences could enable the

improvement of existing services, inform the design of necessary supportive interventions for parents, and promote further autism awareness in Maltese society.

2. Method

A qualitative approach was adopted to acquire an in–depth, comprehensive understanding of the parents' experiences from their perspective (Creswell & Poth, 2018). Parents were encouraged to describe their understanding of the world through the social constructivist paradigm, which considers multiple realities and the context in which these realities are occurring.

2.1. Participants

Participants were three Maltese and three Gozitan parents whose children had been diagnosed within the autism spectrum in the previous five years. They were recruited through the two parent associations: *The Voice for Inclusion Association Gozo* and *Autism Parents Association Malta*. Both parents of each child were invited but only two of the six couples consented to be interviewed together, one couple from Gozo and one from Malta; the other four interviewees were mothers.

2.2. Data Collection

Semi–structured interviews were formulated after consulting the literature (Appendix 1) (Robert–Holmes, 2018). Initial questions about background information were followed by three sets of questions about the parents' journey and response to the diagnosis and the support given during and after the diagnosis. Finally, the parents were encouraged to comment on any other relevant issues (Denscombe, 2014). A pilot interview was conducted with one of the parents to ensure an adequate schedule (Creswell, 2013), but few amendments were required and so the pilot data were incorporated into the findings (van Teijlingen & Vanora, 2002). All participants chose to be interviewed in Maltese via *Zoom* and preferred to turn on their cameras but were only audio–recorded. Each interview lasted around 45 minutes.

2.3. Data Analysis

The data were analysed following the six phases of reflexive thematic analysis (TA) (Braun & Clarke, 2022). First the first author immersed herself in the data by actively and repeatedly listening to the audio recordings. All interviews were then transcribed verbatim in Maltese and those extracts quoted in the text were later translated into English. All data were inductively analysed by coding each segment into different topic areas. The coded extracts in each category were then developed into fewer subthemes. These were explored with the second author and reorganised into the final theme clusters. The themes were again reviewed by both authors, defined and named succinctly and accurately (Braun & Clarke). To ensure validity, particular attention was given to differences in the parents' experiences. Similarly, in the final step, the themes were described and interpreted in light of the research questions with use of "rich, thick descriptions" (Creswell & Poth, 2018, p.263).

2.4. Ethical Considerations

Ethical approval was obtained from the Faculty Research Ethics Committee (FREC) at the University of Malta (Reference Number SWB–2022–00158). Prospective participants were presented with an information letter by the gatekeepers. Written consent was provided before participation. Confidentiality was ensured throughout the study. Care was taken to reduce any distress that might arise as the parents recalled their experiences: none of them felt the need to make use of the list of psychological services provided.

The first author had previously worked with children on the autism spectrum and, therefore, actively bracketed her experience to ensure a full focus on the participants' own experiences: a reflective journal of her subjective processes was discussed with her supervisor.

3. Findings and Discussion

The participants' contexts and characteristics are presented in Table 1. All the autistic children of the participating families were boys with an average age of 5:06 years for those from Gozo, and 4:03 years for those from Malta.

Table 1: Participants' Characteristics				
Participants (Pseudonyms)	**Place of Residence**	**Child's Age**	**First Referral for Diagnostic Assessment**	**Age at Diagnosis**
Amanda	Gozo	6 yrs	Lenti Screening	3 yrs
Claudia	Gozo	4 yrs	Speech Therapist	2:06 yrs
Tony & Mary	Gozo	6 yrs	Lenti Screening	2:09 yrs
Ruth	Malta	3 yrs	Speech Therapist	2:06 yrs
Stella & Mark	Malta	7 yrs	Speech Therapist	2:06 yrs
Viv	Malta	3 yrs	Lenti Screening	1:06 yrs

Table 2 presents an overview of the three main themes, subthemes and codes identified in the data: the first theme captures the struggle parents went through from an initial period of concern about their child's development to the emotional struggles at diagnosis; this is followed by the parents' challenges in their search for support to meet the child's needs; the third theme highlights the limitations families in Gozo had in accessing services and feeling accepted in the community.

Table 2: Overview of the main themes, subthemes and codes		
Themes	**Subthemes**	**Codes**
Struggling to Understand and Accept their Child's Diagnosis	New impact of screening but most alerted through child's atypical behaviours	First signs that led them to search for an explanation
		Search for professional advice
	Diverse reactions to the first communication of the diagnosis	First communication of a diagnosis
		Explaining away the difficulties
	Support or hindrance from family and friends' reactions	Initial reactions to the diagnosis
	Numerous worries and challenges encountered	Parents' initial concerns
		Main challenges faced; financial challenges

Table 2: Overview of the main themes, subthemes and codes

Themes	Subthemes	Codes
The Importance of Support During and After the Diagnosis	Parents' need for more professional support	Support accessed or the lack of it; professionals, family, friends
	Family and friends offering support to the best of their abilities	
	Different degrees of support from school personnel	Varying support from school personnel
	Immense support from other parents with a child diagnosed with ASC	Search for help from other parents with a child diagnosed with ASC
Common and Different Experiences of Gozitan and Maltese Parents	Stigma felt strongly in Gozo	Need for more awareness and understanding of ASC
	Limitations experienced by Gozitan parents due to a lack of specialised services in Gozo	Lack of services in Gozo; injustice towards the Gozitans
	Parents call for a more holistic support process	Suggested changes to be made in the process
		Lack of autism friendly spaces and activities

3.1. Struggling to Understand and Accept their Child's Diagnosis

Five families reported preoccupations about their child's failure to reach developmental milestones, while one family was first alerted through the screening programme *Lenti*. All reported feeling shocked on receiving the diagnosis though expectations and the way it was delivered made a difference.

3.1.1. *New impact of screening but most alerted through child's atypical behaviours*

Three of the parents, who all had tertiary education, started noticing atypical behaviours at an early age, including the child not responding to their name, not playing with blocks and, in one case, faecal smearing. This led Ruth and Stella to seek a speech therapist who then referred them to the CDAU. Well–educated parents are more likely to discern the signs of ASC and seek professional help (Malik–Soni et al., 2022; Rutherford et al., 2018). A new development in the experience of three families (Amanda, Viv, Tony and Mary) was the introduction of a screening programme (*Lenti*) for 18–month–olds (Government of Malta, 2020). However, Amanda and Tony and Mary saw the screening result as a confirmation of their suspicions about their child's difficulties which had also been raised by the childcare educator: "Don't you realise that this boy is in space?" (Tony). However, Viv, whose son was identified by *Lenti* at 1:06 years, was surprised and rather shocked to be told her son had developmental difficulties. This highlights the importance of screening programmes for early identification (Delgado et al., 2023; Eisenhower et al., 2021; Thomas et al., 2016), but at the same time serves as a caution about how screening results should be communicated to the parents.

3.1.2. *Diverse reactions to the first communication of the diagnosis*

Families differed in struggles for clarifying their child's difficulties, also reporting delaying influences of professional and relatives' suggestions. Tony followed the paediatrician's advice and allowed time to pass. Similarly, the speech therapist advised Stella and Mark to "wait, wait and wait". Relatives were reported to particularly try to explain away the difficulties even after the diagnosis: Mary reported that the child's grandfather

argued that her son would heal from ASC. Similarly, some of Viv's relatives stated that her child would grow out of it in a year. Amanda said that the grandparents were in denial, and she was blamed for giving the child "every vaccination there is under the sun".

On the other hand, most parents then found the CDAU process as too slow and sought assessment by a private psychologist. In fact, only Amanda and Stella received the first communication of their children's diagnosis from the CDAU. Claudia had even ignored the referral to the CDAU and went directly to a private psychologist in Gozo. Saggu (2015) too found that parents generally prefer to take the diagnostic path requiring the least amount of waiting. A delay in the time between parents seeking professional advice and receiving a diagnosis was also reported by Crane et al. (2016).

It is striking that, despite harbouring suspicions about their child's difficulties, four families reported being shocked when they received the diagnosis and written report from private or state psychologists (Amanda, Claudia, Ruth, Tony & Mary). For Amanda it was "a very big trauma": the psychologist held the parent interview in an unsuitable room and with the child present, and then she received the report without the psychologist attending the case conference. Even though Stella and Mark had already been told by the paediatrician at the CDAU that their child had a high risk of ASC, they were saddened by the psychologist's confirmation. Dissatisfaction with professionals' inconsideration in communicating the diagnosis has indeed been widely reported (Crane et al., 2016). However, Mary and Viv, though still shocked, said that they were at the same time relieved to be given a reason for their children's tantrums.

Three parents (Ruth, Amanda, Stella and Mark) reported that they spent a long time, from weeks to years, crying after the diagnosis, and they still experience sadness when they see their child struggling or experiencing a meltdown:

> *You always go through the cycle of anger, despair, grief. You go through the whole cycle and the problem is that it does not stop; you go through it over and over again because there are instances when you remember certain things. (Amanda)*

Despite the constant struggles and uncertainties, all participants stated that they were now taking life day by day while doing their utmost to help their child progress (Camilleri, 2022; Mansell & Morris, 2004). Mark also highlighted the importance of acceptance:

> *Listen, I think the medicine for all this to pass is to accept that your son has a condition and has a problem, and you have to accept it, because if you do not accept that, you will be devastated.*

3.1.3. *Support or hindrance from family and friends' reactions*

Positive or negative attitudes of relatives and friends were deeply felt by the parents. Two families (Claudia, Tony & Mary) stated that the news of the diagnosis also shocked their relatives. Claudia's son was the first in the family to be diagnosed with ASC and was seen as the "black sheep". Amanda's relatives, including her husband, "were constantly in denial", though after the diagnosis they "finally realised and then they decided to help". Even when there were already relatives with ASC in the family and so there was more acceptance, Stella and Mark still felt that not everyone understood their situation or how difficult it was to constantly experience it. Rabba, Dissanayake and Barbaro (2019) noted that acceptance by relatives is helpful for parents.

3.1.4. *Numerous worries and challenges encountered*

Parents' most daunting thoughts revolved around their child's independence and future once they were no longer around:

> *Your plans fall apart before your eyes and you feel disillusioned and you start to question, what will the future be like? (Tony).*
>
> *You go through the process of the death of your unborn child when you have the diagnosis of autism. And that was the hardest thing, you have to forget all the dreams that you had for these children and start accepting that you do not know what will happen to these individuals (Amanda).*

Claudia, Ruth, Stella and Mark were also worried whether their children would manage to make friends or end up isolated. All the parents shared concerns about their child's future and were motivated to promote their child's "independence". There was no reference to "autonomy" (Burrell, Ives & Unwin, 2017; Camilleri, 2022; Rabba, Dissanayake & Barbaro, 2019), perhaps because of the confounding of the two terms in Maltese.

Meanwhile, managing their child's behaviour was also difficult. For some parents convincing their child to venture outside their home was the most challenging task, especially following the COVID–19 pandemic. This challenge was exacerbated by society's reaction to the child's behaviour (Camilleri, 2022).

3.2. The Importance of Support During and After the Diagnosis

The parents' experience was made worse because of the lack of adequate services and support.

Tony and Mary said their greatest challenge was gaining access to the best services for their child, which required them to navigate the educational and government system which "on paper is perfect, utopia, but in reality, it devastates you". Moreover, five families commented about the expense of private services, with every private psychological report costing a minimum of three hundred euros. In some cases, there were unforeseen financial setbacks. Ruth and Amanda emphasised the need for further public financial support (Caruana, 2020; Shave & Lashewicz, 2016).

3.2.1. *Parents' need for more professional support*

In the first place, parents missed sensitive professional practice. Mary reported that when she needed the most support, an insensitive professional told her that her child would be unable to find a job. Although her child received some support from the CDAU during the diagnosis, Amanda found no psychological support for herself as a parent. This was similar to Claudia, Viv, Tony and Mary's experience, though Viv put the responsibility on herself:

> *No one came to talk to us, kind of that person that would be a contact point, which calms you down and prepares you gradually for what is coming next for you. (Tony)*
>
> *I just went through it alone…ideally there is more help and more emotional support. Maybe in reality I am supposed to look for more support. (Viv)*

The lack of adequate professional support and communication has been reported in other Maltese studies (Camilleri, 2022; Ciantar, 2018; Spiteri & Borg, 2019) and in the international literature (Crane et al., 2016; Kiami & Goodgold, 2017; Mansell & Morris, 2004).

3.2.2. *Family and friends offering support to the best of their abilities*

Some family members took care of the children as a form of support (Claudia, Ruth, Tony and Mary), which the participants found crucial (Camilleri, 2022). However, because they were not knowledgeable about ASC, the parents felt family members could not provide emotional support:

> *At times you end up not saying anything, you keep going your own way, which means that you are ready not to search for support because you know it will be even more frustrating when trying to search for it. (Mary)*

Apart from family, Stella and Mark received considerable help from their friends, who work in the education sector and informed them regarding support services.

Amanda greatly appreciated her friends' solidarity when they "tried to offer support by pushing their children to play with ours. But obviously, it does not always happen".

3.2.3. *Different degrees of support from school personnel*

Five families reported receiving support from school personnel, particularly from the early learning support teacher and the learning support educator (LSE). Amanda, Tony and Mary considered themselves lucky to have found supportive school personnel:

> *Nowadays, they attend a government school in Gozo, and I thank God that they are very well–adapted and suited for autistic needs. (Amanda)*

In line with this, Antezana et al. (2017) and Mansell and Morris (2004) found that families, particularly those living in rural areas, tend to rely on schools for support.

Conversely, Tony said, "I know for certain that some teachers do not want children with autism in their class" and Mary added that such teachers make considerable efforts to avoid teaching these children. Such unwelcoming approaches associated with stigma were also reported by Bonnici and Bartolo (2021), Camilleri (2022) and Spiteri and Borg (2019).

3.2.4. *Immense support from other parents with a child diagnosed with ASC*

Five families stated that other parents with a child diagnosed with ASC whom they met in various settings (local village, school, therapists, NGOs), supported them:

> *Those who are in the same boat as you, are the greatest point of refuge and the greatest support you can receive, because they can understand what you are saying with their eyes shut. (Mary)*
>
> *The work that is supposed to be done by the professionals, or that contact person that does not exist, is being compensated for by these (parents). (Tony)*

This concurs with the finding that parents seek alternative sources of support when professional support is inadequate (Mansell & Morris, 2004).

Viv was the only parent who did not know any other parents with a child diagnosed with ASC since she did not socialise often.

3.3. Common and Different Experiences of Gozitan and Maltese Parents

The experiences described in the above themes were common across Maltese and Gozitan parents. There were, however, some additional challenges for the latter.

3.3.1. *Stigma felt strongly in Gozo*

Five families reported the need for more awareness and understanding across numerous sectors of society:

> *At times I get tired of justifying my son, I feel that I do not have to…but that is society; society sees him as an outcast. (Stella)*
>
> *Our society, in general, is not yet ready to accept them and give them what is rightfully theirs. (Tony)*

Tony referred to a recent discussion about ASC in the Maltese Parliament where it became apparent that some members were unaware of any research conducted in Malta in this field. The parents themselves, including those with a tertiary level of education, also reported that initially they, and their relatives, were not well informed about ASC. But they were also concerned that childcare workers, school personnel and students at every stage of education were not adequately aware of issues of diversity and inclusion.

Societal stigma did not help and was felt strongly in Gozo. Amanda was preoccupied with how friends would react to the news. She was concerned that many of her friends who were LSEs might end up working with her child. Tony and Mary did not tell their friends about the diagnosis since they were concerned that their child would be labelled. However, due to the closely–knit Gozitan community, they were aware that their friends "knew everything" but pretended not to. The link of stigma and shame to an ASC diagnosis was also reported by Sakai et al. (2019) and Tait et al. (2016). Stigma has been noted to be generally higher in the smaller Gozitan community (Bartolo, 2017).

3.3.2. *Limitations experienced by Gozitan parents due to a lack of specialised services in Gozo*

Gozitan parents reported a number of limitations, mostly stemming from the long distance that involves a ferry trip between their homes and available services. Gozitan parents felt that children with a disability in Gozo were always disadvantaged. All highlighted as unfair that they had to travel to Malta for the services of the CDAU and the Statementing Board. Amanda said that Maltese services were better equipped than Gozitan ones, and that in Gozo there were few professionals with never–ending waiting lists. Tony also was irritated that the "speech therapy unit is in the same building as the psychiatric unit". International studies also reported a lack of specialised services in rural areas, such as Gozo (Ashburner et al., 2016; Gona et al., 2016; Mello et al., 2016). Tony suggested an online filing system for professional services, and the provision of "quality assurance of the therapists' work" in both government and private services.

3.3.3. *Parents call for a more holistic support process*

Families in both Malta and Gozo reported inefficiencies in the diagnostic process and proposed improvements. Tony and Viv raised the issue of a long waiting list for the CDAU. Moreover, Amanda said that the CDAU was "missing a key link; it is missing out the parents and how they feature in the whole process". Amanda also sought advice from the head of speech therapists and a minister about this issue, who informed her that there was a lack of collaboration between the different ministries on this service:

> *It is like now you have this issue, it is up to you to figure out how to cope. (Ruth)*

Similarly, Caruana (2020) reported that parents' experiences were not considered when government–funded disability services were formulated.

The parents (Amanda and Tony) suggested that a contact person, who possesses expertise in the field and ideally has a family member with ASC, is essential. This person would guide parents following their child's diagnosis, creating a more free–flowing process. Another suggestion from Stella was the setting up of a website including all the services available for children with a disability in Malta that could provide the necessary information for parents with newly diagnosed children.

While noting the growing number of autism–friendly spaces and increasing awareness of ASC, which they attributed to the advocacy efforts of the Autism Parents Association, Amanda, Stella and Mark called for more autism–friendly spaces around Malta.

The need for tailored support post–diagnosis has been widely reported (Crane et al., 2016) but the above recommendations seem to be more tied to the local situation.

4. Conclusion and Recommendations

This study presented a snapshot of the current situation in Malta and Gozo regarding the complexities associated with the diagnosis of ASC from the point of view of the parents. These participants' experiences reflect the improvement of services as evidenced in the early identification of the children's autism between 1:06 and 3 years with half of them being alerted through the recent setting up of the *Lenti* screening programme. At the same time, it raises concerns about the way findings from the screening as well as the diagnostic process are communicated to parents. All the participants highlighted the lack of professional support for themselves as the child's carers. They called for regular public service support and guidance, suggesting ways to ensure more accessiblity to information and services. The parents also found the best emotional support through opportunities to share their challenges with other parents. ASC services should best include the promotion of self–help groups and activities (Camilleri, 2022; Chao & Chen, 2023; Clifford & Minnes, 2013; Hidayah & Lestari, 2019; Spiteri & Borg, 2019).

Parents also underlined the need for the improvement of services for children on the autism spectrum, from diagnostic support to education. Professionals need to be trained to cater for children with ASC, as they appear to lack the necessary preparation in this area. Parents again had to seek private services, mainly to avoid delays in the diagnostic process. Some also did not feel supported in the way they were given the diagnosis. While some parents felt their children were receiving adequate support at school, others experienced lack of understanding and commitment from educators. These experiences are similar to those of parents in other countries (DePape & Lindsay, 2015; Gunilla, Gillberg & Miniscalco, 2021). However, they still point to the need for better preparation of practitioners in health and educational services for more understanding and skills in meeting the needs of families and their children within the autism spectrum (Bartolo, 2002; Caruana, 2020; Malik–Soni et al., 2022; Rutherford et al., 2018).

This study also revealed that Maltese society has yet to fully accept and include individuals with ASC. Participants highlighted a lack of understanding of autism both among relatives and the wider society. Indeed, it has been noted that despite the fact that most autistic students are in regular Maltese schools and classes, there is still a lack of awareness, understanding and acceptance of people with autism in Maltese society (Bonnici and Bartolo, 2021). Along the same lines, the participants called for more spaces in the community that were autism friendly and thus also welcoming for their children. It is encouraging to note that eight Maltese enterprises have recently been recognised as autism friendly.

While the above findings were common to families in Malta and Gozo, the study found that the latter experienced specific challenges in at least two areas. Firstly, families in Gozo experience difficulties accessing services, as they have to travel to Malta for essential services such as those of the CDAU and the Education Statementing Board. Health and Educational services should be more responsive to the voices of Gozitan families with children with disability.

Families in Gozo also feel a strong sense of stigma in the smaller more restricted community. They were wary about the impact of others knowing that their child was autistic – a phenomenon that was noted in past Gozitan experiences (Bartolo, 2017) that the study showed still prevails. Wider support to *The Voice for Inclusion Association Gozo* may promote better understanding and acceptance of children with disability on the Island. It would also be useful to encourage at least one Gozo

enterprise to emulate the eight in Malta that have been recognised as autism friendly.

Finally, more research is needed because of the limitations of this study whose small sample does not represent all the experiences of Maltese and Gozitan parents. It is important to note that at the time of the parent interview, the children in this study had been diagnosed for between 6 months to 4½ years and, thus, the parent journey to accessing support services and interventions, as well as the reconstruction of a positive future for their children was still in its early stages. Moreover, the average age of the children of Maltese participants was slightly lower than that of Gozitan children. Additionally, the children were diagnosed at different times, so the findings may not reflect the current services and professional development situation in both islands.

Future research could investigate the experience of a larger sample of Maltese and Gozitan parents through a quantitative representative study so that policymakers could be more fully and persuasively informed about any necessary improvement of services. On the other hand, it should be noted that this study has clearly highlighted the need for more professional support for parents of autistic children as well as the need for more accessible services for families in Gozo.

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Conflicts of interest

The authors report no conflicts of interest.

Appendix 1: Interview Questions

1. **Getting to know the child & family**
   a. Do you reside in Gozo or Malta?
   b. Do you have a boy or girl with autism and how old is your child?
   c. Does s/he have siblings? If yes, are they older or younger?
   d. When was your child diagnosed?

2. **The journey to the diagnosis**
   a. How did it start? Who or what led you to get your child diagnosed?
   b. Describe the steps you took/went through during this process.
   c. How were the results of the assessment communicated to you?

3. **Parents' response to the diagnosis**
   a. What were your initial reactions to the diagnosis?
   b. How did your family and friends react to the diagnosis?
   c. What were your main concerns initially?
   d. Did these concerns change by time?
   e. What did you find most challenging? Why?
   f. What would you change, if anything, in the process you went through for it to be more helpful?

4. **Support given during and after the diagnosis**
   a. Did you receive any kind of support (e.g. support from professionals, support from family/friends, support from school personnel, support from other parents with a diagnosed child, etc.) during and after the diagnosis?
      i. If yes, did you seek for this support yourself or was it provided automatically as part of the diagnosing process? Can you elaborate on this?
      ii. If no, did you try to find support? Can you elaborate on this?
   b. How has this support, or lack of it, affected your coping with the diagnostic process?
   c. What other support, if any, do you wish you had during and after the diagnostic process?

5. **Other comments**

Is there anything else you would like to add or comment about?

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Reasearch Paper

Patients' perception of radiographers' communication skills during planar X–ray imaging: a single centre study

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Abstract

The purpose of the study was to evaluate radiographers' communication skills during planar x–ray imaging examinations at a general hospital from a patient's perspective. A self–designed questionnaire was developed which was distributed to a group of patients attending randomly for a planar x–ray examination between January and March 2023 at a medical imaging department of a general hospital in Malta. Data was collected and analysed to identify trends and understand the patients' perspective of radiographers' communication skills. Participants (n=83) filled out a questionnaire consisting of demographic data and scored a series of statements on a Likert scale of 1–4, with 1 being 'Very unsatisfied' and 4 being 'Very satisfied'. The Friedman test and Kruskal Wallis test were used to analyse the gathered data. Median scores were either 3–Satisfied or 4–Very Satisfied. There were no significant discrepancies when comparing the different demographics included in the study ($p>0.05$). Females provided significantly higher rating scores than males ($p<0.05$). Patients' scores varied the most in the statement *'Radiographers informed me of what they had to do next'*. This is the first study of its kind performed locally evaluating radiographer's communication skills from the patients' perspective. The mechanism in place locally for training radiographers in patient communication appears to be effective, as patients indicated being given instructions clearly and without undue discomfort. To investigate other demographics and evaluate whether there are any relationships between them, additional research would be required. It is recommended that a clearer pathway should be implemented to make it simpler for patients once they have completed the x–ray and put their minds at ease during their entire stay at the hospital. Having radiographers with good communication skills improves the patients' experience when attending for imaging services.

Keywords: Communication skills; patient satisfaction; patient centred care; radiographer.

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Introduction

The role of the radiographer in planar x–ray examinations is one which requires specific skills in positioning the patient correctly to acquire high quality images used for diagnosis. Other aspects in which the radiographer must be proficient in, to ensure patient safety and compliance include patient care and communication skills. The role of the radiographer extends into further depth when communicating with the patient (EFRS, 2022). Further research is needed to explore if any optimisation of

communication skills is needed in clinical departments, within the local scenario. The purpose of this study was to evaluate radiographers' communication skills during planar x–ray imaging examinations art a general hospital from a patient's perspective.

Literature Review

Advanced levels of communication skills are a vital component in the relationships between the radiographer and the patient, such as a proper introduction, giving patients easy–to–understand instructions and explanations, creating a relaxing atmosphere, and showing compassion and kindness (Pollard, et. al., 2019). Improving communication with patients may lead to higher patient satisfaction (Aminololama–Shakeri, et. al., 2019), which in turn may lead to increased confidence in the service and higher bonding between the patient and practitioner (Gutzeit, et. al., 2019).

Radiographers encounter a variety of patients, each with their own specific needs, so it is essential to tailor communication strategies to the specific needs of individual patients, such as those with minor to severe injuries, non–cooperative patients, and children (Burgin et. al., 2019). Improved communication between patients and practitioners lead to more accurate assessments of patient specific requirements and preferences, aiding to provide more effective, person–centred treatment (Lathoura, et. al., 2020).

Method

This study made use of a quantitative, prospective, descriptive, non–experimental, cross–sectional, research design. The research was conducted among patients attending for planar x–ray imaging at the medical imaging department of a general hospital in Malta. Ethical permission for this study was sought and obtained from the Faculty of Health Science Research Ethics Committee (FREC), University of Malta (FREC–FHS–2023–00002).

The target population for this study were all patients in Malta, aged 18–years or older who required a planar x–ray examination to any part of the body. The population to which the researcher had access to included patients from the target population attending during weekdays at the medical imaging department (MID) of a general hospital in Malta during the data collection period. Selected patient participants were invited to participate in the research. Once they gave their voluntary informed consent, they were administered the questionnaires by the receptionist at the Medical Imaging Department who acted as an intermediary person on behalf of the researcher. Once the questionnaire was filled in, the participants were kindly indicated to leave it in a collection box which was available in the reception area.

The period for data collection was selected using convenience sampling, which is a method of choosing a period which was convenient for the researcher (Galloway, 2005). Data collection was performed between January and March 2023. During this period, patients were randomly selected following a list of random numbers generated by Microsoft Excel (Microsoft Corporation, 2018). The MID activity report of 2022 was used to see how many patients undergo an x–ray examination every day. On average, 230 patients are x–rayed every day at the MID. A minimum ratio of 30% was needed to ensure representativeness (Fincham, 2008).

A self–designed questionnaire was used as the data collection tool for this study. The questionnaire was developed based on literature reviewed and in consultation with radiographers with several years of experience. The questionnaire involved two sections:

The first section was demographic data, to allow comparison between different patient subgroups to assess for any significant differences. In this section participants provided information regarding their age, gender, and nationality. Participants were also asked if they ever had previous experience at the MID, not only as a patient, but also as an accompanying relative or worker. Participants with some form of familiarity with the MID may have different expectation from those experiencing the MID for the first time.

The second section included 12 statements together with 3 re–worded questions to facilitate intra–rater reliability that the participant had to grade from a scale of 1–4, with 1 being 'Very unsatisfied', 2 being 'Unsatisfied', 3 being 'Satisfied and 4 being 'Very satisfied'. The grading of the re–worded statements for each radiographer can be compared to enable the calculation of individual reliability.

The questionnaire was developed in English, which was translated into Maltese. The translation was carried out by a qualified translator to ensure accuracy and authenticity of the text. Participants had the option to select their preference of questionnaire language.

Being a self–designed questionnaire, it was tested for both validity and reliability.

Validity was tested through content validity. Using a 4–point rating system. Three radiographers with more than 5–years of working experience in general radiography, were enrolled to perform the validation of the tool. The three radiographers were asked to assess the validity in terms of content and clarity of the statements in the questionnaire. They were asked to rate the statements for both content and clarity by using a 4–point rating scale ranging from 1 (not valid/clear) to 4 (very valid/clear). An average content validity index (CVI) of 95 was acquired in the first round for content (CVI=94) and clarity (CVI=97) hence the tool used for data collection was proven valid since it scored higher than 80 (Polit & Beck, 2006).

The intra–rater reliability of the person filling in the questionnaire was achieved by taking 3 statements from the questionnaire which were re–worded so that they still have the same meaning and included at separate intervals in the questionnaire. Questionnaire statements 6, 8 and 11 were reworded as statements 10, 9 and 17 respectively. A comparison was then made between the scores of the statements that were reworded to see if the participants gave similar scorings. The Kendall Tau test was used to assess intra–rater reliability. The reliability results will be presented in the results section of this paper.

The Friedman test was utilised to compare the average rating scores (on a Likert scale) of several related statements. The Kruskal Wallis test was used to compare the mean rating scores for each statement between participant groups clustered by gender, age, country, prior employment in the health industry, and first exposure to planar X–ray imaging.

Before undertaking the entire study, it was vital to identify any issues and to make any necessary adjustments within the adopted methodology. This was done by performing a pilot study. In this research, a pilot study was conducted by performing the data collection on a small sample of 10 patients to see the logistics and practicality of the data collection method. Participant responses from the pilot study were excluded from the analysis of the data of the main study. Based on the pilot study it was concluded that no amendments were required to the questionnaire (refer to the appendix for a copy of the questionnaire). Due to these outcomes, no changes were made to the methodology based on the results of the pilot study.

Results

All results related to demographic data are summarised in table 1.

One hundred and twenty–five (125) questionnaires were distributed by an intermediary to potential participants with 83 completed questionnaires being returned, resulting in a response rate of 66%. An acceptable survey response rate is between 5% and 30%. Anything above 30% is considered excellent. Again, it is important to stress that there is no universally defined threshold for a 'good' response rate (Fincham, 2008). Questionnaires were handed out during daytime (09.00 to 17.00) between Monday to Friday over a 9–week period (16th January 2023 to 24th March 2023). At a confidence interval of 95%, a sample size of 69 for a 30% population proportion gives a margin of error of 7.9%. Between 3 to 8% margin of error is deemed acceptable (Fincham, 2008).

Age groups were divided in the following categories: '18–29 years', '30–39 years', '40–59 years' and '> 60 years', with the highest number of respondents being in the >60–year category. Forty–four (44) participants were female and 39 respondents were male. All participants associated themselves with either the male or female gender with none of the participants identifying themselves otherwise.

Almost 99% (n=82) of participants were of Maltese nationality with one participant being an Italian national. There were 12 questionnaires completed in Maltese and 71 filled in English.

The last two items within the demographics section were related to whether participants had ever worked in the health sector and whether this was their first experience undergoing a planar x–ray examination. Fifteen (15) participants had worked in the health sector whilst 68 never did. In addition, 33 participants were undergoing their first planar x–ray examination while 50 had previous imaging experience.

Table 1: Summary of demographic data

Response rate	Age groups (Years)				Gender		Nationality		Previous work experience in health sector		Previous x–ray experience	
	18–29	30–39	40–59	>60	Male	Female	Maltese	Foreign	Yes	No	Yes	No
66%	14	17	18	34	39	44	82	1	15	68	33	50

Intra–rater reliability tests for the 3 repeated statements within the questionnaire using the Kendall–Tau coefficient (T), indicated significant ($p<0.05$) moderate to very good agreement between each of the re–worded statement scores (T scores for each statement: 0.48, 0.50 and 0.89) (Polit & Beck, 2017).

Table 2 shows the median scores from all participants for all the statements included in the questionnaire. All the median scores for all statements were >3, indicating that patients were satisfied with the radiographers' overall communication performance.

Female participants provided higher median rating scores over the male respondents for all statements. The variation between gender scores was only significant ($p<0.05$) in 4 statements:

- '*Radiographers spoke to me in a way that made me feel comfortable*',
- '*Radiographers showed me respect*',
- '*Radiographers informed me about what I had to do next*', and
- '*Radiographers took good care of me*' (Table 3).

Table 2: Mean scores for questionnaire statements

Statement	Median score
Radiographers spoke to me in a way that made me feel comfortable.	4
Radiographers showed me respect.	4
Radiographers indicated interest in my thoughts about my health.	3
Radiographers recognised my main health worries.	3
Communication with the radiographer made me feel at ease.	4
Radiographers gave me the appropriate length of time.	4
Radiographers listened carefully to what I had to say.	4
Radiographers involved me in decision making as much as needed.	4
Radiographers informed me about what I had to do next.	3
Radiographers identified the main reason for the x–ray examination.	4
Radiographers took good care of me.	4
Radiographers allocated the right amount of time for me.	4

Table 3: Gender comparison				
Statement	**Gender**	**Sample size**	**Median score**	**P–value**
1. Radiographers spoke to me in a way that made me feel comfortable	Male	39	4	0.004
	Female	44	4	
2. Radiographers showed me respect	Male	39	3	0.006
	Female	44	4	
3. Radiographers indicated interest in my thoughts about my health	Male	39	3	0.713
	Female	44	3	
4. Radiographers recognised my main health worries	Male	39	3	0.390
	Female	44	3	
5. Communication with the radiographer made me feel at ease.	Male	39	4	0.080
	Female	44	4	
6. The radiographers gave me the appropriate length of time	Male	39	3	0.378
	Female	44	4	
7. Radiographers listened carefully to what I had to say	Male	39	4	0.282
	Female	44	4	
8. Radiographers involved me in decision making as much as needed.	Male	39	4	0.193
	Female	44	4	
9. Radiographers informed me about what I had to do next	Male	39	3	0.022
	Female	44	3	
10. Radiographers identified the main reason for the x–ray examination.	Male	39	3	0.130
	Female	44	4	
11. Radiographers took good care of me	Male	39	3	0.024
	Female	44	4	
12. Radiographers allocated the right amount of time for me	Male	39	3	0.165
	Female	44	4	

There was no significant difference between the scores due to the different nationality of the participants, but one must keep in mind that there was only one patient who was a non–Maltese national. There were no significant ($p>0.05$) variations between the median scores for all statements for the different age categories.

Additionally, there were no significant ($p>0.05$) variations between the median scores for all statements for patients with and without experience in the health sector. For 11 out of the 12 statements, patients with previous experience in the health sector had higher median ratings compared to patients without experience. '*Radiographers allowed me to take decisions as much as I needed'*, was the statement where those without previous health experience scored higher, but the variation was not found to be significant ($p>0.05$).

There were also no significant ($p>0.05$) variations between the median scores for all statements for patients attending for their first planar x–ray and those who had previous imaging experience.

Discussion

Communication is mandatory as outlined in the Basic Safety Standard EU Directive (European Commission, 2018). Patients need the necessary information about the risks and benefits of their planar examination to be able to make an informed decision in consenting or otherwise for the examination. Radiographers may sometimes encounter difficulties informing patients of radiation risk without raising unnecessary concerns. This study demonstrated that, patients were satisfied with the communication between themselves and the radiographer. Pollard et. al., (2019) and Burgin et. al., (2019) identified key themes which promote good communication between the patient and radiographers such as '*positive body language*', '*simple language*', '*introduction and greeting*', '*instruction*', '*ease*', '*kindness*' and '*clear communication*'. These themes appear to be present within the local scenario as median scores (>3) indicate patients being satisfied in all aspects.

This study showed that patients were able to express their needs and concerns, making them more likely to feel heard as indicated by the scores from statements 1, 5 and 8. When patients are more able to express their concerns, they are more likely to be cooperative during the examination resulting in better quality images (Ajam, et. al., 2020). Patients' happiness and productivity objectives are critical to boosting the quality and quantity of treatment in radiology departments. Staff coordination and training in communication and interpersonal skills might enhance these metrics.

This study showed that patients loved the individualised care they received, and the transparency shown by the radiographers as indicated by the scores from statements 2, 3, 4, 7, 11, and 12. Rese3arch has shown that patients are grateful to the radiographer who takes the time to explain the process, treat them with dignity and respect, and make them feel at ease throughout the examination (Newton–Hughes & Strudwick, 2023; Raaschou, et. al., 2019).

Males and females have distinct needs, ideas, and perspectives. Because males and females are restricted by gender conventions and prejudices, they frequently approach disease and pain differently. Males may try to look strong out of concern that showing any signs of pain or discomfort will be interpreted as a sign of weakness. As a result, males may minimise their condition and suppress crucial medical information. As females are thought to have a friendlier and more involved nonverbal communication style, they may be more open about themselves during conversations (McIntosh, 2022). Such disparities in needs, ideas, perspectives, and patient preferences between male and female patients may have been the reason why female patients provided higher scores than males in this study.

Since there was only one foreign patient who could have had potential communication issues due to language, it was not possible to perform any sort of analysis or reach any conclusions from this study. However, literature findings suggest that radiographers require strong communication skills to deliver better patient care during planar X–ray imaging, particularly in multilingual settings as language barriers cause imaging communication issues. Imaging procedures might be delayed, or patients could be subjected to inappropriate radiation doses if there are communication breakdowns. For this reason, radiographers must understand the significance of good communication skills and the possible influence of language barriers on communication throughout the planar X–ray imaging process (Mokavelaga & Pape, 2021). Radiographers, need to be adequately trained in patient communication. Understanding and appreciating one another's feelings, perspectives, and priorities is just as important as communicating facts and figures while conversing. Specifically, in the context of cultural diversity, the significance of cultural competency and language expertise in developing practical and good communication with patients and the obstacles radiographers have in delivering culturally appropriate treatment are emphasised (Chau, 2020; van Vuuren, et. al., 2021).

Literature findings suggest that patients who had previous experience of the imaging department either because they worked there or had previous imaging experience tend to have higher expectations than those who did not (Hyde, et., at, 2018). However, this study showed that there were no significant differences within this patient cohort, which could be due to the small sample size where significance was not reached.

Limitations

At the time the study was conducted, other studies were also being carried out involving patient participation. Only one receptionist had the responsibility of acting as intermediary person on behalf of the researcher to invite patients and distribute the questionnaires. The receptionist's duty rota was not always aligned to regular office hours. These factors limited the number of

patients participating in this study. A larger sample size would ensure generalisation of findings and reduce the probability of not achieving significance.

Conclusion

Inquiring about patients' privacy and safety, offering language–interpretation services, using the proper terminology to organise patients, and listening to patients' worriess are just some of the communication strategies recommended for radiographers (Soo, et. al., 2019). Effective two–way dialogue between radiographers and patients is crucial to quality healthcare. Clear and concise communication raises patients' level of understanding, increases the likelihood that they will follow the radiographer's instructions, and provides emotional support (Aakhiro, 2021). There is a need for increased focus on knowledge and skills in communication among radiographers in clinical practice. It could be achieved through education and training, focusing on theoretical knowledge, reflection, and critical thinking (Reitan, & Sanderud, 2020).

The current local training in place for radiographers in patient communication appears to be effective, as patients were satisfied with the given instructions, which they perceived as clear and provided without undue discomfort. Additional research would be required to investigate a wider range of demographics such as level of education, locality, professional status, and others, and compare them to how such patients perceive radiographer communication skills. It is recommended that a clearer pathway should be implemented to make it simpler for patients once they have completed the x–ray and put their minds at ease during their entire stay at the hospital.

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Conflict of interest

The authors report no conflicts of interest.

Appendix A: Questionnaire

Section A: General Questions

6. Gender: Male ☐ Female ☐

7. Nationality: Malta ☐ Other _____

8. Age: 18–19 ☐ 30.39 ☐ 40–59 ☐ 60+ ☐

9. Have you ever worked in the health sector? Yes ☐ No ☐

10. Is this your first time undergoing a planar x–ray exam? Yes ☐ No ☐

Section B: Patient's perception of radiographers' communication skills during planar x–ray imaging

In This section you are required to give a score in the allocated box for each statement from 1–4. The scores description are as follows:

- 1 – Very unsatisfied
- 2 – Unsatisfied
- 3 – Satisfied
- 4 – Very satisfied

Statements: What rating would you give to the following statements:

11. Radiographers spoke to me in a way that made me feel comfortable ☐

12. Radiographers showed me respect ☐

13. Radiographers indicated interest in my thoughts about my health ☐

14. Radiographers recognised my main healthworries ☐

15. Communication with the radiographer made me feel at ease. ☐

16. The radiographers gave me the appropriate length of time ☐

17. Radiographers listened carefully to what I had to say ☐

18. Radiographers involved me in decision making as much as needed. ☐

19. Radiographers informed me about what I had to do next ☐

20. Radiographers identified the main reason for the *x*–ray examination. ☐

21. Radiographers took good care of me ☐

22. Radiographers allocated the right amount of time for me ☐

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Reasearch Paper

Identifying young adults at high risk of prediabetes and diabetes in Malta: a cross–sectional survey

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Abstract:

The aim of this study was to quantify prediabetes risk and associated risk factors amongst young adults. We also sought to assess the validity and reliability of the risk assessment tool used. Fasting plasma glucose was also collected to further assess risk. A cross–sectional, correlational, study was conducted. Convenience sampling was used with a target sample size of 374. Out of a total of 14,483 eligible participants, 176 (response rate = 1.22%) young adults aged 18–35 attending two higher education institutions had their data collected from the 22nd of December, 2020 up until the 30th of April, 2021. An online questionnaire was used, including fasting plasma glucose tests for 57 participants. Analysis was carried out using the IBM® SPSS® Statistics Version 27. The Kolmogorov–Smirnov and Shapiro–Wilk test, Mann–Whitney U test, Pearson and Spearman correlation, Fisher's exact test, Univariate General Linear Model and the receiver operating characteristic analysis were all used to analyse the data. 5.3% (n=3) of participants, who were all male, obtained an abnormal FPG value (≥5.6 mmol/L), signifying prediabetes and one case of diabetes (8.57 mmol/L). Significant risk factors for prediabetes were sibling history of diabetes, high blood pressure, waist circumference and smoking. The area under the ROC curve of the German Diabetes Risk Score resulted in 0.787, with a sensitivity of 66.6% and a specificity of 78.0% when scoring 30 points. The German Diabetes Risk Score, while showing good performance, was not statistically significant in this population and not useful in identifying prediabetes/diabetes in local young adults. This may have been due to low response rate and small sample size, leading to a lack of representativeness of the larger population, which may affect the generalisability of the findings. The utilisation of fasting plasma glucose to identify such subjects appears to be superior and further diverse studies are needed to validate the findings and investigate the feasibility of wide–scale screening with refined prediabetes risk assessment tools.

Keywords: Young adults, Prediabetes, Impaired fasting glucose, German Diabetes Risk Score, Screening, Type 2 diabetes mellitus

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1. Introduction

The global prevalence of type 1 (T1DM) or type 2 diabetes mellitus (T2DM) in adults is 10.5%. It affected an estimated 537 million adults in 2021, rising to a

prediction of 783 million by 2045 (International Diabetes Federation, 2021). T2DM accounts for about 90% of all cases of diabetes. Epidemiological surveys show that the prevalence of T2DM in Malta in 2016 stood at 10.39% (Cuschieri et al, 2016a), with an increase to 11.2% in 2021 for total diabetes (International Diabetes Federation, 2021). Early detection and prevention of T2DM is important as the disease carries an increased risk of both all–cause and cardiovascular morbidity and mortality (Wang et al, 2017). Additionally, it carries a strong socioeconomic impact by imposing a significant strain on health services (Alkandari et al, 2018).

There are several risk factors for T2DM, and consequently such factors need to be identified and reversed to prevent progression to full–blown T2DM. Prediabetes is a state of intermediate hyperglycaemia below the thresholds for diagnosis of T2DM and represents an at–risk state for development of overt T2DM. The global prevalence of prediabetes has been estimated to be 6.2% by the IDF (2021), based on impaired fasting glucose (IFG) levels, which can be referred to as isolated IFG (I–IFG). Prediabetes is characterised by the cooccurrence of two metabolic defects – insulin resistance and diminished insulin secretion (Grundy, 2012), which can be manifested as either impaired glucose tolerance (IGT) or IFG (Sasaki et al, 2020). The latter are normally associated with intermediate glycaemic variables between normal and diabetes which do not meet the criteria for classification of clinical diabetes (Falguera et al, 2020). The American Diabetes Association (ADA) in 2021 identified these values as 5.6 mmol/L to 6.9 mmol/L for IFG and 7.8 mmol/L to 11.0 mmol/L for IGT (American Diabetes Association, 2021).

Prediabetes is normally associated with the metabolic syndrome, which is a cluster of risk factors as defined by the National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) (Huang, 2009). These criteria state that metabolic syndrome is present if three or more of the following are present: fasting blood glucose above 100 mg/dl, blood pressure over 130/85mmHG, elevated triglyceride levels (≥150 mg/dL), low high–density lipoprotein cholesterol levels (<40 mg/dL in men, <50 mg/dL in women) and elevated waist circumference (>40 inches for males, >35 inches for females). T2DM is becoming more common in children and younger adults, with around 20% of adolescents and 25% of young adults in the US having prediabetes (Andes et al, 2019). This is associated with the rising prevalence of obesity, calorie dense diets, and physical inactivity in these age groups (Amutha and Mohan, 2016). These same factors play a critical role in the increasing prevalence of T2DM in Malta (Cuschieri et al, 2016b).

2. Aim and Objectives

This study aimed to use a questionnaire, the German Diabetes Risk Score (GDRS), to evaluate the risk of developing T2DM in young adults (age 18–35) of Maltese ethnicity.

Furthermore, fasting plasma glucose measurement was used in a subset of the study cohort to assess the prevalence of prediabetes and evaluate the performance of the GDRS as a screening tool in the high–risk Maltese population.

3. Methods

3.1. Participants

This study was conducted in a university and vocational college in Malta, inviting all students enrolled in these two institutions aged between 18–35 years (a total of 14,483 students) to participate in an online survey. In 2020, there were 9,674 students in this age range at the university and 4,809 at the vocational college. The sample size calculator provided a minimum sample size of 374 participants, with a margin error of +/–5% and CI level of 95%. Weighting statistics showed that the male age group of 18–19 years was underrepresented and the female age group of 20–24 years was overrepresented.

3.2. Data collection and measurement

Data was collected by a cross–sectional online survey distributed through the university's electronic Student Information Management System (eSIMS) and through the vocational college's registrar's office via email, between December 2020 and April 2021.

The second part of the study involved inviting those participants who consented to bloodletting during the online survey to attend for FPG sampling, in a clinic at the Centre for Molecular Medicine and Biobanking at the university. Participants were instructed to fast for 8 hours and FPG measurement was performed using routine hospital biochemical analysers.

3.3. German Diabetes Risk Score

The primary data collection tool was the German Diabetes Risk Score (GDRS). This was initially developed as an online tool from data of the EPIC–Potsdam study for estimations of the 5–year risk of developing T2DM (Paprott et al, 2016). It is the German Diabetes Association's primary screening tool for diabetes. The latest simplified version of this tool dating to 2014 was used in the study. This was the diabetes risk tool of interest since it accounts for people aged from 18 years, includes an FPG test and more risk factors than other available tools.

The score points on the GDRS reflect the strength and direction of association between the known risk factors for T2DM: namely age; physical activity; hypertension; whole grain/meat/coffee consumption; smoking; height; waist circumference; family history of diabetes, and diabetes risk observed. The latter is determined as each risk factor is given a score based on its risk of T2DM, and the scores are added together to determine overall diabetes risk. The questionnaire also includes a FPG or HbA_{1c} (glycated haemoglobin) test. It categorises diabetes risk according to the score obtained, (<46 – low risk, > 63 – high/very high risk). These cut–offs are slightly altered when FPG or HbA_{1c} measurement is incorporated into the risk prediction model (Table 1).

Due to COVID–19 restrictions, it was necessary to distribute the questionnaire online, with the participants providing their height and waist circumference in centimetres. Instructions were provided on how to measure waist circumference. The score points were determined by the researcher after the completed online questionnaires.

Table 1 Risk Evaluation based on DRS Points plus HbA_{1c} or Fasting Glucose Test (Paprott et al, 2016)

DRS Points	**<46**	**46–56**	**57–63**	**>63**
Diabetes risk	low	still low	elevated	high to very high
HbA_{1c}/Fasting	**DRS Points**			
Glucose	**<46**	**46–56**	**57–63**	**>63**
5.7–6.4% (3946 mmol/mol)/ 100–125 mg/dl (5.6–6.9 mmol/l)	still low	elevated	high to very high	high to very high
<5.7% (<39 mmol/mol)/ <100mg/dl (<5.6mmol/l)	low	still low	elevated	high to very high

DRS, diabetes risk score; HbA_{1c}, glycated haemoglobin

3.4. Ethics and consent

This study was carried out in accordance with the Declaration of Helsinki and approved by the institutional ethics review board of the University of Malta (UREC FORM V_15062020 6004). Permission was granted by the authors of the GDRS to use the tool. Written informed consent was obtained from all participants (Appendix B). Upon opening the link to the questionnaire informative points regarding the consent were provided and participants were required to complete it only after agreeing to the written consent. It was clearly stated that all information will remain confidential, and that data would be destroyed after five years. In fact, each participant was assigned a numerical code.

It was made clearly that participants were free to withdraw from the study at any stage during the research process, where their data and information would be erased from the study and discarded. It was ensured that the participants were not deceived by any means and risks of harms were minimised.

Careful consideration was taken to de–identify anthropometric and lifestyle data of the GDRS from personal details to safeguard anonymity as required by the General Data Protection Regulation. A total of two Microsoft Excel sheets were used: one with the patient's name, identification number, demographic details and code number assigned were stored on one database, whilst the data retrieved from the GDRS tool were coded and inputted on an Excel sheet in a separate database. Participants identified as having a high risk of T2DM or abnormal findings were contacted by the principal investigator and referred for further testing and follow–up as necessary.

3.5. Statistical analysis

Descriptive data relaying the proportion of participants, their demographic characteristics, risk factors expressed as frequencies and percentages (Kaur, Stoltzfus and Yellapu, 2018) were analysed. The normality of continuous variables, including age, GDRS points and FPG values, was assessed by the Shapiro–Wilk and Kolmogorov–Smirnoff tests. The latter tests are fundamental for choosing the correct statistical methods and ensuring the validity of the analysis results. The null hypothesis (H_0) specifies that distribution of variables is normal and is accepted if the P value exceeds the 0.05 level of significance. The alternative hypothesis (H_1) specifies that the continuous variables are not normal and is accepted if the P value is less than the 0.05 criterion. All continuous parameters of the questionnaire exhibited a skewed non–normal distribution, and non–parametric statistics with medians and interquartile ranges are presented. The Univariate General Linear Model was used to identify the most significant GDRS predictors, which are the independent variables, associated with FPG variation, the dependent variable. This was a test of choice since there were multiple independent variables and it provides a comprehensive framework for hypothesis testing, estimating effects and controlling for confounding variables. Receiver operating characteristic (ROC) analysis was used to compute the area under the curve (AUC) to assess the performance of the GDRS in discriminating prediabetes from normoglycaemia. The highest Youden index (sensitivity + specificity - 1) was used to determine optimal cut–off points. This analysis was implemented to assess for specificity and sensitivity of the GDRS for abnormal FPG values. Statistical significance was defined as a P–value of <0.05. Weighting was applied to account for over–or under–representation of certain age and gender groups in the study, using national statistical data on the student population in the selected institutions. Data analysis was carried out using the IBM® SPSS® Statistics Version 27.

4. Results

4.1. Response rate and participant's characteristics

From a total of 14,483 eligible participants, 176 participants completed the online survey, of whom 93 participants consented to bloodletting and 57 attended for the blood tests when invited by email or phone message. The salient characteristics of the study participants, sub–stratified according to the GDRS risk factors are presented in the supplementary material The median age of subjects was 22 years (IQR 20–24) with 72.7% of the participants being female.

4.2. Prediabetes related risk factors in young adults

The majority of participants reported that they participate in regular physical activity (64%, n = 113) and reported no history of hypertension (96%, n = 168). Most participants reported a low intake of whole grain foods, with 82% (n = 144) of participants consuming two or less portions of whole grains a day, thus increasing their tendency to develop T2DM. Eighty–six percent (n = 150) of participants consumed meat less than three to four times a week. Most participants were non–smokers (87%, n = 154). Of the 176 participants, 75% (n = 131) were shorter than 176 cm, this being approximately the mid–range height in the GDRS, whilst 25% (n = 45) were taller than 176 cm. Most of the participants (84%, n = 147) had a waist circumference less than 95 cm, this being approximately the mid–range waist circumference in the GDRS. Additionally, 14% (n = 26) of the participants had a family history of T2DM in a first–degree relative.

4.3. Prediabetes risk in the bloodletting subset

In this section a subset of participants who consented/volunteered for bloodletting are described. Of the 176 participants, 57 participants attended for bloodletting. Table 2 shows the participant characteristics of this subgroup. Table 3 shows the GDRS category when FPG is combined with the score points. These results indicate

that 93% (n = 53) scored in a 'low' risk category, 5% (n = 3) a 'still low' risk category, and 2% (n = 1) got a value which was out of the FPG maximum range and did not fit in the categories. None of these participants ranked in the 'elevated' or 'high to very high' risk category.

Table 2 Participant characteristics as outlined by the GDRS of the FPG bloodletting subgroup with normoglycaemia and abnormal FPG

	Total participants n = 57	Normoglycaemia n = 54	Abnormal FPG n = 3
Physical activity (n, %)			
No	27 (47.4)	25 (46.3)	2 (66.7)
Yes	30 (52.6)	29 (53.7)	1 (33.3)
High blood pressure			
No	55 (96.5)	53 (98.1)	2 (66.7)
Yes	2 (3.5)	1 (1.9)	1 (33.3)
Consumption of whole grain bread/rolls muesli			
0	17 (29.8)	16 (29.6)	1 (33.3)
1	17 (29.8)	17 (31.5)	0 (0.0)
2	13 (22.8)	11 (20.4)	2 (66.7)
3	2 (3.5)	2 (3.7)	0 (0.0)
4	4 (7.0)	4 (7.4)	0 (0.0)
>4	4 (7.0)	4 (7.4)	0 (0.0)
Consumption of meat			
Never or rarely	5 (8.8)	5 (9.3)	0 (0.0)
1–2 times per week	19 (33.3)	18 (33.3)	1 (33.3)
3–4 times per week	27 (47.4)	26 (48.1)	1 (33.3)
5–6 times per week	3 (5.3)	3 (5.6)	0 (0.0)
Daily	2 (3.5)	1 (1.9)	1 (33.3)
Several times a day	1 (1.8)	1 (1.9)	0 (0.0)
Cups of coffee daily			
0–1	31 (54.4)	30 (55.6)	1 (33.3)
2–5	23 (40.4)	21 (38.9)	2 (66.7)
>5	3 (5.3)	3 (5.6)	0 (0.0)

Table 2 Participant characteristics as outlined by the GDRS of the FPG bloodletting subgroup with normoglycaemia and abnormal FPG

	Total participants n = 57	Normoglycaemia n = 54	Abnormal FPG n = 3
Smoking status			
I never smoked	40 (70.2)	38 (70.4)	2 (66.7)
I used to smoke on average less than 20 cigarettes a day	8 (14.0)	8 (14.8)	0 (0.0)
I used to smoke on average 20 or more cigarettes a day	1 (1.8)	1 (1.9)	0 (0.0)
I smoke on average less than 20 cigarettes a day	8 (14.0)	7 (13.0)	1 (33.3)
I smoke on average 20 or more cigarettes a day	0 (0.0)	0 (0.0)	0 (0.0)
Height, cm			
<152	3 (5.3)	3 (5.6)	0 (0.0)
152–159	9 (15.8)	9 (16.7)	0 (0.0)
160–167	16 (28.1)	15 (27.8)	1 (33.3)
168–175	14 (24.6)	14 (26.0)	0 (0.0)
176–183	14 (24.6)	12 (22.2)	2 (66.7)
184–191	0 (0.0)	0 (0.0)	0 (0.0)
≥192	1 (1.8)	1 (1.9)	0 (0.0)
Waist circumference, cm			
<75	15 (26.3)	15 (27.8)	0 (0.0)
75–79	12 (21.1)	11 (20.4)	1 (33.3)
80–84	11 (19.3)	10 (18.5)	1 (33.3)
85–89	7 (12.3)	7 (13.0)	0 (0.0)
90–94	4 (7.0)	4 (7.4)	0 (0.0)
95–99	2 (3.5)	1 (1.9)	1 (33.3)
100–104	1 (1.8)	1 (1.9)	0 (0.0)
105–109	5 (8.8)	5 (9.3)	0 (0.0)
110–114	0 (0.0)	0 (0.0)	0 (0.0)
115–119	0 (0.0)	0 (0.0)	0 (0.0)
≥120	0 (0.0)	0 (0.0)	0 (0.0)

Table 2 Participant characteristics as outlined by the GDRS of the FPG bloodletting subgroup with normoglycaemia and abnormal FPG

	Total participants n = 57	Normoglycaemia n = 54	Abnormal FPG n = 3
Parents' history of T2DM			
No, or I don't know	50 (87.7)	49 (90.7)	1 (33.3)
Yes, one parent has T2DM	7 (12.3)	5 (9.3)	2 (66.7)
Yes, both parents have T2DM	0 (0.0)	0 (0.0)	0 (0.0)
Siblings' history of T2DM			
No, or I don't know	54 (94.7)	52 (96.3)	2 (66.7)
Yes, at least one of my siblings has T2DM	3 (5.3)	2 (3.7)	1 (33.3)

FPG, fasting plasma glucose; GDRS, German Diabetes Risk Score; SD, standard deviation

Table 3 GDRS & FPG category classification and mean FPG value in the participants who consented for bloodletting (original and weighted data)

GDRS & FPG category n (%)	Total participants n = 57 (percentages of total population from original data)	Total participants n = 60 (weighted)	Participants with abnormal FPG n = 3
Low	53 (30.1)	54 (30.9)	0 (0.0)
Still low	3 (1.7)	4 (2.1)	2 (66.7)
Elevated	0 (0.0)	0 (0.0)	0 (0.0)
High to very high	0 (0.0)	0 (0.0)	0 (0.0)
Out of range (FPG value >6.9mmol/L)	1 (0.6)	2 (1.0)	1 (33.3)
FPG value (Mean ± SD)	5.00 ± 0.6	5.10 ± 0.7	

FPG, fasting plasma glucose; GDRS, German Diabetes Risk Score; SD, standard deviation

This study identified a prediabetes prevalence of 5.3%, specifically in the form of I–IFG. Only one participant satisfied the criteria for T2DM, at age 33, the oldest participant in the bloodletting category. All participants with elevated FPG values (>5.6mmol/l) were in the oldest age quintile, and a weak positive correlation between age and FPG values was identified (Spearman correlation coefficient = 0.276, p =0.037). There were no significant differences in mean age between the overall participant group (male = 22.60, female = 22.8) and the FPG sample group (male = 24.14, female = 22.26).

The participants having FPG values in the prediabetes range were classified as being in the 'still low' category on the GDRS. One participant met the criteria for the diagnosis of diabetes mellitus (FPG > 6.9 mmol/L) and could not be categorised and was classified as 'out of range'. Even though his FPG value was abnormal, his GDRS score without FPG was still categorised as 'low' (Table 3).

4.4. The predictors of the GDRS score

The most significant predictors on the GDRS associated with FPG variation were found to be high blood pressure,

meat consumption, smoking, waist circumference and sibling family history (p = 0.001, p = 0.064, p = 0.009, p = 0.002, p = 0.0001, respectively). A backward procedure was used to obtain the Parsimonious model which includes solely the significant predictors (Table 4).

Table 4 The Parsimonious Model Relating FPG to the Predictors (Tests of Between Subjects Effects (Dependent Variable: FPG (mmol/L))

Source	Sum of Squares	df	Mean Square	F	*P* value
High Blood Pressure	2.219	1	2.219	13.366	<0.01
Meat	1.907	5	0.381	2.297	.064
Smoking	2.208	3	0.736	4.433	<0.01
Waist circumference	4.852	7	0.693	4.175	<0.01
FH Siblings	3.157	1	3.157	19.015	<0.01
Error	6.475	39	0.166		

R squared = 0.683 df, degree of freedom; FH, family history

4.5. The sensitivity and specificity of the GDRS

The performance of the GDRS in discriminating normoglycaemic from prediabetic glucose levels was evaluated by ROC analysis. The GDRS demonstrated a moderate discriminatory capacity (AUC = 0.787), with a score exceeding 30 points having a sensitivity of 66.6% and a specificity of 78% (1 – 0.22) for predicting prediabetic FPG values. The sensitivity and specificity values of the GDRS are exhibited in Figure 1.

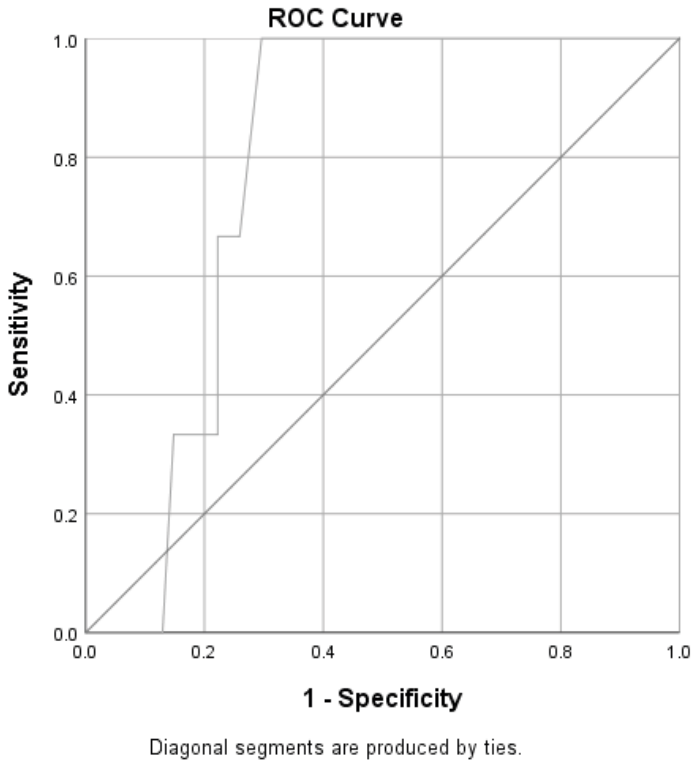

Fig. 1. ROC analysis using the GDRS as a predictor of abnormal FPG

5. Discussion

5.1. Prevalence of prediabetes

Calculating the prevalence of the intermediate stage between normoglycaemia and T2DM is essential for planning effective national preventive and treatment programs (Cuschieri et al, 2016b; Wang et al, 2017). The prevalence of prediabetes based on the GDRS in this cross–sectional study was 5.3%, which is relatively low when compared to prediabetes prevalence in young adults in the US (Andes et al, 2019). This finding is unexpected given the rising global trends, but definitive conclusions cannot be made due to the small sample size. Additionally, this is the first local study to gather such data on young adults, indicating a need for further research in this area.

5.2. Risk factors associated with FPG variation

The main variables on the GDRS associated with FPG variation were high blood pressure, meat consumption, smoking, waist circumference, and sibling family history.

The low prevalence of reported high blood pressure (5.1%) in this study was low and is likely due to the relatively young study group. This association has been widely recognised in studies in Europe (Manios et al, 2020), the United Kingdom (UK) (Mainous et al, 2014) and the United States (Andes et al, 2019) which also found a positive correlation. High blood pressure's primary determinants are BMI, body composition, and the ratio of adipose tissue to lean body mass, with 15 to 20 percent of adolescents with primary hypertension also having metabolic syndrome (Litwin and Kułaga, 2021).

The borderline significant effect of meat consumption on prediabetes risk aligns with some studies linking high red meat intake to dysglycemia, potentially due to the global rise of fast food restaurants and unhealthy diets that include processed meat (Jambi et al, 2020; Ley et al, 2014). However, the GDRS assesses beef, pork, or lamb consumption, not processed meat, which contrasts with other studies emphasising processed meat's impact (Pan et al, 2011). This unexpected result suggests a need for further investigation into different types of meat consumption.

Smoking was statistically significantly associated with prediabetes risk, with former or current smokers of ≥20 cigarettes per day showing the highest risks. Findings from a meta–analysis have shown that active smoking increases the risk of developing diabetes by 1.44–fold higher compared with not smoking (Heianza et al, 2012). This is also reflected in most available risk scores which include smoking status as a risk predictor (Jambi et al, 2020).

Ajlouni et al (2008) and Lee et al (2011) found a direct association of waist circumference with I–IFG, which agree with these findings. In the GDRS study by Paprott et al (2017), waist circumference was one of the predictors with the highest impact on overall reduction of diabetes risk. Waist circumference is a more accurate measure of abdominal fat mass and cardiovascular risk than BMI and is used as a diagnostic criterion for metabolic syndrome (Sonmez et al, 2013).

The genetic predisposition to T2DM, particularly the sibling history of diabetes, requires more research. Environmental factors may also interact with genetic susceptibility to T2DM and modify its expression (Franks, Pearson and Florez, 2013; Galicia–Garcia et al, 2020) Some studies have found that having a sibling with diabetes may increase the odds of HbA_{1c} within the upper limits of normal in individuals without diabetes, possibly due to shared environments and socioeconomic circumstances (Lee et al, 2018). Other cross–sectional studies have not found a significant difference between groups with a parent and sibling history of diabetes or a sibling only history of diabetes (Wu et al, 2017; Chiu et al, 2020). Shared cultural practices and behaviours within families may also play a role (Said, Salem and Baraka, 2016).

In the subjects with abnormal FPG, different risk factors were present. However, all of them had at least one of the significant predictors as outlined above. The two participants who satisfied the 'prediabetes' criteria and obtained a 'still low' category had the following risk factors: one of the participants had a parent with T2DM, high waist circumference and no physical activity, and the other was an active smoker, with height in the shorter range, daily meat consumption and no whole grain consumption. Therefore, the former had three risk factors, of which one was significant, and the latter had four risk factors of which two were significant. The participant who met the criteria for DM had the following risk factors: both a sibling and parent with T2DM, high meat consumption, high BP and no physical activity. Consequently, five risk factors were present of which three were significant. Additionally, he was the oldest participant in the FBG subgroup. Although this

was not the scope of the research study, previous research has shown that increasing age is a risk factor for diabetes (Andes et al, 2019; Mainous et al, 2014; Wang et al, 2017).

5.3. Performance Measures of the GDRS

The GDRS' performance measure resulted in an AUC of 0.79 (95% CI 0.67 to 0.91), with a sensitivity of 66.6% and a specificity of 78.0% when obtaining 30 points. Overall, this reveals a good model, with the former value being close to 0.8, which is then classified as a very good model (Bahijri et al, 2016). In fact, this is better than the ROC–AUC of the GDRS for detection of prediabetes in 35–70–year–olds in Paprott et al (2016). The value for the latter cohort is 0.71 (0.69 to 0.74). However, it scores slightly inferior to the ROC–AUC of the cross–sectional study sample found in the same study for detection of prevalent undiagnosed diabetes, which is 0.84 (0.81 to 0.86). In the simplified version of the GDRS, which is the one used in this research study, a slightly similar discrimination measure of ROC–AUC 0.83 (0.80 to 0.86) was shown. Nevertheless, the P value of the performance of the GDRS in this study is 0.1, making it nonsignificant. The GDRS was not sensitive enough to detect individuals with elevated FPG, therefore, not being accurate in prediction risk of developing diabetes. However, it classified the person who was diagnosed with diabetes as "out of range", meaning that it may be better in detecting individuals with abnormal FPG when diabetes is already present. The sensitivity value of the GDRS detected in this study was higher than that of FINDRISC at a score of ≥15, which was 38%, but FINDRISC had a higher specificity at 90% (Jølle et al, 2019). In Paprott et al (2016), the cut–off values for a maximum in terms of sensitivity (95%) and specificity (73%) was calculated according to five–year predicted risk percentages instead of the GDRS points resulting in a positive predictive value (PPV) of 7% and a negative predictive value (NPV) of 100%.

6. Strengths and Limitations

The study did not reach the calculated sample size of 374 participants, necessitating caution when interpreting the results. Weighting was applied to make the study population as representative of the whole population of comparative age ranges as possible. There were several reasons for not obtaining the essential sample size. The questionnaire was mostly distributed via the eSIMS portal in the university college sample and by direct email to the MCAST sample. Initially, the objective was to invite participants to complete the questionnaire in person, with the researcher filling in the responses to ensure uniformity of measurements. However, the COVID–19 situation necessitated a shift to self–reporting measures, a common practice in large epidemiological surveys (Soriguer et al, 2012). Self–reporting can introduce various biases including recall bias, social desirability bias and measurement bias. Recall bias happens when participants might not accurately remember past behaviours or events, leading to inaccuracies. In this case, the questionnaire mostly focused on current, daily or weekly practices which should not have affected recall bias in a young population but one way of minimizing this error is by using a diary to write down the information required for the questionnaire before filling it in. Social desirability bias refers to participants responding in a manner they believe is socially acceptable rather than truthfully. One way of reducing this bias is to validate the self–reporting instrument, however, the GDRS had already been validated before. Therefore, measurement scales such as Marlowe–Crowne Social Desirability Scale or Martin–Larsen Approval Motivation score would be valuable tools to identify and measure the social desirability components of the self–reported information (Althubaiti, 2016). Measurement bias can be found in the self–reported height and waist circumference which could have possibly led to reduced standardisation and increased variance in these variables. The latter bias can be minimised by obtaining measurements by trained staff instead of self–reported anthropometrics (Lu et al 2016) or by taking multiple readings and averaging them (Bann et al, 2018). Nevertheless, online administration of a tool can be effective and cheap as it can be accessed by a large population using the internet (Zhou et al, 2013). Also, evidence shows that simple clinical risk tools with self–report perform as well as complex models (Rosella et al, 2011). The COVID–19 situation also impacted the collection of blood samples, where much fewer participants attended than those who filled in the questionnaire. Secondly, the questionnaire required personal information which some participants hesitated to share, such as their identification number.

Since the questionnaire was open to all UM and MCAST students between the age of 18 and 35, there could have been an element of self–selection bias. For example, people who already have known risk factors for diabetes would be less inclined to fill in the questionnaire (Downes et al, 2016). Moreover, people who attended the educational institutions included in this study may not be representative of individuals in this age group who do

not. This can be attributed to a lower health literacy of the latter. Education is regarded as one of the components of health literacy (Vozikis, Drivas and Milioris, 2014).

The GDRS does not consider gender or ethnic differences when assessing abdominal obesity, which may be important due to Malta's multicultural population (Vella, 2015). The WHO presented sex–specific WC cut–off values for Caucasian individuals, to define overweight or obese people. Consequently, it is suggested that the sex–specific WC cut–off values should be established for various ethnic groups (Sonmez et al, 2013). However, one strength of using this questionnaire is that it was previously validated in other studies. Moreover, it was cost–effective and easy to use as the risk factors were not difficult to measure.

Blood sampling in a university clinic location was ideal to facilitate participant access. However, taking a single FPG measurement has limitations, as re–testing is generally recommended in a clinical setting. Not using an oral glucose tolerance test (OGTT) may exclude those with IGT, but it was not used in this study due to insufficient funds and time constraints. FPG is the most common glucose dysregulation marker in young adults (Andes et al, 2019), but the OGTT is considered the most sensitive and reliable metric (Wang et al, 2017). In fact, in Bahijri et al (2020), it is stated that without use of an OGTT, a large proportion of individuals with dsyglcaemia would remain undiagnosed. However, the largest number of undiagnosed individuals is captured using the three glycaemic markers, these being FPG, OGTT and HbA_{1c} (Wang et al, 2017). According to the Standards of Medical Care by the ADA (2021), all three glycaemic markers are equally appropriate.

7. Conclusion

This study used the GDRS to assess prediabetes prevalence and risk factors in young adults aged 18 to 35 attending two higher education institutions in Malta. Despite the GDRS showing good performance, it was not statistically significant, with a prediabetes prevalence of 5.3% and one participant meeting T2DM criteria. Practical implications suggest early screening and intervention, particularly for those with a family history of diabetes, and public health campaigns to reduce meat intake and promote healthier lifestyles. Future research should increase the sample size to improve statistical power and employ stratified random sampling to better reflect population demographics. Additional studies should develop a local risk screening tool, investigate specific risk factors, use advanced anthropometric measures, enhance methodological rigor with OGTT and repeat tests, and integrate diabetes education into school curriculums and digital health platforms to improve early detection and prevention strategies in Malta.

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Conflicts of Interest

The authors report no conflicts of interest.

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Review Article

The reduction in breast cancer–related lymphoedema with kinesiotaping

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Abstract

Breast cancer–related lymphoedema (BCRL) is known to be one of the complications associated with the treatment of breast cancer. Kinesiotaping (KT) techniques are recommended in the management of lymphoedema, however, the current literature is ambiguous about its safety and benefits. To identify literature on efficacy of KT in reducing BCRL, adjunct to other conventional methods. The research question was formulated using the PICO framework: **(P)** females suffering from BCRL, **(I)** KT, **(C)** Complex Decongestive Therapy (CDT), **(O)** reduction in BCRL. A systematic literature search was conducted through several electronic databases and reference hand–searching, through the use of the Preferred Reporting Items for Systematic Reviews and Meta–Analyses (PRISMA 2009) framework by means of the PRISMA 27–item Checklist (2020). Limiters and inclusion/exclusion criteria were applied to refine the search outcome. Study designs were restricted to systematic reviews (SRs), meta–analyses and randomised controlled trials (RCTs) in the English language. The studies included were those investigating the effects of KT on BCRL in female participants versus CDT. Five key studies were selected – one SR and four RCTs. The CASP tool was used as the tool for critical appraisal and evaluation of literature. Outcomes of KT (reduction in lymphoedema) are dependent on the phase when it is applied. In the intensive phase of CDT, three studies found that KT was less effective than bandaging in the reduction of limb volume and other lymphoedema–related changes. When applied during the maintenance phase, two studies reported that KT was more effective than compression garments (CGs). The number of SRs and RCTs are low, with small sample sizes and lack of diversity in the interventions used. These, together with the absence of follow–up periods, all hindered the rigour of the presented findings. The findings suggested that KT is more effective when replacing CGs in the maintenance phase of CDT; and less effective when used instead of bandaging in the intensive phase. KT in combination with bandaging then resulted in significant reductions in BCRL but was found to be less effective than bandaging only. A combination of KT with CDT and bandaging then led to the most persistent volume reduction in the follow–up period.

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Keywords: Breast cancer, kinesiotaping, lymphoedema, complex decongestive therapy, bandages, compression garments.

1. Introduction

Breast cancer is the most frequently diagnosed cancer and the 5th leading cause of cancer–related mortality worldwide (World Health Organisation [WHO] 2021). Treatment for breast cancer may lead to adverse effects including breast cancer–related lymphoedema (BCRL), a clinical condition which may be detrimental to quality of life (QOL) (Wanchai et al. 2016).

Complex decongestive therapy (CDT) is currently the gold standard choice of care for lymphoedema. It consists of a two–phase multi–modality approach – the intensive and the maintenance phase (Wanchai et al. 2016). Successful outcomes, related to the degree of lymphoedema reduction from CDT are heavily reliant on the patient's compliance to the multitude of applications involved (Parker & Ayre 2019). Exploring alternative treatment approaches may result in better patient compliance leading to greater therapeutic success (Pereira de Godoy et al. 2017).

The International Society of Lymphology (ISL) names Kinesio–taping as a promising but inconclusive option for the reduction of limb volume (ISL 2020). The method centres around tape that creates convolutions and lifts the skin, easing the pressure on the subcutaneous lymphatic vessels. This activates the microcirculation and enlarges the interstitial space, promoting the evacuation of congested lymph fluid from the swollen limb (Vilela 2015, Bronisława et al. 2014). Other reported benefits of using kinesio–taping include the reduction of pain and discomfort, and mechanical support of muscles and joints (Smykla et al. 2013).

The lack of established guidelines pertaining to the use of kinesio–taping in the reduction of lymphoedema warrants exploration, in view of the increasing aptitude of patients and physiotherapists alike towards using this technique (ISL 2020). This review aimed at retrieving and critically appraising the current literature as guided by means of the evidence–based practice five–step approach by Sackett et al. (2000) (Appendix 1).

The Population, Intervention, Comparison and Outcome (PICO) framework (Richardson et al. 1995) formulated the research question: *Is the use of kinesio–tape effective in reducing breast cancer–related lymphoedema in females, when compared to the use of complex decongestive therapy approaches alone?*

2. Search Method

Several databases were accessed and searched from the multiple–database software available on Hybrid Discovery (HyDi), including: PubMed, Cochrane CENTRAL, Scopus, MEDLINE Complete, CINAHL Complete and MEDLINE ProQuest. The reference lists of the derived studies were analysed manually, to avoid missing out on any relevant publications.

The key terms used for the identified PICO elements were "breast cancer", "lymphoedema" and "kinesio–tape". Alternative terms were found by means of the Medical Subject Headings in the PubMed database (Table 1).

Table 1 – Keywords and Alternative Term

PICO elements	Description	Key terms	Alternative terms
Population	Females who suffered from breast cancer–related lymphoedema	Breast cancer	Breast carcinoma, breast tumour, breast tumour, breast malignancy, mammary neoplasm, mamm ary cancer, mammary carcinoma, breast surgery, axillary lymph node dissection
Intervention	Kinesio–tape (KT)	Kinesio tape	KT, kinesio taping, taping, tape, athletic tape, kinesio tape
Comparison	Complex decongestive therapy (CDT)	No terms utilised in search for CDT	No terms utilised in search for CDT

Table 1 – Keywords and Alternative Term			
PICO elements	**Description**	**Key terms**	**Alternative terms**
Outcome	Reduction in BCRL	Lymphoedema	Breast cancer–related lymphoedema, lymphoedema, lymphedema, BCRL, arm swelling, upper limb swelling, upper extremity swelling

The Preferred Reporting Items for Systematic Reviews and Meta–Analyses (PRISMA 2009) framework guided the selection process by means of the PRISMA 27–item Checklist (2020) (Appendix 2). 219 hits were obtained from the initial search and three additional articles were obtained through hand–searching.

After removing the duplicate studies, 161 studies were screened by two reviewers, to reduce selection bias. In line with the PRISMA framework, the retrieved studies were discarded if the title, or later the abstract, were deemed irrelevant, bringing the search down to 18 articles. These were further narrowed down to 5 articles, ones which were directly related to the focus of this study.

3. Eligibility Criteria

The articles derived were further scrutinized using purposefully established eligibility criteria (Tables 2 and 3) to logically select this review's key studies.

Table 2 – Inclusion criteria
Female participants diagnosed with BCRL following breast cancer treatment – which include chemotherapy, radiotherapy and surgical interventions)
SRs, Meta–analyses, RCTs
KT intervention
A comparison group/s receiving treatment with any of the CDT components

Table 3 – Exclusion criteria
Studies with male breast cancer patients
Articles not written in English or Maltese
Cohort studies, pilot studies, non–analytic studies (case reports/series) and expert opinions
Comparison group receiving treatment with any of the CDT components, these being manual lymphatic drainage, bandage compression treatment, functional limb exercises or skin care but independent from the CDT approach which encompasses the application of all components.

Further limiters were applied according to the database being searched, as shown in Table 4.

Table 4 – Description of Search Strategy

Database	Keyword combination	Limiters	Field searched	Hits
PubMed	("breast cancer" OR "breast carcinoma" OR "breast tumour" OR "breast tumour" OR "breast malignancy" OR "mammary neoplasm" OR "mammary cancer" OR "mammary carcinoma" or "breast surgery" OR "axillary lymph node dissection") AND ("breast–cancer–related lymphoedema" OR "lymphedema" OR "lymphoedema" OR "BCRL" OR "arm swelling" OR "upper limb swelling" OR "upper extremity swelling") AND ("KT" OR "kinesio taping" OR "taping" OR "tape" OR "athletic tape" OR "kinesiotape")	English language; MA, SRs and RCTs	All fields (no option to use title/abstract)	23
Cochrane	Same as keyword combination used for PubMed	English language (no option to use MA, SRs or RCTs)	Title/abstract/ keyword	50
HyDi Medline Complete (EBSCO host)	Same as keyword combination used for PubMed	English language; MA, SRs and RCTs	All fields (no option to use title/abstract)	22
Scopus	Same as keyword combination used for PubMed	English language (no option to use MA, SRs or RCTs)	Title/abstract/ keyword	92
HyDi CINAHL Complete (EBSCO host)	Same as keyword combination used for PubMed	English language; MA, SRs and RCTs		
HyDi Medline ProQuest	Same as keyword combination used for PubMed	English language; MA, SRs and RCTs		

The Critical Appraisal Skills Programme was used to assess for quality following the Critical Appraisal Skills Programme (CASP) checklists (CASP checklists – critical appraisal skills programme), allowing reviewers for a comprehensive and systematic revision of the quality of the chosen studies, identifying their methodological strengths and weaknesses, along with outlining the usefulness of their findings (Singh 2013).

4. Literature Review

The PRISMA flow diagram (Figure 1) demonstrates the search strategy trail summarising the entire screening process undertaken by the two reviewers, resulting in five chosen articles – one systematic review (SR) and four randomised controlled trials (RCTs), listed in Tables 5.1 and 5.2.

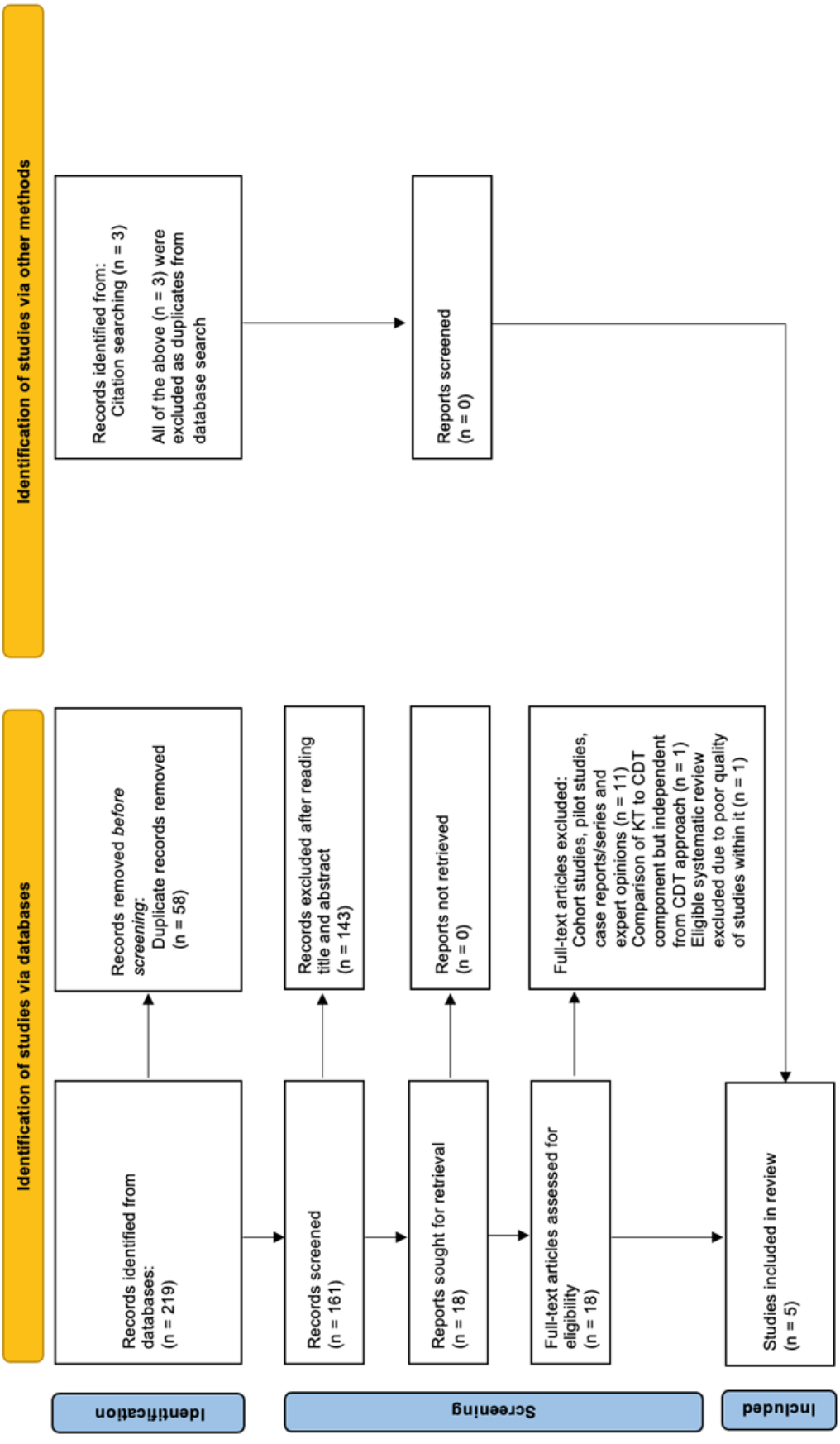

Figure 1 – PRISMA Flow Diagram (Page MJ et al., PRISMA 2020 statement)

Table 5.1 – Details of Selected Studies			
Authors, year	Kasawara, Rossetti, Ferreira, Added, Shiwa, Carvas, Batista (2018)	Torres–Lacomba, Navarro–Brazález, Prieto–Gomez, Ferrandez, Bouchet, Romey–Barrero (2020)	Otero, Delgado, Cortijo, Barrero, Iriarte, Avendano–Coy (2019)
Title	Effects of Kinesio Taping on breast cancer–related lymphedema: A meta–analysis in clinical trials	Effectiveness of four types of bandages and Kinesio–tape for treating breast–cancer–related lymphoedema: a randomized, single–blind, clinical trial	Kinesio taping versus compression garments for treating breast cancer–related lymphedema: a randomized, cross–over, controlled trial
Study design	Randomised, single–blind, clinical trial (N=150)	Randomised, single–blind, clinical trial (N=150)	Randomised, cross–over, controlled trial (N=30)
Aim	Identify most effective treatment for BCRL from KT and four types of bandages	Identify most effective treatment for BCRL from KT and four types of bandages	Compare the effectiveness of KT to CGs during the maintenance phase of CDT for BCRL
Results	Significant improvements in volume were greatest in simplified multilayer and cohesive bandage groups, and least in KT and adhesive bandage groups. No significant differences in other BCRL	Significant improvements in volume were greatest in simplified multilayer and cohesive bandage groups, and least in KT and adhesive bandage groups. No significant differences in other BCRL symptoms between groups. KT deemed most comfortable	Greater reduction in RVC, improvements in ROM of five upper limb movements and BCRL–related symptoms, and greater comfort with KT

Table 5.2 – Details of Selected Studies		
Authors, year	Tantawy, Abdelbasset, Nambi, Kamel (2019)	Pekyavas, Tunay, Akbayrak, Kaya, Karatas (2014)
Title	Comparative Study Between the Effects of Kinesio Taping and Pressure Garment on Secondary Upper Extremity Lymphedema and Quality of Life Following Mastectomy: A Randomized Controlled Trial	Complex decongestive therapy and taping for patients with postmastectomy lymphedema: A randomized controlled study
Study design	Randomised, controlled trial (N=66)	Randomised controlled trial (N=45)
Aim	Compare the effects of KT and PGs on BCRL	Investigate treatment of BCRL in intensive phase of treatment with CDT; CDT with KT and bandage; and CDT with KT excluding bandage

Table 5.2 – Details of Selected Studies		
Results	Greater volume reduction and improvement in BCRL–related symptoms with KT	Significant volume reduction in all groups but greatest in CDT with bandage and KT – also resulted in longevity of treatment after 4–week control period. No significant differences in other BCRL–associated symptoms between all groups

5. Findings of the SR

Kasawara et al.'s SR (2018) investigated the effects of kinesio–taping on BCRL in seven identified studies, based on the following components.

5.1. Heterogeneity

The heterogeneity across the studies was shown to be statistically significant (p<0.10) with I^2>50% and Tau^2>1 readings and was hence investigated further by means of a sensitivity analysis.

5.2. Presentation of Results

Kasawara et al. (2018) documented and presented their results in tables, including a description of their meta–analysis. A forest plot was used to summarise the meta–analysis results. The change in the volume of lymphoedema post–treatment was measured using the mean and standard deviation (SD) values, to determine the effects of kinesio–taping.

This SR used studies with different units of volumetric measurement for the outcome of interest. For this reason, the mean differences from the separate studies cannot be precisely pooled to yield a weighted mean difference (Andrade 2020). The standardised mean difference (SMD) between the treatment and the control group was calculated for each study using mean and SD values. A 95% confidence interval (CI) was set to calculate the pooled SMD and CI range of the meta–analysis.

Since 3 out of 6 studies included in the meta–analysis had three study arms, two separate tables of results – A and B (Kasawara et al. 2018, p.7, Figure 2) – and their forest plots were drawn up. Within table A, a comparison of the treatment and one of each study's control groups was made. In table B, the control group of these 3 studies was changed to their remaining study arm, while the treatment group was kept the same. In doing so, the heterogeneity of the study groups was re–assessed and found to be statistically insignificant for both table A (p=0.78, I^2=0% and Tau^2=0) and B (p=0.39, I^2=3.15%, Tau^2=0.004).

5.3. Changes in Volume of Lymphoedema

All the studies reported a decrease in the volume of BCRL with KT treatment. However, only 2 of the 7 studies – Pop et al. (2014) and Melgaard (2016) – reported a significant difference in the reduction of lymphoedema between the KT and control groups. This meta–analysis (Kasawara et al. 2018), which collectively analysed results of six of these studies, showed that there was no significant difference in the reduction of lymphoedema between the participants in the KT group vs the comparison group in both table A (SMD=0.04, 95% CI: –0.24; 0.33) and table B (SMD=0.12, 95% CI: –0.16; 0.41). Hence, Kasawara et al. (2018) concluded that KT does result in a reduction of limb volume but was not more effective than the other comparison treatments.

5.4. Other Lymphoedema–related changes and adverse effects

Three of the studies used in this SR (Kasawara et al. 2018) considered the patients' QOL: Melgaard (2016) and Tsai et al. (2009) reported significant improvements in QOL with KT treatment, while Pekyavas et al. (2014) did not report any significant change. All studies concluded that patient comfort, satisfaction and convenience were better with KT as opposed to compression bandaging. Lastly, KT treatment resulted in no adverse effects when used to treat BCRL.

6. Findings of the RCTs

6.1. Presentation of Results

All RCTs presented their results in table format. Most studies presented the means and SD, except for one study

that reported the standard error of the mean. Another study also reported the median and interquartile range.

The statistical results of all RCTs were interpreted using *p*–values to reflect the strength of the observed results against the null hypothesis. The RCTs discussed, pre–set their statistical significance level at a *p*–value of <0.05 with a 95% CI.

6.2. Intensive Phase

The intensive/decongestive phase (Michopoulos et al. 2020), is comprised of a 2–week outpatient program consisting of manual lymphatic drainage (MLD), compression bandaging, exercise, skin and nail care. These aim to mobilize the accumulated fluid, restore the size of the limb, reduce fibrosclerotic subcutaneous tissue alterations and improve the general skin condition (Wanchai et al. 2016).

6.3. Changes in Volume of Lymphoedema

In the RCT conducted by Torres–Lacomba et al. (2020), significant differences were found in all treatment groups when comparing the percentage reduction in excess volume (p<0.001) between baseline and post–treatment. Specifically, simplified multilayer and cohesive bandages resulted in the greatest reductions in the volume of oedema, measured in millilitres. Statistically significant differences in reduction in excess volume was also found between most of the groups (p<0.001), with KT always proving to be less effective than bandaging. Insignificant differences were found in the comparisons of cohesive–vs–simplified multilayer bandages (p=0.456), adhesive–vs–multilayer bandages (p=0.232) and adhesive bandage–vs–KT (p=0.071). This shows that all bandages were more effective than KT in reducing lymphoedematous volume, except for the adhesive bandage. The groups with least percentage changes in volume (30.8%) were those using KT and adhesive bandaging. There was also a 54.6% difference in volume reduction between the most (simplified multilayer bandage) and least effective (KT) groups.

In the second study by Pekyavas et al. (2014), all three study groups had a significant change in arm volume, recorded in millilitres – CDT with bandaging (p=0.023); CDT with bandage and KT (p=0.008); CDT with KT but without bandage (p=0.008). However, the 'CDT with bandage and KT' group was the only one that showed a persistent decrease in arm volume at the end of the four–week period (p=0.040). Hence, the addition of KT underneath the bandage, as part of the standard CDT approach, results in longevity of the lymphoedema treatment effects. This group also had the highest improvements in mean differences between the bilateral arm volumes, when compared to the other groups.

6.4. Other Lymphoedema–related Changes

Torres–Lacomba et al. (2020) revealed significant improvements in perceived comfort (p<0.001), feeling of heaviness (p=0.031) and tightness (p=0.026) in all the groups, but no intergroup differences resulted. KT was considered the most comfortable, whilst the multilayer bandage was the least.

Pekyavas et al. (2014) reported a significant decrease in upper limb heaviness in all groups (p<0.05), both during treatment and control periods. The pain intensity was remarkably reduced between baseline and end–of–control measurements, in the groups using CDT with bandage and KT (p=0.011) and CDT with KT but without bandage (p=0.000). All the treatment groups also had a positive effect (p<0.05) on BCRL–associated limitations in activities of daily living (ADLs) from prior to treatment up till the control period. Several outcome parameters including pain, discomfort, heaviness, numbness, stiffness, QOL, limitations in ADLs, patient satisfaction from treatment at night/daily activities, itching and wound formation at the end of treatment were investigated. Significant differences were found in all groups between baseline, post–treatment, and end–of–control measurements. However, no significant differences were found when comparing all outcome measures between the three groups (p>0.05).

6.5. Maintenance Phase

The maintenance phase is a lifelong continuation of the following self–care practices – skin care, exercise, MLD and the donning of compression garments (CGs) during the day (Wanchai et al. 2016).

6.6. Changes in Volume of Lymphoedema

Otero et al. (2019) recorded the change in upper–limb volume with treatment through the percentage of 'relative volume change' (RVC). This outcome took into consideration the volume of the unaffected arm to ensure that no bias was introduced due to changes in BMI during the treatment period. Due to lack of literature

on this variable, Otero et al. (2019) also made use of the percentage of 'relative volume difference' (RVD).

Both interventions resulted in a significant reduction in volume, with greater RVC and RVD in the KT group. The difference in the RVC and RVD between both groups was statistically significant (p<0.001), showing that KT intervention was more effective than compression garments (CGs) in reducing the volume of lymphoedema. The results were similar for both interventions regardless of their order with respect to the in–between wash–out period, during which there were no significant change in volume due to carryover, period, or sequence effects (p<0.05). According to Tantawy et al. (2019), the sum of limb circumferences (in centimetres) decreased significantly following both KT (p=0.01) and pressure garment (PG) (p=0.04) interventions, with the KT application proving to be more effective upon comparison (p=0.01).

6.7. Other Lymphoedema–related Changes

Otero et al (2019) reported self–perceived comfort to be significantly greater (p<0.001) when using KT over CGs. The use of KT resulted in significant improvements in upper limb range of motion (ROM) (p<0.05) in five specific movements – shoulder flexion and abduction, elbow flexion, wrist flexion and extension as opposed to CGs which resulted in no significant improvements (p>0.05). KT was also effective in reducing lymphoedema–related symptoms (p<0.05), while CGs did not bring about any significant change. Although both groups individually resulted in significant reductions in tightness (p<0.05), the KT group was superior to CGs (p<0.05).

Tantawy et al. (2019) documented a significant decrease in shoulder pain and disability (p=0.01) with KT, improvement in handgrip strength (p=0.02) and all QOL functional domains including physical, role, emotional, cognitive, and social scores (p<0.05). It also resulted in statistically significant improvements (p<0.05) in other lymphoedema–related symptoms, two of which were pain and fatigue. On the other hand, the PGs did not bring about any significant differences in shoulder pain and disability, handgrip strength, physical and role functional scores, and pain and fatigue symptom scores (p>0.05). In saying so, both the KT (p=0.001) and the PG (p=0.04) resulted in significant improvements in the overall QOL. Upon comparison, all the improvements noted in both groups were significantly higher in the KT group (p<0.05).

6.8. Adverse Effects

Two participants withdrew from two different bandaging groups due to unspecified discomfort, while another from the KT group experienced skin irritation (Torres–Lacomba et al. 2020). Pekyavas et al. (2014) did not mention any adverse effects or account for the four drop–outs during the control period. In the study by Otero et al. (2019), 20% of the participants experienced skin peeling after removing KT. While no adverse effects were reported by Tantawy et al. (2019), four participants dropped out due to discomfort in the PG group.

6.9. Confounding Variables

Most of the participants included in the key studies had a BMI>25kg/m^2 and some even >30kg/m^2, which is defined as overweight and obese respectively (WHO 2021). Wu et al. (2019) reported that excess bodyweight not only increases the risk of developing lymphoedema but may also limits the efficacy of elastic compression, thus leading to worsening of this condition. However, this study does not target the rest of the population within the healthy weight range and limits the effectiveness of the studies' treatment intervention.

6.10. Summary of findings

In the intensive phase, KT together with bandaging resulted in significant reductions in the volume of BCRL but was found to be less effective than bandaging only (Torres–Lacomba et al. 2020; Pekyavas et al. 2014). However, Pekyavas et al. (2014) noted that the use of CDT with KT applied behind the bandaging brought about the most persistent volume reduction following the follow–up period. These same studies also revealed positive effects of KT in other lymphoedema–related symptoms, outcomes which were not significantly different from the comparison bandaging groups, except for KT being significantly deemed the most comfortable. The latter aligns with the findings of most of the studies included in the SR by Kasawara et al. (2018).

In the maintenance phase, Otero et al. (2019) and Tantawy et al. (2019) reported significant differences between the intervention and comparison groups for their outcome measures, all in favour of KT being more effective.

Overall, the findings above indicate that using KT in the intensive phase has no additional benefits when compared to only bandaging as part of the standard

CDT, apart from possibly increasing the longevity of the treatment effects when used alongside the standard CDT. Meanwhile, interventions using KT seem superior over CGs and PGs in the maintenance phase of CDT for BCRL. The latter can be associated with a higher perceived comfort, which was constant across all studies, increasing the patient's compliance to treatment. This is a highly relevant factor to consider, since BCRL is a long–term condition with no cure to date. Most drop–outs were attributed to discomfort from the comparison interventions. Although KT was associated with skin complications in only two studies (Torres–Lacomba et al. 2020 and Otero et al. 2019), this should not be overlooked as this predisposes patients with BCRL to a higher risk of infection due to possibly impaired local immunity (Yuan, Arcucci et al. 2019).

7. Areas for further research

The key studies used in this review have been deemed to be good sources of evidence, however, future studies using larger–scale trials would ascertain findings with more confidence or expose small but significant differences in the effects of interventions. Ethical considerations, always at the heart of scientific research, would explain why KT has not been investigated as a standalone treatment modality for BCRL in the intensive phase of treatment. Based on the results of this study, however, the exclusive use of KT can be ethically investigated during the maintenance phase of treatment in future trials. Being a chronic condition, BCRL and its long–term management should be investigated using longitudinal studies to elucidate the optimal treatment regime in its varying phases.

8. Conclusion

This paper set out to explore the effects of KT in comparison to CDT on reducing BCRL. From the evidence gathered, the authors of this paper have concluded that during the intensive phase, bandaging remains more effective than KT as part of the CDT approach. During the maintenance phase, KT is a more effective alternative to CGs.

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Conflicts of Interest

The authors report no conflicts of interest.

APPENDIX 1: Evidence–Based Practice Five–Step Approach (Sackett et al. 2000)

Evidence–Based Practice Five–Step Approach (Sackett et al. 2000)	
EBP Step	**Description**
Step 1	Converting the need for information (about prevention, diagnosis, prognosis, therapy, causation, etc.) into an answerable question.
Step 2	Tracking down the best evidence with which to answer that question.
Step 3	Critically appraising that evidence for its validity (closeness to the truth), impact (size of effect), and applicability (usefulness in our clinical practice).
Step 4	Integrating the critical appraisal with our clinical expertise and with our patient's unique biology, values, and circumstances.
Step 5	Evaluating our effectiveness and efficiency in executing steps 1 – 4 and seeking ways to improve for next time.

APPENDIX 2: The PRISMA 2020 Checklist

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	

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PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

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