Development, validation and implementation of a novel dietary salt monitor in type 2 diabetes in UK

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A thesis submitted in partial fulfilment of the requirements of London Metropolitan University for the degree of Doctor of Philosophy

March 2022

Abstract

The risk of cardiovascular morbidity and mortality increases manyfold in Type 2 diabetes, owing to the higher prevalence rates of hypertension. The role of dietary salt intake has been well established in the prevention and management of high blood pressure. However, there is paucity of research interventions and education programme aimed at lowering dietary salt intake in type 2 diabetic population. The aim of this research study is to develop, validate and implement the use of 'dietary salt monitor' for reducing dietary salt intake in participants with Type 2 diabetes.

A 24h dietary recall using multiple pass recall method was obtained from the participants with type 2 diabetes and concomitant hypertension (n=50), attending outpatient diabetic foot clinic at NHS hospital in Basildon, Essex. More than a quarter of the participants (28%) consumed salt above the recommended daily limit of $\leq$6g. The top ten contributors of salt identified using pivot tables were bread and rolls, processed meats, added salt, ready meals, meat dishes, spreading fats, canned beans, soups, cheese, and sandwiches. An interviewer-administered questionnaire captured the knowledge, attitudes, and practices (KAP) related to dietary salt intake and showed a mean KAP score for the group as 22.6 (SD 6.1) against a maximum achievable score of 40. Poor perception of one's salt intake; non-practice of reading salt content on nutrition label, frequent addition of salt to food and lack of understanding on daily salt limit and food sources of salt were identified as potential barriers in adherence to the recommended salt intake. The dietary data of these type 2 diabetic participants was further analysed for the development of a novel 'dietary salt monitor'. It included a short list of 23 food categories that were carefully identified based on its salt density, contribution of salt to the diet, non - achievement of 2017 salt targets, challenges faced by food industry for further salt reduction, foods unrecognised as high in salt by consumers, sustainability, change in cooking practices during COVID-19 and overall nutritional composition of the food category, to fulfil its role as an educational intervention.

The dietary salt monitor was validated against 24h urinary excretions and food records gathered from university students. The Bland and Altman method for agreement between dietary salt monitor and urinary sodium excretion method suggested a bias of 1.5g/ d (upper LOA 7.68 and lower LOA -4.72). The results for cross classification between this tool and urinary biomarker suggested a low level of misclassification (n=1, 11%), but it varied at individual level.

The effectiveness of this dietary salt monitor was pilot tested in an online nutrition education intervention, where type 2 diabetes participants (n=22) were recruited from various online platforms including the Diabetes UK website. This dietary salt monitor was integrated in a web form and supported by a short educational video highlighting the salt content of the food categories and key strategies as '4R's - **R**educing portion, **R**educing frequent intake, **R**educed salt food, **R**ead nutrition label, for lowering salt intake. This short-term intervention study (6 weeks) resulted in a statistically significant reduction in median salt intake for the group, with baseline of 7.9 g/d shifting to 5.2 g/d post the intervention (p=0.001, effect size = 0.6).

This study marked the development of UK's first dietary salt monitor for use in Type 2 diabetes and is effective for reducing salt intake in this group. The tool is proposed to be further used for monitoring salt intake of these patients in collaboration with their health professionals in NHS, private medical setting and signposted at online platforms as Diabetes UK to reach out to diabetic community, at large.

Published Abstracts

Babber, R. and Bhakta, D. (2020). Barriers in adherence to dietary salt intake recommendations in participants with type 2 diabetes and co-morbid hypertension. *Proceedings of the Nutrition Society, 79*(OCE3), E770. doi: 0.1017/S0029665120007594 (see Appendix R)

Babber, R., and Bhakta, D. (2022). Dietary salt monitor – a novel nutrition education intervention for reducing salt intake in Type 2 Diabetes. *Proceedings of the Nutrition Society, 81*(OCE5), E216. doi:10.1017/S002966512200249 (see Appendix R)

Accepted Abstracts

Babber, R., and Bhakta, D. (2022). Development of a novel nutrition education intervention for reducing dietary salt intake in Type 2 diabetes in UK. British Dietetic Research Symposium, in press

Attendance at Conferences

Attendance and Presentation at London Met Student and Research Conference- 14-15 July 2020, online.

Attendance and Poster Presentation at Nutrition Society Live, 2020

Attendance at Diabetes Professional Care, 2020, online.

Attendance and Poster presentation at Nutrition Society's Summer Conference 2022, Food and Nutrition: Pathways to a sustainable future

Attendance and Poster Presentation at BDA Research Symposium 2022

Acknowledgements

It is beyond words to express how thankful I have been to be blessed and live my dream of going through this PhD journey. And I have been immensely fortunate to be surrounded, associated, and nurtured by such kind and extraordinary team.

Firstly, I would like to express my deepest gratitude to my supervisor Dr Dee Bhakta, who has been a pillar of my strength throughout the overwhelming and challenging circumstances, of this research study. Her support, guidance and unique charisma has been instrumental for boosting my confidence and constantly motivating me to do my best. I am thankful for her expert advice, teaching and support throughout this journey.

I am very grateful to Prof. David McCarthy for the guidance and help, through the rather daunting process of NHS ethical approval and for supervision. And thank you for the appreciation and feedback, each time we meet and after the research presentations.

I am also thankful to my supervisors for trusting me with teaching responsibilities for their undergraduate and postgraduate students.

I am thankful to the Research Team, Ms Carol Alves and Ms Raiji Koothor at Basildon and Thurrock University Hospital, for the help and arrangements for obtaining NHS passport, research training and facility for conducting my research work. I would also like to pay my regards to Dr Michael Mulchay, Consultant – Endocrinology and Diabetes Mellitus, for his welcoming approach and assistance with recruitment of participants from Diabetes Foot Clinic.

And this journey would have never been possible without the support of the most special person in my life – my husband, Dr Jitin Bhugra. Thank you for supporting me in every possible way and always being there for me.

I am thankful to almighty to bestow me with the joy of motherhood during this period and gave me the zeal for carrying out motherly duties alongside the academic work. Lots of love to my son, my life – Savir!

I owe my passion for learning to my parents. Thank you mummy and papa for your blessings, endless love and providing me with the best childhood. For the values you have taught us and always encouraging me to strive for the best.

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ABBREVIATIONS

ACE	Angiotensin converting enzyme
ADVANCE	Action in Diabetes and Vascular Disease, Preterax and Diamicron MR Controlled Evaluation
ARB	Angiotensin Receptor Blocker
B.A plot	Bland Altman Plot
B.P	Blood pressure
BHF	British Heart Foundation
BIA	Bioelectrical impedance analysis
BMI	Body Mass Index
BNF	British Nutrition Foundation
CAD	Coronary artery disease
CAFE	Compositional Analyses from Frequency Estimates
CASH	Consensus Action on Salt and Health
CCBs	Calcium Channel Blockers
CCHS	Canadian Community Health Survey
CHEP	Canadian Hypertension Education programme
CIAA	Confederation of the Food and Drink Industries of the EU
CKD	Chronic Kidney Disease
Cl	Chloride
COFIDS	Composition of foods integrated dataset
COT	Committee on Toxicity
CVA	Cerebrovascular accident
CVD	Cardio-vascular disease
DALYs	Disability Adjusted Life Years
DAPA	Dietary assessment and physical activity measurements
DASH	Dietary Approaches to Stop Hypertension
DBP	Diastolic Blood Pressure
DESMOND	Diabetes Education for Ongoing and Newly Diagnosed Diabetes
DINER	Data into Nutrients for Epidemiological Research
DOH	Department of Health
DOM	Dietitians in Obesity Management
DRWF	Diabetes Research and Wellness Foundation
DSME	Diabetes self-management education
DXA	Dual-energy X-ray Absorptiometry
EI	Energy Intake

EmER	Estimated individual minimum energy requirements
EMR	Electronic Medical Record
ENaC	Epithelial Sodium Channel
EPIC	European Prospective Investigation into Cancer and Nutrition
FBDG	Food-based Dietary Guidance
FETA	FFQ EPIC Tool for Analysis
FFM	Fat free mass
FM	Fat mass
FOP	Front of pack
FSA	Food Standard Agency
GCP	Good Clinical Practice
HbA1c	Hemoglobin A1c
HC	Hip circumference
HCP	Healthcare professional
HOPE	Heart Outcomes Prevention Evaluation study
HOT	Hypertension Optimal Treatment study
HRA	Health Research Committee
HTN	Hypertension
IDF	International Diabetes Federation
IQR	Interquartile range
IRAS	Integrated Research Application System
KAP	Knowledge, Attitude and Practice
LOA	Limits of Agreement
MAFF	Ministry of Agriculture, Fisheries and Food
MI	Myocardial Infarction
MPR	Multiple pass recall method
Na	Sodium
Na MRI	Sodium Magnetic Resonance Imaging
NaCl	Sodium Chloride
NANS	National Adult Nutrition Survey
NCFS	National Children's Food Survey
NDA	National Diabetes Audit
NDNS	National Diet and Nutrition Survey
NHANES	National Health and Nutrition Examination
NHS	National Healthcare System
NICE	National Institute for Health and Clinical Excellence

NMEIT	No Material Ethical Issue Tool
NO	Nitric oxide
NTFS	National Teens' Food Survey
PABA	Para-aminobenzoic acid
PAHO	Pan American Health Organization
PBC	Perceived Behavioural Control
PHE	Public Health England
PIS	Participant Information Sheet
PROBE	Prospective, Randomized, Open with Blinded Endpoint evaluation
PS	Portion size
PSEA	Portion Size Estimation Aids
PSEE	Portion Size Estimation Element
RAAS	Renin-Angiotensin Aldosterone System
RACC	Reference Amounts Customarily Consumed
RCT	Randomized control trial
REC	Research Ethics Committee
SACN	Scientific Advisory Committee on Nutrition
SAPP	Sodium Acid pyrophosphate
SBP	Systolic Blood Pressure
SD	Standard deviation
SFFQ	Short Food Frequency Questionnaire
SHMP	Sodium Hexametaphosphate
SPP	Sodium Pyrophosphate
SS	Serving size
STPP	Sodium Tripolyphosphate
SVR	Systemic Vascular Resistance
T2DM	Type 2 Diabetes Mellitus
TBW	Total body water
TOHP II	Trial of Hypertension Prevention II
TONE	Trial of Nonpharmacologic Interventions in the Elderly
TPB	Theory of Planned Behaviour
UK	United Kingdom
UKPDS	United Kingdom Prospective Diabetes Study
USDA	United States Department of Agriculture
WC	Waist circumference
WCRF	World Cancer Research Fund

WEAX	Water Extractable Arabinoxylans
WHO	World Health Association
WHR	Waist Hip Ratio
WHtR	Waist to Height Ratio

Chapter 1: General Introduction and Review of Literature

1.1 Overview

The growing challenge of lifestyle diseases as Type 2 diabetes mellitus (T2DM) has posed immense economic burden on health care system across the world. Though the management of this condition itself is an important step in preventing and delaying progression of cardio-vascular disease (CVD), the increased prevalence of hypertension in T2DM increases the CVD risk by manyfold. There has been extensive number of research studies that have established the significance for hypertension management in type 2 diabetic population, for reducing mortality as well as CVD rates. The physiological mechanisms explaining the role of excessive salt intake in the development of hypertension has been well studied and a multicentre landmark study-INTERSALT had confirmed the direct relationship. Thus, targeting salt reduction, through awareness, promotion, and strategies for implementing this dietary advice is vital for diabetic population.

1.2 T2DM – a major public health challenge

Definition Type 2 diabetes is a chronic medical condition characterized by hyperglycaemia and occurs due to a progressive loss of adequate β-cell insulin secretion frequently on the background of insulin resistance (ADA, 2021).

1.2.1 Prevalence of T2DM

Globally, an estimated 462 million individuals are affected by T2DM, corresponding to 6.28% of the world's population (Khan et al., 2020). More than 1 million deaths were attributed to this condition in 2017 alone, ranking it as the ninth leading cause of mortality. This is an alarming rise when compared with 1990, when type 2 diabetes was ranked as the eighteenth leading cause of deaths. In terms of Disability Adjusted Life Years (DALYs), diabetes ranks as the seventh leading disease. There are about 4.7 million people living with diabetes mellitus in the UK and 90% have T2DM (Diabetes UK, 2019).

1.2.2 Economic burden of diabetes

Diabetes is a chronic condition, its management and care include considerable burden not only on individual but a substantial cost to the National Healthcare System (NHS) (Hex et al., 2012). The NHS spends £10 billion every year on diabetes and 80% of this is spent on treating its complications alone (Diabetes UK, 2019). Amongst the range of modifiable risk factors that may increase the incidence and progression of diabetes complications, one very significant but of silent nature is hypertension (Emdin et al., 2015; Katayama, Hatano and Issiki, 2018; Yamazaki, Hitomi and Nishiyama, 2018). The financial modelling based on economic research predictions by the Nuffield School of Economics (Keng et al., 2019) suggested vast economic savings can be achieved with attainment of the diabetes treatment targets for HbA1c, blood pressure and cholesterol.

1.3 Concomitance of T2DM and hypertension

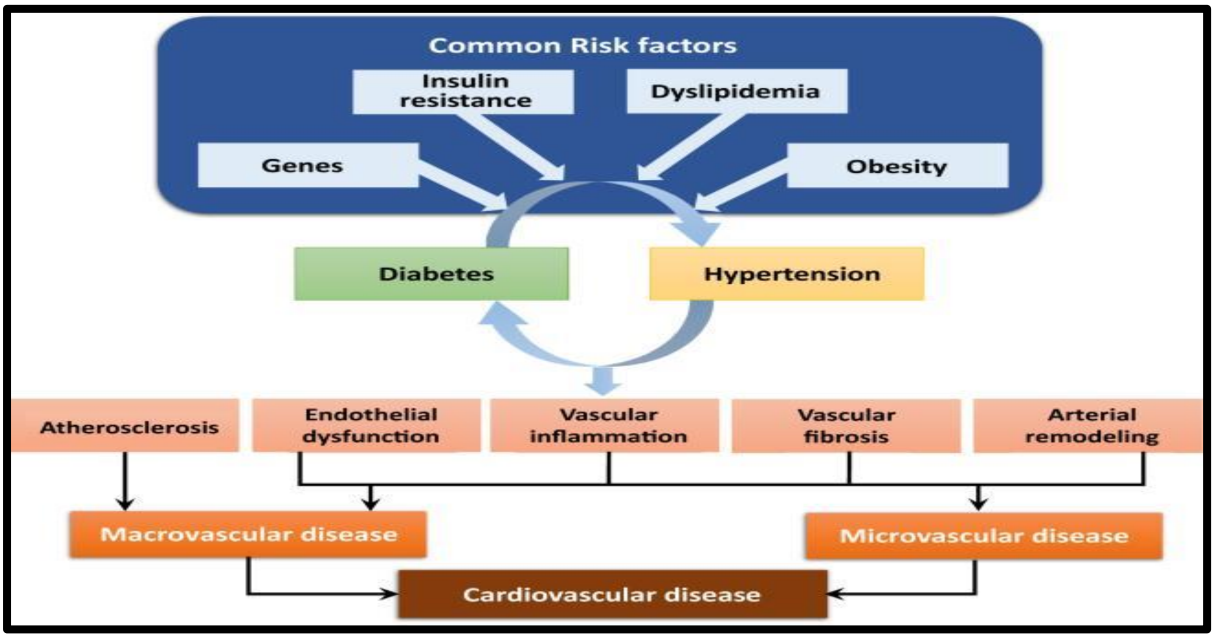
Hypertension is present in up to two-thirds of the patients living with T2DM (Rizvi, 2017; Zhou et al., 2017; Pavlou et al., 2018). The type 2 diabetic patients experience increased peripheral artery resistance caused by vascular remodelling and increased body fluid volume associated with insulin resistance-induced hyperinsulinemia and hyperglycaemia. Both these mechanisms elevate systemic blood pressure (Ohishi et al., 2018).

A population-based prospective cohort study investigating the bidirectional causal relations of T2DM with hypertension using an individual-level data for 318 664 UK Biobank participants, reported a causal relationship of T2DM to hypertension risk. The author mentioned that the precise mechanism of this causal relationship is unknown, but it was speculated that an accelerated arterial stiffness resulting from T2DM was associated with a greater increase in SBP instead of a higher DBP during the aging process (Sun et al., 2019). Some of the earlier observation studies also established the association of T2DM and hyperglycaemia with incident hypertension (Goff et al., 2003; Lai et al., 2009; Levin et al., 2010). The studies explaining the probable mechanism for causality of hypertension in T2DM, is probably due to underlying factors associated with T2DM such as broad cardio-metabolic disorders, including obesity, insulin resistance, β-cell dysfunction, inflammation, oxidative stress, vascular dysfunction, sodium retention, sympathetic excitation, renin-angiotensin-aldosterone system activation, and kidney damage, which has been widely proposed in the initiation of hypertension. (Cheung and Li, 2012; Ferrannini and Cushman, 2012; Vargas-Uricoechea and Caceres-Acosta, 2018).

A literature review conducted by Climie et al. (2019) shared a different perspective on relationship between T2DM and hypertension. Since not all those with T2DM have hypertension and vice versa, it is more likely that one perpetuates the other. At the crossroads between these two health conditions is a bidirectional relationship between the macro-vasculature and microvasculature. The large elastic arteries lose their buffering capacity and increase in stiffness (Chirinos et al., 2013; Prenner and Chirinos, 2015; Loehr et al., 2016) which may accentuate the transmission of pulsatility from the macro-circulation to the microcirculation. In the microvasculature, multiple abnormalities in structure and function occur, including reduced nitric oxide (NO) availability, rarefaction of arterioles, capillaries, and venules, decreased arteriolar diameter, and increased wall-to-lumen ratio of small arteries. This may lead to further impairment of insulin-mediated glucose disposal (Stehouwer, 2018) and increase in peripheral resistance.

Raised blood pressure increases the incidence of both micro- and macrovascular complications in type 2 diabetic patients, while the co-existence of these two major risk factors leads to a four-fold increased risk for cardiovascular disease (Ferrannini and Cushman, 2012; Rizvi, 2017 and Pavlou et al., 2018). There is also substantial overlap in the cardiovascular complications of diabetes and hypertension related primarily to microvascular and macrovascular disease (Petrie et al., 2018). Common mechanisms, such as upregulation of the renin-angiotensin-aldosterone system, oxidative stress, inflammation, and activation of the immune system likely contribute to the concomitance of diabetes and hypertension (see figure 1.1) and higher CVD risk. The study conducted by Chen, Magliano and Zimmet (2011) explored the extent of excess risk of cardiovascular events in diabetic individuals attributable to hypertension. It showed that while the risk of death (7%) and cardiovascular events (9%) could be attributed to diabetes, the risk of death and cardiovascular events attributed to co-existent hypertension were far higher; 44% and 41% respectively.

Figure 1.1: Vascular processes whereby diabetes and hypertension pre-disposes to cardiovascular disease, (Source: Petrie et al., 2018).



1.4 <u>Hypertension management in T2DM</u>

1.4a Definitions

Blood pressure is the pressure, measured in millimetres of mercury, within the major arterial system of the body. It is conventionally separated into systolic and diastolic determinations. Systolic blood pressure is the maximum blood pressure during contraction of the ventricles; diastolic blood pressure is the minimum pressure recorded just prior to the next contraction.

1.4b Classification for hypertension

<u>Stage 1 hypertension</u> is a clinic blood pressure ranging from 140/90 mmHg to 159/99 mmHg, and an ambulatory daytime average or home blood pressure average ranging from 135/85 mmHg to 149/94 mmHg.

<u>Stage 2 hypertension</u> is a clinic blood pressure of 160/100 mmHg or higher but less than 180/120 mmHg, and an ambulatory daytime average or home blood pressure average of 150/95 mmHg or higher.

<u>Severe hypertension</u> is a clinic systolic blood pressure of 180 mmHg or higher, or a clinic diastolic blood pressure of 120 mmHg or higher.

1.4c Medical management of hypertension

Table 1.1: Classes of antihypertensive medications with mode of action and common examples (Source: Adapted from Jackson, 2015)

Class	Examples
Targeting renin-angiotensin system They act to reduce production of the peptide hormone angiotensin II or reduce its receptor binding. Angiotensin II causes sympathetic nervous system activation, increased pituitary secretion of antidiuretic and adrenocorticotrophic hormones, and increased adrenocortical secretion of aldosterone. By antagonizing the RAS pathway, systemic vascular resistance (SVR) and arterial pressure are reduced**.**	
Angiotensin- converting enzyme (ACE) inhibitors	Captopril, lisinopril, ramipril
Angiotensin receptor blockers (ARBs)	Candesartan, losartan, valsartan
Direct renin antagonists	Aliskiren
Adrenoceptor antagonists These compounds inhibit the action of adrenaline (epinephrine), noradrenaline (norepinephrine), and other catecholamines that control autonomic outflow and some functions of the central nervous system at the adrenergic receptors or inhibit their release. Their physiological effects include the dilation of blood vessels, which lowers blood pressure and slows heart rate.	
β-Blockers	Atenolol, metoprolol, propranolol
α-Blockers	Doxazosin, labetalol (also a β-blocker), phentolamine, phenoxybenzamine
Calcium channel blockers (CCBs) CCBs act on L-type calcium channels present in vascular smooth muscle and in myocardial and nodal tissues. Those with higher affinity to vascular smooth muscle cause peripheral vasodilatation and reduced SVR.	
Phenylalkamines	Verapamil
Dihydropyridines	Amlodipine, nifedipine, nimodipine
Benzothiazepines	Diltiazem
Diuretics Diuretics act by reducing sodium chloride reabsorption at different sites in the nephron, thereby increasing urinary sodium, and consequently, water loss and thus the volume of blood and blood pressure.	
Thiazides	Bendroflumethiazide, hydrochlorothiazide
Loop	Furosemide, bumetanide
Potassium sparing/ aldosterone antagonist	Amiloride, spironolactone

Medical Management of hypertension in patients with T2DM

Hypertension in patients with diabetes should be treated aggressively with lifestyle modification and drug treatment. Recommendations on the management of hypertension and blood pressure thresholds are from the *NICE—Hypertension in adults: diagnosis and management guideline (NG136, March 2022),* NICE recommends that the same blood pressure thresholds and treatment targets are used for patients with or without type 2 diabetes. Following is the algorithm for the medical management of hypertension as recommended by NICE guidance.

Step 1: Offer an ACE inhibitor or angiotensin receptor blocker (ARB)

Step 2: In addition to an ACE inhibitor or ARB, add in a calcium channel blocker or thiazide-like diuretic. Offer a thiazide-like diuretic if there is evidence of heart failure.

Step 3: Offer an ACE inhibitor or ARB, a calcium channel blocker and a thiazide-like diuretic.

Step 4: Before considering further treatment for a person with resistant hypertension, confirm elevated clinic blood pressure measurements using ambulatory or home blood pressure recordings, assess for postural hypotension and discuss adherence. If further treatment is required, consider seeking specialist advice, or the addition of low-dose spironolactone if potassium is 4.5 mmol/litre or less; or an alpha blocker or a beta blocker if potassium is greater than 4.5 mmol/litre.

1.4d Evidence for hypertension management in T2DM

Blood pressure measurement is one of the key care processes as outlined in National Institute for Health and Clinical Excellence (NICE) recommended nine care processes for patients with T2DM. NICE has defined a treatment target of $\leq$140/90mmHg for reducing cardiovascular risk, progression of eye and kidney disease. The Position statement published by American Diabetes Association in 2017 also stated that strong evidence from clinical trials and meta-analysis supports lowering blood pressure in type 2 diabetic population and sets the treatment target as <140/90 mmHg (De Boer et al., 2017).

A systematic review and metanalysis of 40 large scale randomized trials including type 2 diabetic patients reported that each 10mmHg lower SBP was associated with a significantly lower risk of mortality and other clinical outcomes as absolute risk reduction of cardiovascular events, coronary heart disease, stroke, albuminuria, and retinopathy (Emdin et al., 2015). There is plethora of literature and research evidence supporting the effect of hypertension management on lowered vascular risk in type 2 diabetes and some of the landmark studies assuring these health benefits using pharmacological approach are summarized here (see table 1.1).

The role of lifestyle management for hypertension management is very crucial and supported by accumulated evidence in the past as well as recent studies (Chobanian et al., 2003; Graham et al., 2007; Mancia et al., 2007; Rabi et al., 2020; Leblanc et al., 2011; Ahmadi et al., 2019). The lifestyle approach includes weight loss, dietary modifications, increasing physical activity, and reducing alcohol intake. Other interventions like tobacco cessation, meditation, acupuncture, biofeedback, home monitoring, dietary supplements, and the use of continuous positive airway pressure for patients with obstructive sleep apnea have also been examined (Verma et al., 2021). A combination of antihypertensive drug therapy and lifestyle management is recommended for controlling blood pressure and improving cardiovascular outcomes in type 2 diabetes (Pavlou et al., 2018; Khangura, Kurukulasuriya and Sowers, 2016). The findings of National Diabetes Audit report 2019-2020 highlighted that the percentage of people achieving blood pressure target has not improved in the last 5 years, 73.7%/ 73.6%, 2015/ 2020 (NHS Digital, 2020), signifying more work needs to be undertaken for achievement of optimal blood pressure targets in hypertension management in T2DM.

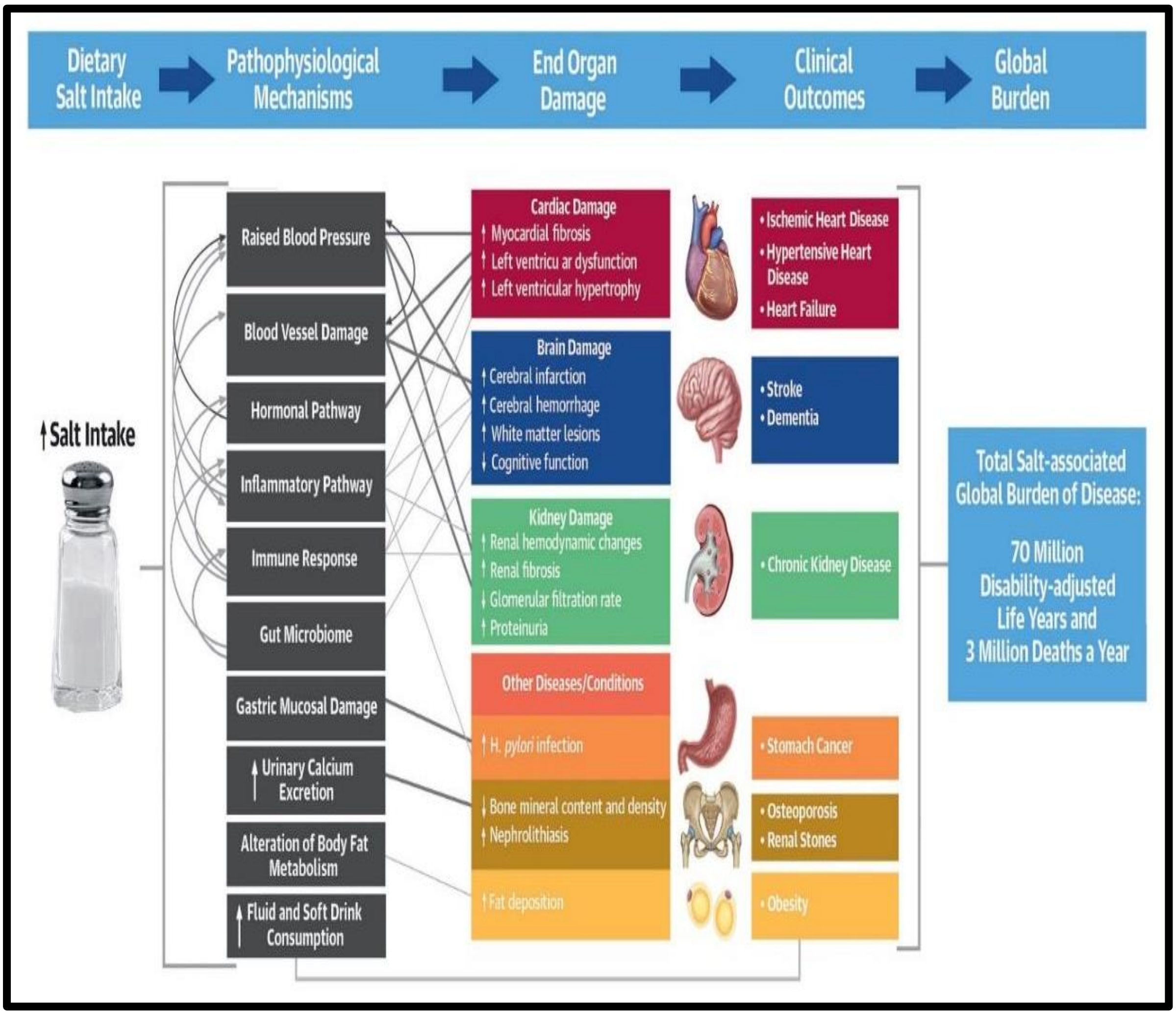
Table 1.2: Evidence summarizing role of hypertension management in T2DM

Clinical trial and year of publication	Study design and participant's characteristics	Methods/ Intervention	Results
United Kingdom Prospective Diabetes Study (UKPDS) UKPDS group, 1998	Randomized control trial (RCT), n= 1148 hypertensive patients with T2DM Mean age 56, mean blood pressure 160/94 mmHg Country: England, Scotland, and Northern Ireland	Tight control group, aiming at a B.P of <150/85 mm Hg (with the use of an ACE inhibitor captopril or a β blocker atenolol), n=758 Less tight control aiming at a BP of <180/105 mm Hg, n=390	Mean blood pressure during follow up was significantly reduced in the group assigned tight blood pressure control as compared to less tight control group (144/82; 154/87 mmHg, p=0.0001). Significantly lower diabetes-related mortality, stroke, and microvascular complications.
Hypertension Optimal Treatment study (HOT) Hansson et al., 1999	Prospective, Randomized, Open with Blinded Endpoint evaluation (PROBE) design Multicenter trial in 26 countries from Europe, North and South America, and Asia.	Three groups aiming at DBP: ≤90mmHg ≤85mmHg ≤80mmHg	Significant reduction in cardiovascular events in diabetes patients with DBP< 80 vs <90mmHg
Appropriate Blood Pressure Control in Diabetes (ABCD) Estacio and Schrier, 1998	Prospective, Randomized, Interventional Clinical Trial, n=950 patients with T2DM Country: USA	Two groups, 470 hypertensive patients (diastolic blood pressure (DBP) of ≥ 90.0 mmHg) and 480 normotensive patients, DBP= 80.0 mmHg, randomly assigned to moderate or intensive antihypertensive treatment.	All-cause mortality in the hypertensive cohort after 5 years was markedly lower in the intensive than in the moderate blood pressure control group.
Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation (ADVANCE) trial. Patel et al., 2007	RCT, n=11,140 patients with T2DM 215 collaborating centers in 20 countries from Asia, Australasia, Europe, and North America.	Active therapy group: fixed combination of perindopril and indapamide, n=5569 Control group: matching placebo, in addition to current therapy, n=5571	Active therapy group: mean reduction in SBP of 5.6mm Hg and DBP of 2.2mm Hg. Reduction in blood pressure led to significant clinical benefits in patients with type 2 diabetes, irrespective of baseline blood pressure values, and subsequently improved mortality rates, and macro- and microvascular outcomes
Heart Outcomes Prevention Evaluation (HOPE) study Sleight, 2000	RCT,129 centers across Canada, USA, Western European countries, Argentina, Brazil, and Mexico.	Ramipril group n= 651, Control/ Placebo Group, n= 826	Significant 25% reduction in risk for myocardial infarction (MI), stroke, or cardiovascular death. Median follow up-4.5 years.

1.5 Dietary salt intake and blood pressure

Worldwide, 70 million disability-adjusted life-years and 3 million deaths in 2017 were attributed to high salt intake, making it one of the top 3 dietary risk factors (GBD 2017 Diet Collaborators, 2019). Multiple mechanisms relate excessive dietary salt intake to blood pressure and its impacts on health beyond hypertension is summarized and illustrated by He et al., 2020 (see figure 1.2).

Figure 1.2: Salt and Health, Source: He et al., 2020



1.5.1 Physiological mechanisms explaining relationship of excessive salt intake and blood pressure

1.5.1a Renin-Angiotensin Aldosterone System (RAAS): Excess salt intake suppresses the RAAS, which in turn reduces sodium reabsorption and thereby facilitates its excretion (MacGregor et al., 1981). The RAAS relies on the kidney and as the kidney's functional deterioration and structural changes progresses with age, the RAAS is increasingly impaired, leading to sodium and water retention (Yoon and Choi, 2014) and increased vasculature resistance (Hunter, Dhaun and Bailey, 2022). As a result, smaller increases in salt intake induce greater rises in BP.

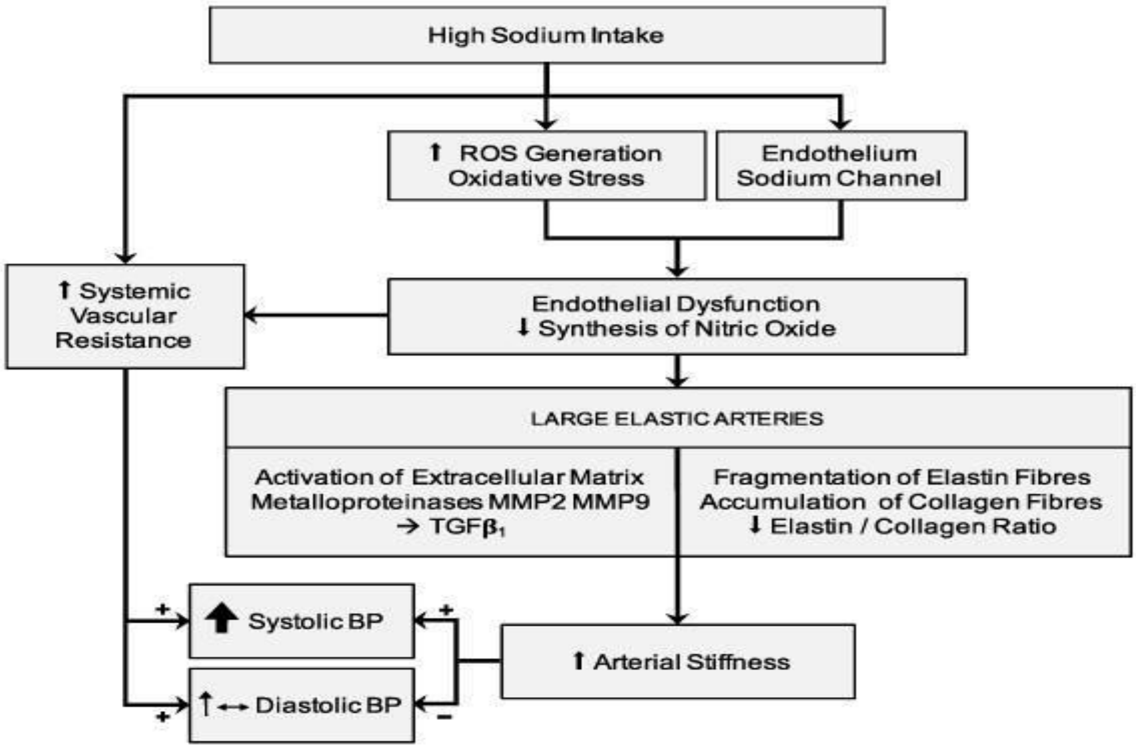
1.5.1b Plasma sodium level: Excess salt intake increases plasma sodium levels in both normotensive and hypertensive individuals. A rise in plasma sodium is immediately buffered by the increased osmolality in the extracellular space. It also stimulates the thirst centre, leading to water intake and secretion of arginine vasopressin, resulting in water retention (He et al., 2001). These mechanisms restore plasma sodium to its previous level, but also increase extracellular fluid volume, which stimulates other compensatory mechanisms involved in the autoregulatory effect on resistance vessels (Manning et al., 1979), plasma sodium may also affect BP directly, independently of and additively to its effect on extracellular volume (Friedman, McIndoe and Tanaka, 1990), through its effect on the hypothalamus (De Wardener, 2001), the local renin-angiotensin system (Gu et al, 1998), the heart and vasculature (Farquhar et al., 2015), inflammatory mechanisms (McMaster et al., 2015), and the immune response (McMaster et al., 2015), all of which influence BP.

1.5.1c Arterial stiffness: An excessive dietary salt intake induces alterations in the extracellular matrix of arterial wall, favouring arterial stiffening and thus an elevated blood pressure through the complex array of mechanisms as illustrated in figure 1.3.

1.5.1d New insights explaining relationship of dietary salt and high blood pressure: The discovery of new technology ^{23}Na-MRI (Kopp et al., 2013) has suggested that sodium is present in non-osmotic tissues as skin and muscle, thus introduced the concept of three-compartment model (interstitial, intravascular, and tissue Na compartment). Sodium is stored in tissue compartment for those on high salt diet or inability to excrete sodium due to compromised kidney function (Polychronopoulou, Braconnier and Burnier, 2019). Based on this new model of sodium stored in body, the studies conducted by Yan et al., 2017 and Li et al., 2017 have gathered evidence, that sodium can affect the gut microbiome, and induce pro-inflammatory and immune responses, which might contribute to the development of salt-sensitive hypertension.
Yan et al 2020 conducted studies both in rats and humans and revealed a novel mechanism linking the role of intestinal flora in high blood pressure. The findings of

the study stated that a high-salt diet decreased the levels of *Bacteroides fragilis* (an important symbiont in the human gut) and its associated metabolite arachidonic acid. This was accompanied by an increase in intestinal corticosterone production and the downregulation of key inhibitory enzymes which they hypothesized led to the accumulation and overactivation of the aldosterone pathway and thus resulting in blood pressure elevation.

Figure 1.3: Relationship of dietary salt intake, arterial stiffness, and hypertension (Source: Grillo et al., 2019)



1.5.2 <u>Relationship of sodium and salt intake</u>

The key evidence for the association between high dietary intakes of salt and blood pressure relates to sodium. The major source of sodium in the diet is from salt (sodium chloride, 40% sodium and 60% chloride).

5 g salt (NaCl) = 2000 mg sodium (Na) = 87 mmol sodium = 87 mEq sodium

Sodium is an essential element that is required in small amounts for the normal functioning of the body. It is required to conduct nerve impulses, contract, and relax muscles, and maintain the proper balance of water and minerals. Although sodium is essential for maintaining vital functions, the amount needed by the human body to carry out its functions is small, roughly 184 to 230mg per day (WHO, 2007). Salt used as an ingredient for food, either directly sold to consumers or used for food manufacturing, shall not be less than 97% of sodium chloride (FAO/ WHO 2006), on a dry matter basis, exclusive of additives. The words salt and sodium are often used interchangeably (WHO 2016). Most sodium is consumed in the form of sodium chloride and the public understands the term salt better than sodium. EU Regulation 1169/2011 (EU 2011) on food information to consumers requires the declaration of the salt content calculated as salt equivalents from the sodium content of a product.

1.5.3 Evidence for relationship of salt and blood pressure

There is vast body of evidence for the causal relationship between salt and blood pressure, available from animal, epidemiological investigations, and randomized trials. The strongest data comes from the INTERSALT study that measured 24h urine electrolytes and blood pressure in 10,079 men and women aged 20 to 59 years in 32 countries around the world. For all 52 centers, there was a positive correlation between urinary sodium excretion and both systolic and diastolic blood pressure (Elliott et al., 1996). This finding was confirmed by another large epidemiological study (Khaw et al., 2004) and experiments at population level (Karppanen and Mervaala, 2006; He, Pombo-Rodrigues and MacGregor, 2014).

There have been several meta-analyses of randomized salt-reduction trials and a recent review of these meta-analysis published by He et al. (2020) reported a substantial fall in blood pressure of hypertensive as compared to normotensive participants.

These findings suggested that while reducing salt to the World Health Organization–recommended intake of 5 g/day will bring health gains, a further reduction to 3 g/day will be more beneficial. NICE has recommended 3 g/day as the long-term population salt intake target (NICE, 2010). In the United States, 4 g/day has been recommended for >50% of the population including those with hypertension, diabetes, or chronic kidney disease (USDA, 2010).

1.6 Key role of dietary salt restriction in holistic management of hypertension

Dietary salt restriction is additive to other nonpharmacological and pharmacological interventions in lowering blood pressure. The DASH (Dietary Approaches to Stop Hypertension)-Sodium trial demonstrated that the greatest reductions in BP were achieved when combining the DASH diet to a low salt intake (Sacks et al., 2001). The findings of the TONE, Trial of Nonpharmacologic Interventions in the Elderly (Whelton et al., 1998), salt reduction combined with weight loss was more effective than either intervention alone in maintaining BP control after withdrawal of antihypertensive therapy in individuals who are older, obese, and hypertensive. Similarly, the TOHP II (Trial of Hypertension Prevention) showed that combining salt and weight reduction had a greater effect on reducing hypertension incidence in people who are overweight with high-normal BP during 6month follow-up period (The Trials of Hypertension Prevention Collaborative Research Group, 1997).

1.7 Dietary salt restriction and T2DM

Since diabetes is a metabolic disease, diet is the foundation for its care and management. Before insulin was discovered, replacement of dietary carbohydrate with protein and fats was the mainstay, and clinicians checked levels of glucose and ketones in patient's urine to monitor metabolic control (Greener, 2018). Today, people with diabetes can eat, essentially, a normal healthy diet as part of 'an integrated package of education and clinical care' (Dyson et al., 2018). Diabetes UK's updated 2018 guidelines, provide evidence-based recommendations for the prevention and management of diabetes and is focused on food, rather than nutrients. These guidelines recommend dietary patterns, specifically the Mediterranean and DASH-style diets, to reduce CVD risk factors and CVD events in people with diabetes (Dyson et al., 2018; Greener, 2018). One of the key features of these diets is to decrease salt intake alongside other domains as increased intake of whole grain, fruits and vegetables, fish, nuts and legumes and reduced intake of red and processed meat, refined carbohydrates, sugar -sweetened beverages; saturated fats and limiting trans fats (Esposito et al., 2017; Dyson et al., 2018; La Verde et al., 2018; Benson and Hayeys, 2020; Fuster et al., 2021).

Dietary salt restriction is as an essential constituent of diabetes care for prevention, management of hypertension as well as slowing progression of diabetes complications

(Horikawa and Sone, 2017). Several research studies have confirmed the benefits of salt restriction in T2DM as lowering blood pressure (Houlihan et al., 2002; Suckling et al., 2016; Ren et al., 2021), slowing progression of diabetic kidney disease (Suckling et al., 2010), long-term renal protective and cardio-protective effects (Heerspink et al., 2012) and association with improved glycaemic control (Bralic Lang, Bergman Markovic and Davorka Vrdoljak, 2015). Thus, guidance on dietary salt intake has been included by various dietary guidelines for type 2 diabetes (see table 3.1).

Table 1.3: Goals for daily salt intake defined in leading dietary guidelines for T2DM

Name of association	**Author & Year**	**Recommended dietary salt limit (g/d)**
Diabetes UK	Dyson et al., 2018	≤ 6 g/d
American Diabetes Association	American Diabetes Association, 2018	Limit sodium to <2300 mg/d (salt 5.75 g/d). Further restriction may be appropriate for those with elevated blood pressure.
European Association for the Study of Diabetes	Mann et al., 2004	<6 g/d Further restriction may be appropriate for those with elevated blood pressure.
Japan Diabetes Society	Mann et al., 2013	<6 g/d in patients with diabetes and hypertension and in those with overt nephropathy.

Salt sensitivity of blood pressure is reported to be elevated in patients with diabetes. (Katayama, Hatano and Issike, 2018). Hyperinsulinemia caused by insulin resistance is also involved in accelerating the reabsorption of sodium from the renal tubules (Zhou, Wang, and Yu, 2014). Excessive salt intake inhibits nocturnal blood pressure reduction, or, in other words, nocturnal blood pressure is set higher than usual to excrete excess sodium, making the patient a non-dipper (Gans et al., 1992). A person with a drop of more than 10% in nocturnal arterial blood pressure is referred to as a dipper and one with a smaller decrease is referred to as a non-dipper. Some clinical trials have demonstrated the efficacy of salt reduction, in patients with type 2 diabetes and are summarized here.

A pioneer study carried out a 12-week randomized double-blind, crossover trial of salt restriction with salt or placebo tablets, each for 6 weeks, in 46 individuals with diet-controlled type 2 diabetes mellitus or impaired glucose tolerance and untreated normal or high normal blood pressure (BP). From salt to placebo, 24h urinary sodium was reduced by 49±9 mmol (2.9 g salt). This reduction in salt intake led to statistically significant fall in systolic blood pressure from 136±2 mm Hg to 131±2 mm Hg (Suckling et al., 2016).

A recent meta-analysis of eight randomized control trials with 10 trials (7 cross-over and 3 parallel designs), also concluded a positive outcome of dietary salt restriction on blood pressure in T2DM. Compared with ordinary salt intake, dietary salt restriction significantly lowered systolic and diastolic blood pressure (−5.574 mm Hg and −1.675 mm Hg respectively) with low heterogeneity among the studies (Ren et al., 2021).

1.8 <u>Trends in dietary salt intake</u>

The recent systematic review conducted by Thout et al., 2019 published the updated evidence for global estimates of salt intake. The review identified thirteen nationally representative studies which have assessed salt intake estimates using the gold standard 24h urine collection method. It concluded that salt intake levels in all countries exceeded the WHO-recommended level of 5 g salt/day.

The Scientific Advisory Committee on Nutrition (SACN) recommends a target reduction in the average salt intake of the UK population to a maximum of 6 g/day (SACN, 2003). This level has been set as the UK government recommended maximum salt intake for adults and children aged 11 years and over. The latest reports for National Diet and Nutrition Survey, (NDNS) described population mean estimated salt intake for adults aged 19 to 64 years in England in 2018/19 and the trend analysis results (see figure 1.4) showed a statistically significant downward step-change in estimated salt intake between 2005/06 and 2008/09. There were no significant step changes after 2008/09. For men and women combined, the linear trend from 2008/09 to 2018/19 was close to zero, indicating no change in estimated population salt intake over this period (Ashford et al., 2020).

Figure 1.4: Geometric mean of estimated salt intake (g/day) in England between 2005/06 and 2018/19 (Source: Ashford et al., 2020).

Survey group	Combined		Men		Women	
	n	Geometric mean intake (g/day)	n	Geometric mean intake (g/day)	n	Geometric mean intake (g/day)
2005/06	445	8.1	187	9.3	258	7.1
2008/09	688	7.5	301	8.5	387	6.7
2009/10	109	7.4	50	8.7	59	6.2
2010/11	109	6.9	56	8.6	53	5.6
2011/12	725	7.7	325	8.9	400	6.7
2012/13	155	7.0	60	7.7	95	6.4
2014	689	7.2	298	8.5	391	6.2
2018/19	596	7.5	286	8.3	310	6.8

Notably, research studies with type 2 diabetic population have also established salt intake higher than the target and is summarized in Chapter 3.

1.9 Methods for estimating dietary salt intake

Monitoring of population sodium intake is essential for compliance with the WHO target of a 30% relative reduction in mean population sodium intake. In 2006, WHO identified a population mean intake of sodium of <2000 mg (5 g salt) as optimal (WHO, 2013) and in 2012, following two systematic reviews (Aburto et al., 2013 and He, Li and Macgregor et al., 2013). The Scientific Advisory Committee on Nutrition (SACN) recommended a target reduction in the average salt intake of the population to no more than 6g per day. This daily limit has been adopted by the UK government as the recommended maximum salt intake for adults (SACN, 2003) for lowering the ever-impending CVD burden. These recommendations are based on the feasibility of reducing population salt intake to these levels, but not on the potential maximum beneficial effects of salt reduction (He, Jenner, and Macgregor, 2010). In 2010, National Institute for Health and Clinical Excellence (NICE) published the report that recommended salt reduction be accelerated with the aim of achieving an average intake of 6g/day in 2015 and 3g/ day in 2025 (NICE, 2010).

Currently, several methods are used for estimating dietary salt intake at population and individual level. A written survey was issued to governments across the world to establish the details of their monitoring methods. Of the 30 countries that reported conducting formal government salt monitoring activities, 73% were high income countries. Less than half of the 30 countries, used the most accurate assessment of salt through 24h urine collections, and only two of these were developing countries. The remainder mainly relied on estimates through dietary surveys (Hawkes and Webster, 2012).

1.10 Dietary assessment for dietary salt intake

It is labour intensive and often under-estimates intake due to under-reporting and difficulties quantifying sodium content in a variety of recipes, as well as discretionary salt intake. The respondents may change their behaviour when collecting dietary data prospectively (such as in a weighed diet record), and under-reporting of intake, both generally and of foods and nutrients is common (Freisling et al., 2012; Gemming et al., 2013). Sodium intake is highly correlated with total energy intake, due to its inclusion in a wide variety of foods and meals (Whelton et al., 2012). Under-reporting of energy (and therefore sodium) has been shown to be greater for those with higher body mass index (Bailey et al., 2007).

Dietary surveys enable identification of important dietary sources of sodium, which can inform public health interventions to lower sodium intake (McLean, 2014). Following are the dietary survey method used for assessing dietary salt intake levels:

1.10a 24h dietary recall: A systematic questionnaire/survey designed to capture all foods consumed in a defined twenty-four-hour period. It is considered as an ideal method commonly used by government agencies for national surveys as foods with a certain threshold of intake and sodium content per serving can be added (Charlton et al., 2008). Several governments have extensive experience with this survey methodology as the National Health and Nutrition Examination (NHANES) and the Canadian Community Health Survey (CCHS). A comparison of 24h recall using the United States Department of Agriculture (USDA) Automated Multiple-pass Recall

Method used in NHANES with 24h urine in healthy volunteers aged 30–69 years found the mean (95% CI) reporting accuracy of 24h recall was 0.93 (0.89, 0.97) for men and 0.90 (0.87, 0.94) for women, suggesting it as a valid method for assessing dietary sodium intake (Rhodes et al., 2013).

1.10b Food Frequency Questionnaires (FFQ): Participants indicate their usual dietary intake – how frequently certain foods and food groups on a pre-defined list are consumed during a specified period. It is relatively inexpensive method, used for population surveys and represents usual nutrient intake, as diet is assessed over long periods of time as previous 12 months. FFQ's can be expanded or contracted to include or isolate high salt food items. Although, these questionnaires are typically long because of the need to be comprehensive of common food products, online or web-based versions are often easier and quick to complete (WHO/ PAHO, 2010). Due to their ease of administration and relatively low respondent burden FFQs had been used extensively in large-scale cohort (prospective) studies as: The Whitehall II study (Mosdol et al., 2007); The European Prospective Investigation into Cancer and Nutrition (EPIC) (Riboli et al, 2002) and The UK Women's Cohort Study (Greenwood et al., 2000). Commonly used FFQ's for sodium intake are the Block FFQ, the Harvard FFQ and the Diet History Questionnaire developed at the National Cancer Institute (Subar et al., 2001). Overall, the FFQ serves best to rank order individuals rather than to estimate absolute levels of sodium intake (Carithers et al., 2009; Fayet et al., 2011).

A systematic review of 18 studies was conducted by McLean et al., 2017 to investigate whether FFQ's are a reliable and valid way of measuring usual dietary sodium intake. Overall, there was poor agreement between estimates from FFQ and 24h urine. This study recommended that all FFQs used to estimate dietary sodium intake undergo validation against multiple 24h urine collections.

1.10c Food records: This method involves documenting all foods consumed over a specified time prospectively by the participant and involve estimates of portion size either through weighing (weighed food record) or using other prompts and measures. Weighed food records are often regarded as the most accurate way of assessing nutrient intakes (McLean et al., 2018). The prospective nature of data recording minimizes recall bias, and weighing all food consumed enables accurate assessment of portion size. To assess usual intake, several days of recording are undertaken, and are usually specified to include week and weekend days and may include assessment over several weeks or months. Accurate weighed food records, however, require detailed training of participants and a high degree of commitment on participant’s behalf. This method has a major limitation as participants might alter their eating behaviour on the day of recording, be less likely to eat out on recording days or be more likely to consume foods considered desirable or healthy (Garden et al., 2018). One calibration study using the mean of six 24h urine collections over a 12-month period as the reference gold standard measure, showed that a seven-day diet record was a more reliable estimate of intake than the FFQ when it came to quantifying intake (Day et al., 2001).

1.10d Duplicate food collection or weighed food consumption: This dietary method involves preparation of two identical plates of every food consumed, one of which is sent to a laboratory for chemical analysis of nutrient content. Accurate weighing of all foods consumed combined with analysis or calculation of nutrient composition. It is usually used only for research and very time consuming with heavy burden on participants and is relatively expensive (Abbey et al., 2010).

1.11 Urinary sodium excretion assay

1.11a 24h urine collection is widely regarded as the gold standard for assessment of sodium intake and is often used to compare and validate other methods of sodium intake assessment. Approximately 90% of ingested sodium is excreted in the urine and losses through sweat and faeces have been estimated to be around 10% under normal conditions (Holbrook et al., 1984). 24h urine collection has been used to assess population sodium intake in the landmark INTERSALT study and, more recently in the United Kingdom to evaluate the success of its population sodium reduction strategy (He, Brinsden and Macgregor, 2014). The recent report published by National Diet and Nutrition Survey (NDNS) on assessment of sodium intake in adults in England, using 24h urine method showed the linear trend from 2008/09 to 2018/19 was close to zero, indicating no change in estimated population salt intake over this period. Although 24h urinary assessment of sodium is likely to be more valid than dietary assessment, collection of 24h urine involves considerable burden for participants, which may influence response rates and collection in representative population surveys. Due to the difficulties associated with the accurate collection of a complete 24h collection, both under-collection and over-collection of samples has been reported (McLean, 2014). Para-aminobenzoic acid (PABA) has been widely used to assess completeness of urine collections, including in recent UK population surveys (Cox et al., 2018).

1.11b Spot urine sampling is potentially a convenient and affordable alternative for assessing sodium intake. Studies suggest that while spot urinary sodium is a poor predictor of 24h sodium excretion in individuals, it may in the future provide population estimates adequate for monitoring (McLean, Williams, and Mann, 2014). However, there are still a few questions about reliability of spot urine collections as a means of monitoring population changes. In spot urine specimens, errors involve the substantial variations of the sodium concentration in the urine depending on the time of the collection and differences in muscle mass, that might influence the spot urine sodium-to-creatinine ratio (Mann and Garber, 2010; He et al, 2018).

1.12 Dietary salt reduction initiatives: UK

The United Kingdom was among the first countries to introduce a salt reduction program in 2003 to reduce cardiovascular disease (CVD) incidence risk and the components of UK salt reduction model are outlined in UK salt model (see figure 1.5) and the timelines are defined in table 1.4.

The UK salt reduction model relied on an integrated approach of knowledge dissemination through Public Health Campaigns, voluntary agreement with industry for product re-formulation and periodic monitoring of the progress through PHE surveys on salt content of food products and assessing population’s salt intake through 24h urinary sodium excretion survey.

Figure 1.5: UK salt reduction model, (Source: He et al., 2020)

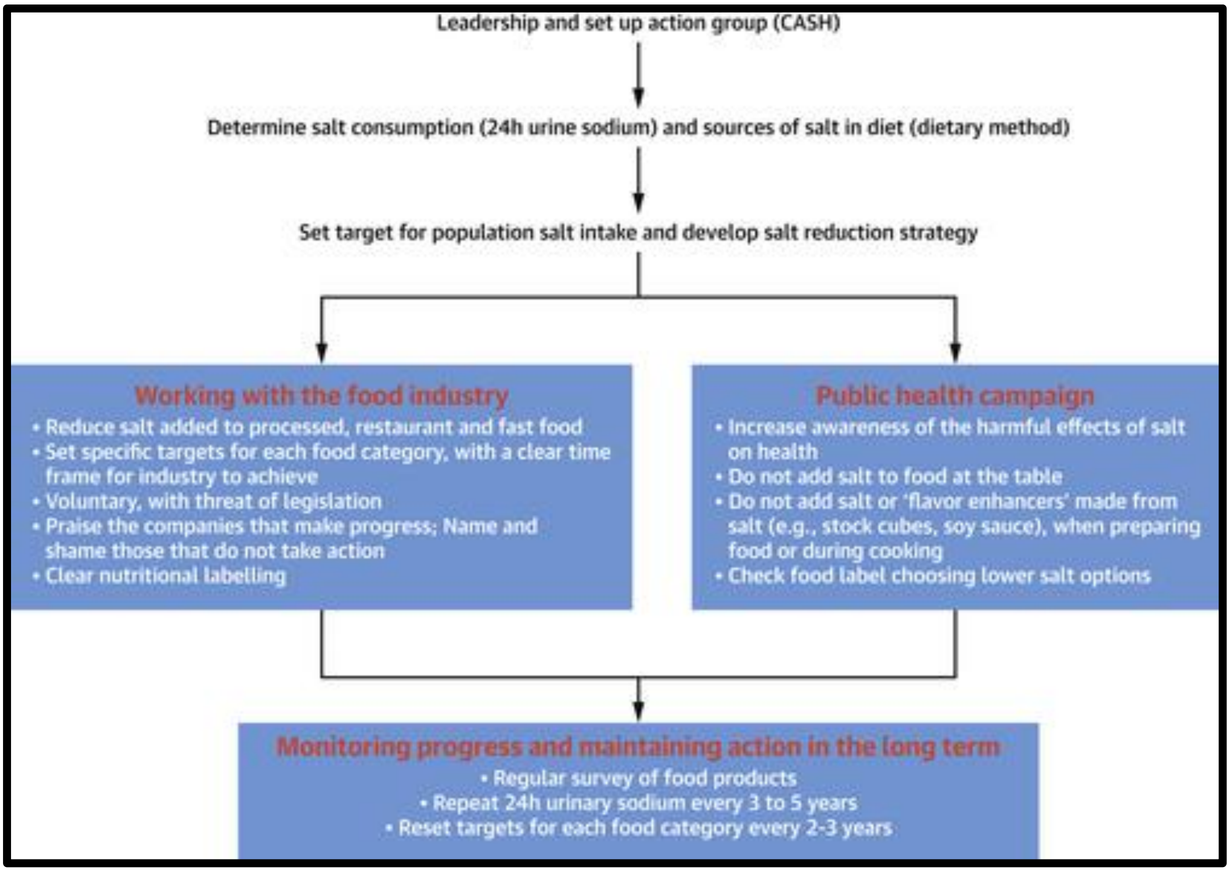


Table 1.4: UK Salt reduction timelines

Year	Salt reduction strategy	Remarks
2002	PUBLIC HEALTH CAMPAIGN – 'Sid the slug', 'Check the label' and 'Is your food full of it?'.	Food Standard Agency (FSA) committed to nationwide salt reduction initiative “6g/day”.
2006	Voluntary salt reduction targets for food industry.	FSA set the targets for 85 categories of food to be met by 2010. Targets excluded “out of home sector”
2008	10 % reduction in salt intake	FSA set 2012 voluntary salt reduction targets.
2011	Salt reduction program through Public Health Responsibility Deal.	FSA transferred to Dept. of Health (DOH). Key health commitments made by food industry based on 2012 targets.
2012	Achieved lowest salt intake of any developed country in world – 8.6g to 8.1g/day.	DOH published new salt target for caterers focusing on training, reformulation and procurement.
2014	New salt limits beyond 2012 for food industry Out of Home sector ‘Maximum per serving salt targets’	Targets for 76 category of food and 10% lower than 2012.
2017	Public Health England (PHE) published new salt targets	Joint Report from the Scientific Advisory Committee on Nutrition (SACN) and the Committee on Toxicity (COT) recommended that the government should encourage the food industry to consider the use of sodium replacers to reduce the sodium content of food.
2018	PHE released their analysis of industry progress achieving 2017 targets. Chief Medical Officer Annual Report recommendation were: Mandate of salt targets Mandating FOP label	Only 52% of average targets were met (retailers meeting 73% and manufacturers just 37%).
2019	Green Paper on prevention- Advancing health through 2020 - released by Secretary of State for Health	The Green Paper stated that revised salt reduction targets would be published in 2020 for industry to achieve by mid-2023.
2020	PHE published new salt targets for industry, to be achieved by 2024	8 new sub-categories; ready meal sides and accompaniments, popcorn- sweet and savoury, flavoured nuts, chilli sauce, condiments, pizza with cured meat toppings and other toppings, dips.

Despite its initial success, the UK salt reduction program has stalled recently and is yet to achieve targets. The salt reduction program was highly successful initially because of the government pressure on industry to reduce salt content, resulting in a decline in the average population-level salt intake. A study conducted by Griffith, O'Connell, and Smith, 2017 reported 5.1% reduction in the salt content of the UK grocery basket of a nationally representative sample of households from 2005 to 2011. These estimated reductions are consistent with the reduction reported by He, Brinsden and MacGregor, 2014 in high-salt products in supermarkets (from 3.3 to 1.8 g of salt per serving of product), which identified bread as the single largest contribution to salt to the UK diet- 18% of total salt intake. The salt reductions were also driven mainly by product reformulation, as opposed to net product introduction and changes in consumer preferences. The observed decline in program effectiveness after 2011 was attributed to reduction in the government pressure on industry (MacGregor, He and Rodrigues, 2015). To get back on track, the program will benefit from a strict enforcement of salt reduction targets, for example, through legislation or financial penalties for food companies failing to comply; setting more stringent salt targets and extending salt targets to the out-of-home sector, which remained lenient and lack the proper monitoring mechanisms (Alonso et al., 2021). The author also conducted a modelling study to review impact of 2003-2018 salt reduction in England and reported this reduction projects 193 870 fewer premature CVD cases and 542 850 extra quality adjusted life years (QALYs) among the adult population in England by 2050. More importantly, further strengthening and scaling up of the salt reduction program, to achieve the WHO recommendation of 5 grams/day per adult by 2030, could bring further large reductions in CVD burden with 213 880 further premature CVD cases avoided by 2050. These health gains could bring substantial accumulated savings to the UK government of £5330 million by 2050 due to reductions in population need for health care and social care.

1.13 <u>Awareness on dietary salt intake</u>

The public health initiatives to reduce population's salt intake level is focused on food industry, to reformulate varying categories of processed foods. Although this strategy is the most cost-effective way to provide widespread availability of reduced salt foods to the consumer, it is very time consuming and a long-term plan. Improving consumer's knowledge and attitude to adopt healthy salt specific behaviour is an important aspect of addressing health crisis associated with excess salt consumption (Sarmugam and Worsley, 2014).

The findings of systematic review on knowledge, attitudes and behaviours related to dietary salt intake in high-income countries, reported lack of fundamental knowledge regarding primary food sources, relationship of sodium and salt intake and even the daily recommended salt level (Bhana, Utter and Eyles, 2018).

The survey conducted by Leyvraz et al. (2018) described the KAP (Knowledge, Attitude and Practices) of adults 588 participants aged 25 to 65 years. The majority of the participants knew that high salt intake can cause health problems (85%) and thought that it is important to limit salt intake (91%). However, slightly over half (56%) of the respondents regularly tried to limit their salt intake while only 8% of the respondents thought that they consumed too much salt. Salt and salty condiments were added most of the time during cooking (92% and 64%, respectively) but rarely at the table (11%).

The results of a cross-sectional survey conducted in Australian adult population concluded that majority were unaware of their own salt intake. Twenty-nine percent of the participants believed their own individual salt intake exceeded dietary recommendations and only 28% could correctly identify the maximum recommended daily intake for salt (Grimes et al., 2017b).

The results of an online cohort study consisting of a representative sample from Germany, Austria, United States of America, Hungary, India, China, South Africa, and Brazil revealed that although salt reduction was seen to be healthy and important, over one third of participants were not interested in salt reduction and the majority were unaware of recommendations (Newson et al., 2013). Similar finding related to the poor level of awareness on recommended daily salt level were reported in UK based research survey conducted by Marshall, Bower and Schroder (2007) and other cross-sectional surveys (Claro., et al., 2012; Charlton, et al., 2010; Webster, et al., 2010).

Millet et al. (2012) performed secondary analysis of data from the Health Survey for England and investigated knowledge of government guidance and voluntary use of salt in food preparation. 69% of the respondents were aware that the government had issued guidance advising that they should restrict their salt intake. Only, one third of respondents (33.3%) were able to state that the recommended daily level of salt intake was 6g.

1.15 Salt reduction, nutrition education and T2DM

Diabetes is a lifelong disorder and lifestyle adjustments are central to the diabetes care process. The treatment of diabetes demands self-management on day-to-day basis. People with diabetes rarely spend more than two to three hours per year with a healthcare professional, and for the remaining 8,757 hours they must manage their diabetes themselves. They need the knowledge and skills to manage their condition (NHS, 2019).

Knowledge plays a vital role in early prevention and management of any disease condition. Positive knowledge, attitude and practice (KAP) are important for diabetes patients. Several studies have established the relationship of good diabetes knowledge and positive health outcomes (Fenwick et al., 2013; van der Heide et al., 2014; Kassahun et al., 2016; Rachmawati, Sahar and Wati, 2019). A systematic review and meta-analysis of 42 randomized controlled trials concluded that diabetes self-management education can reduce all-cause mortality risk in type 2 diabetes patients (He et al., 2016). Patient education on the adverse effects of a high dietary sodium intake is needed to prevent and manage hypertension and diabetes (Kim, 2016).

Dietary management for type 2 diabetes advocates healthy eating as a principal recommendation. However, the varying nutritional aspect of health eating behaviour demands moderation in intake of various food groups. Adherence to the daily salt intake recommendation is relevant for diabetes patients with or without hypertension. However, keeping a count of one’s salt intake is complex as it ranges from discretionary use in cooking or at table to salt in practically most of the processed foods and hidden salt in bakery products. Therefore, comprehensive knowledge of dietary sources of salt, label reading and creative ways to cook food without or minimal salt is essential for adhering to dietary salt intake recommendations.

The raised awareness levels and positive attitude related to dietary intake corresponds to healthy salt consumption practices (Johnson et al., 2017). Gee et al. (2013) investigated the health behaviour of hypertensive patients with diabetes and reported that only 65% received advice from healthcare professional on limiting daily salt intake. Lack of guidance on lowering salt intake and thus, lower degree of readiness for practicing a moderate intake of salt in diet, can highly complicate the health status of patients already facing dual challenges of diabetes and hypertension. There are structured diabetes education programme (summarized in Chapter 6) that covers comprehensive understanding of health eating principles including salt intake recommendation. A systematic review of education in type 2 diabetes, showed that structured education improved fasting blood glucose levels, HbA1c, self-management skills, diabetes knowledge, self-efficacy/empowerment, patient satisfaction and body weight at 12 months (Steinsbekk et al., 2012).

Since the focus of guidelines for T2DM is shifting beyond a sole emphasis on glycaemic control to managing the cardiovascular complications of diabetes (Davie et al., 2018; Buse et al., 2019; Cosentino et al., 2019) and studies focusing on lowering dietary salt intake in this population shall be of great value in attenuating the burden of cardiovascular disease. Thus, with the present study the researcher proposes to develop and validate dietary salt monitor, to capture and account for various sources of salt in diet and use this as part of a structured education programme to increase awareness of foods high in salt and encourage behaviour to reduce salt intake overall.

Research aim and objectives

Aim

To determine barriers in adherence to dietary salt intake recommendations in type 2 diabetics, development, validation, and effectiveness of a novel dietary salt calculator as an educational tool.

Objectives

1. To determine knowledge, attitudes and practices related to dietary salt intake in patients with type 2 diabetes and comorbid hypertension.
2. To develop a novel UK dietary salt monitor that represents the dietary patterns of type 2 diabetics.
3. To conduct validation study of a dietary salt monitor, based on a short food frequency questionnaire against 24h urinary salt excretions and food records.
4. To evaluate the use of dietary salt monitor in reducing dietary salt intake in participants with T2DM.

Chapter 2: General Methods

2.1 Phases of research study

Figure 2.1: Phases of PhD study

PHASE 1	**Determination of barriers in adherence to dietary salt recommendations** (Patients with T2DM +HTN from Diabetic Clinic, Basildon Hospital, n=50)
PHASE 2	**Development of a novel dietary salt monitor**
PHASE 3	**Validation of dietary salt monitor** (Student group, London Metropolitan University, n=9)
PHASE 4	**Use of dietary salt monitor as a dietary education intervention** (Volunteers from social media and advert on Diabetes UK website, n=22)

2.2 Ethical approval

The ethical approval was obtained from Research Ethics Review Panel at London Metropolitan University and from NHS Cambridge East Research Committee. The process of NHS approval is comprehensive, and all the requisite documentation were submitted through an online portal - Integrated Research Application System (IRAS version 5.1.0) and the process is explained in figure 2.2.

Figure 2.2: Step-by-step procedure for obtaining the NHS ethic approval

NHS RESEARCH ETHICS COMMITTEE APPROVAL PROCEDURE
1. **Pre- Health Research Authority (HRA) approval submission**- Research site identification ● Meeting with the clinical collaborator at Research department, Basildon Hospital for obtaining letter of support.
2. IRAS Application ● IRAS Log in ● IRAS Project Filter: IRAS form includes filling up full set of project data and uploading supporting documents as curriculum vitae for student, supervisor, and collaborator; research protocol; copy of participant information sheet and consent form, insurance letter and covering letter to NHS Research Ethics Committee, REC. ● Electronic authorization by sponsor, chief investigator, and supervisor. ● CBS – Central Booking Service was required, as the project required proportionate review. This research study didn't involve 'Material Ethical Issues" and falls under low-risk category as determined by the No Material Ethical Issue Tool (NMEIT). ● E-submission of IRAS form Email confirmation received as IRAS application was booked. Booking information needs to be entered on IRAS Form. ● Feedback of the application submitted: Favourable opinion is Approval or Provisional opinion /Not Favourable opinion. ● Provisional opinion was received **-** clarification was provided for the query raised by the NHS Cambridge East Research Committee and revised documentation was submitted. Email request to REC for activation of e- submission was sent. ● NHS REC approval was received after the re-submission (Appendix A).

2.3 Researcher training and further documentation

After obtaining NHS ethics approval, copy of the same was forwarded to the research coordinator at Basildon Hospital. Online training for Good Clinical Practice (GCP) was completed by the researcher. Disclosure and Barring Service check was obtained and occupational health check -up was completed at Royal Free hospital, London.

The documentation submitted to obtain 'letter of access' for conducting this research study at Basildon hospital included NHS Research Passport Application form, GCP certificate, DBS certificate, clearance letter from occupational health and copy of all the research documents- Participant information sheet (PIS), consent form, research proposal and research questionnaire. Mandatory trainings undertaken by the researcher at the research site included online module on Electronic Medical Record (EMR), research registration on EDGE system and shadowing research nurse at Basildon Hospital**.** A copy of all the documents submitted with IRAS application are available in Appendix B-I.

2.4 Anthropometric measurements and body composition: The different measurement techniques and methods used for collecting anthropometric, biochemical, biophysical, dietary information across the phases of this academic study are summarized in table 2.1.

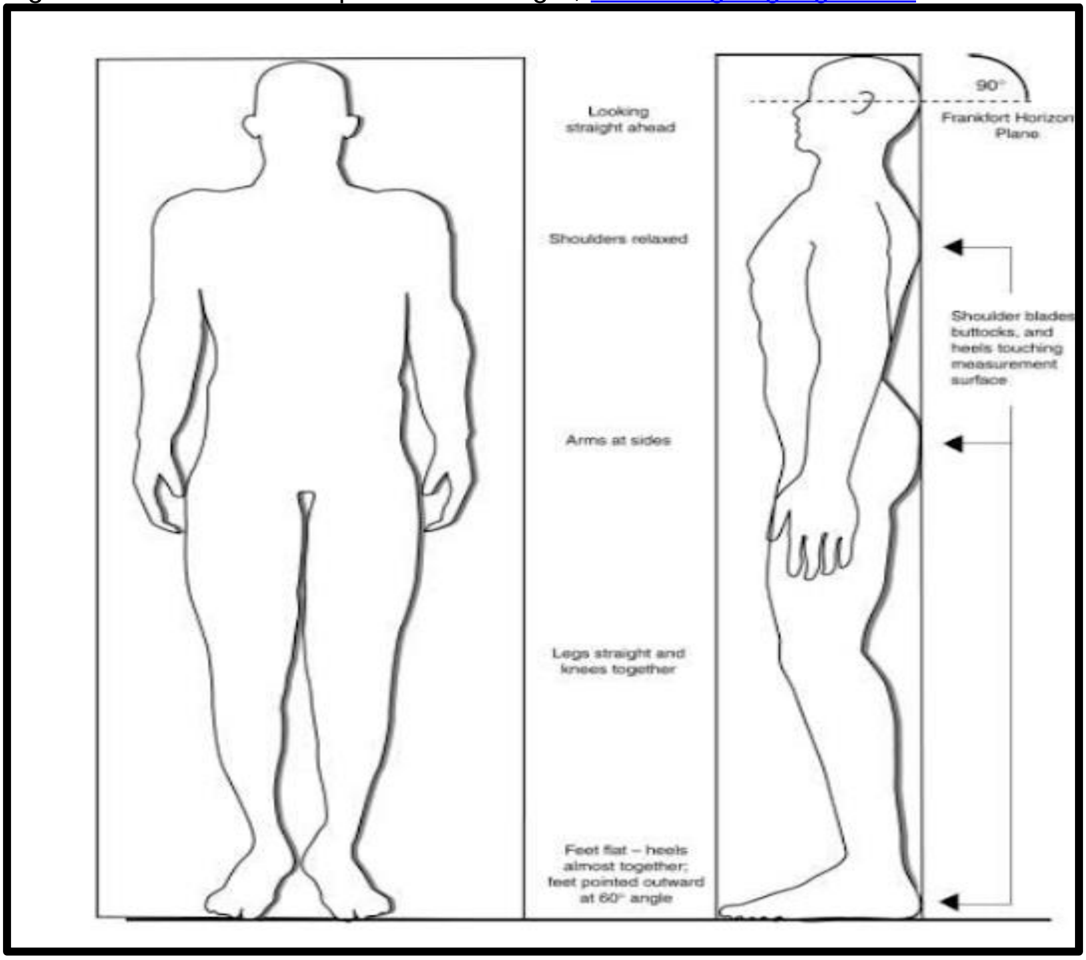
Table 2.1: Methods used in different phases of the research study

Study Phase	Phase 1	Phase 3	Phase 4
Target group	Participants with T2DM + HTN (face to face session with researcher)	Student group- London Metropolitan University (data collated via email by researcher)	Participants with T2DM (recruited online and data collated through google forms & e-mail)
Weight	Recorded from EMR	Measured by trained nutrition students on Tanita Body composition monitor	Self- reported
Height	Recorded from EMR	Measured by trained nutrition students using wall mounted height measure (Doherty premier)	Self- reported
Waist circumference	Not available	Measured by trained nutrition students using non stretchable tape as per standard protocol	Not included in research questionnaire
Hip circumference	Not included in the research questionnaire	Measured by trained nutrition students using non stretchable tape as per standard protocol.	Not included in research questionnaire
Dietary methods	24h dietary recall	Food record, Dietary salt monitor based on SFFQ	Dietary salt monitor based on SFFQ
Others	Hba1c, cholesterol and blood pressure from EMR	24h urinary sodium excretion method, Body fat % using Tanita, Index computed: BMI, WHR and WHtR	Self -reported BP readings

Abbreviations: T2DM, type 2 diabetes mellitus; HTN, hypertension; EMR, electronic medical records; SFFQ, short food frequency questionnaire; BMI, body mass index; WHR, waist hip ratio; WHtR, waist to height ratio

2.4.1. Weight was measured using standard protocol including light clothing, barefoot and maintaining appropriate posture (Dietary assessment and physical activity measurements toolkit, 2016); measured to nearest 0.1kg using Tanita body composition monitor (TBF-410GS). Height was measured in cm to nearest 0.1cm using Doherty premier wall mounted height measure. A correct measurement protocol as illustrated in figure 2.3 was followed, the participants were asked to stand straight, without shoes and with the heels together, head in Frankfort plane (Daboul et al., 2012 and Dietary assessment and physical activity measurements toolkit, 2016).

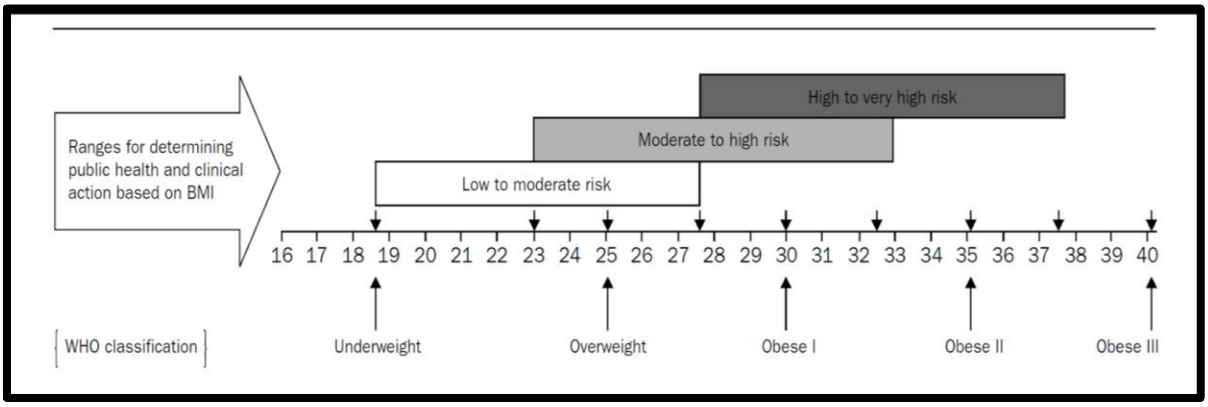
Figure 2.3: Measurement protocol for height, www.images.google.com



For the patients with diabetic foot in Phase 1 of the study, weight and height were recorded from EMR, that was either self-reported or standard protocol suited best to the participant's status as foot ulcers/ amputee/wheelchair-assisted were used (Mozumdar and Roy, 2004; Dietary assessment and physical activity measurements toolkit, 2016; Best and Shepherd, 2020). The Phase 4 of study was an online dietary intervention study, self-reported height and weight was included. Several research studies have established that self-reported height and weight are strongly correlated to measured counterparts and supported the practice of using self-reported anthropometric measurements in public health research (Harvey-Berino et al., 2011; Bowring et al., 2012; Quick et al., 2015; Olfert et al., 2018; Krukowski and Ross, 2020).

2.4.2 Body Mass Index (BMI) was computed as weight (kg)/ height (m^2) for the participants of each phase. WHO's International BMI classification for categorising the participants into normal weight, overweight and obese was used for participants of white ethnicity and is stated in figure. Although several research studies have stated that South Asians have higher incidence of developing Type 2 diabetes even at lower BMI as compared to Europeans, the WHO consensus paper emphasized the use of similar international guidelines for Asians and have left it to discretion of countries to decide their public health action points (WHO, 2004). A population-based cohort study estimated ethnicity-based obesity cut off points associated with diabetes co-incidence and reported British South Asians and African-Caribbeans had equivalent diabetes incidence rates at substantially lower obesity levels than the conventional European cut-points (Tillin et al., 2015). A recent study conducted in UK by Caleyachetty et al. (2021) also concluded that revisions of ethnicity-specific BMI cut offs are needed to ensure that minority ethnic populations are provided with appropriate clinical surveillance to optimise the prevention, early diagnosis, and timely management of type 2 diabetes. NICE- guidelines have stated that normal BMI for south Asians or Chinese descent to be likely between18.5-22.9kg/m2 (NICE, 2017) and the similar cut offs were indicated by Misra (2015) based on his research work in India. Thus, in view of recent research evidence and NICE guideline, BMI cut offs specific for Asians were used to classify the participants into normal weight, overweight and obese.

Figure 2.4: WHO's BMI classification (WHO, 2004)



2.4.3 Waist Circumference: Since abdominal obesity carries more health risk compared with total obesity assessed by BMI, waist measurement should be included when stratifying obesity-related health risk (Snijder et al., 2003; Pischon et al., 2008; Jacobs et al., 2010; Ross et al., 2020). A single record of waist circumference (WC) was recorded and measured using non-stretchable tape for the participants by trained nutrition students using standard protocol recommended by the World Health Association (WHO). This protocol indicated measurement to be taken midway between the lowest rib margin and the iliac crest at the mid-axillary line (World Health

Organisation, 2000). NICE guidelines and International Diabetes Federation (IDF) cut-offs for waist circumference were followed for participants with white ethnic background and Asian ethnicity respectively. Based on NICE guidelines for waist circumference cut-off's, men with a waist circumference of 94cm or more and women with a waist circumference of 80cm or more are at increased risk of health problems (World Health Organisation, 2011; National Institute for Health and Care Excellence, 2014). IDF recommended cut-off's as ≥90cm for men and ≥80cm for women for South Asian, Chinese, and Japanese populations (Alberti et al., 2007).

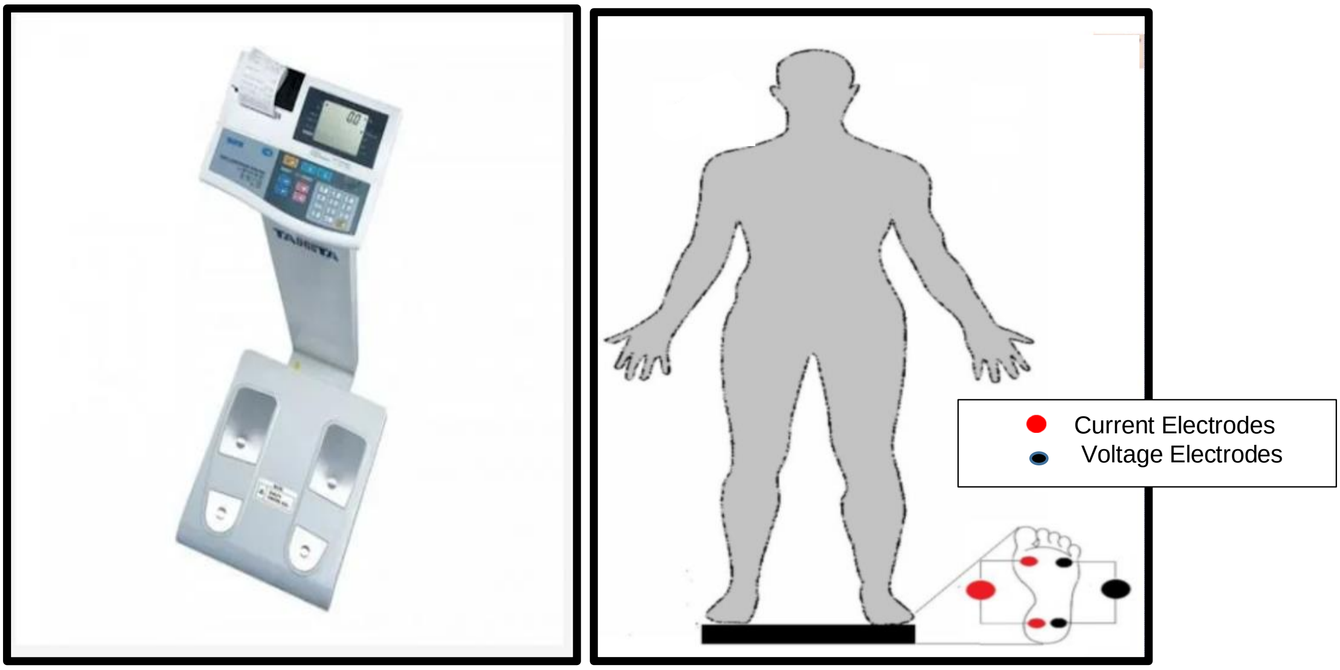
2.4.4 Hip Circumference**:** A single record of hip circumference (HC) was measured using standardized protocol by trained nutrition students using a non-stretchable tape. This included measuring from the side at the maximal extension of buttocks (Goh et al., 2014).

2.4.5 Waist-to-hip Ratio (WHR) was calculated using standard equation where waist circumference, WC (in cm) was divided by HC (in cm).

2.4.6 Waist-to-height ratio (WHtR) was calculated using standard equation WC/ Ht and a boundary value of WHtR 0.5 as a risk assessment tool was used (Hsieh, and Yoshinaga, 1995; Ashwell, LeJeune and McPherson, 1996; Ashwell and Gibson, 2014).

2.4.7 Body fat percentage was assessed for the participants of phase 3 using Tanita (TBF-410 GS) which works on the principle of Bioelectrical impedance analysis (BIA). Body composition estimation using bioimpedance measurements is based on determination of body volume through the basic means of resistance. In biological systems resistance is caused by total water across the body, and reactance occurs due to the capacitance of the cell membrane (Kyle et al., 2005). Human body as a volume is composed generally of fat mass (FM) which is considered as a non-conductor of electric charge and is equal to the difference between body weight and fat free mass (FFM). Studies show that total body water (TBW) is the major compound of FFM and is equal to 73.2% in normal hydration status (Kyle, Genton and Pichard, 2002)) and is considered as the conducting volume that helps the passing of electric current due to conductivity of electrolytes dissolved in body water. Tanita, TBF 410GS uses singly frequency (50KHz) and assesses whole body impedance using foot to foot method (see fig 2.5). Foot to foot measurements were introduced by Nunez et al. 1997 using a pressure-contact foot-pad electrode. The standard protocol for assessing body composition as per the manufacturer's guideline and supported by various research studies was followed for the participants (Khalil, Mohktar and Ibrahim, 2014; Vasold et al., 2019) except for 12hr fasting rule since it was impractical for student participants to comply with it. Tanita (TBF-410GS) scale has been validated against dual-energy X-ray absorptiometry (DXA) in weight loss trial of premenopausal women and linear regression showed relative agreement between BIA and DXA methods at baseline (R^2=0.952) and was concluded to be an acceptable tool for measuring body composition changes (Grazios et al., 2011).

Figure 2.5: Tanita body composition monitor (TBF-410GS) using foot to foot method for whole body impedance measurement, image adapted from Khalil, Mokhtar and Ibrahim, 2014.



2.5 <u>Health parameters</u>: The various bio-chemical and bio-physical parameters as Hb1Ac, total cholesterol level and blood pressure readings (SBP/ DBP) were compared to treatment goals specified by NICE guidelines and used as reference criteria for National Diabetes Audit (NDA, 2018).

2.6 <u>Dietary analysis</u>: The methodology for various dietary assessment methods used in this research as 24h dietary recall, food record and dietary salt monitor based on short food frequency questionnaire (v1.2020 and v2.2021) is detailed in its respective chapters (see Chapter 3, 4, 5, 6). Nutritics software was used for generating nutrient profile at individual and group level for 24h dietary recall and food records. Nutritics used the 2015 COFIDS, Composition of foods integrated dataset including McCance and Widdowson 7th edition, 2015 nutritional composition database. Nutritics database includes information on portion size, and this was used for finalizing the portion size guide and assigning salt values for the categories of dietary salt monitor.

2.7 <u>24h urinary sodium excretion assay</u>: The details for principle of working and its methodology is discussed in Chapter 5.

Chapter 3: Knowledge, attitudes, and practices related to dietary salt intake in T2DM

Overview

Previous research studies outside of UK, have indicated non-adherence to daily recommended limit of dietary salt intake in type 2 diabetes. These studies have established poor awareness on varying aspects of dietary salt intake as dietary salt limit, sources of salt in diet and lack of interest in reading salt content on nutrition label. To date, this is first UK study exploring the knowledge, attitudes, and practices (KAP) towards dietary salt intake in participants with type 2 diabetes. A total of 50 participants were recruited from a diabetes foot clinic in NHS hospital. The mean KAP score for the group was 22.6 (SD 6.1) against a maximum achievable score of 40, as determined by the research questionnaire. Majority (98%) of the participants had no awareness of the daily salt limit, despite a dual diagnosis of hypertension and type 2 diabetes. Although only eight percent of the participants perceived themselves as eating far too much salt, the data from 24hr dietary recall indicated more than a quarter of participants (28%) consuming above the limit of 6g. Lack of knowledge on common food sources of salt as bread, smoked fish, pickles, biscuits, and tomato ketchup; lower interest in reading salt content on nutrition label and frequent use of salt in cooking were identified as the barriers in adherence to daily salt limits. These findings highlighted dietary salt intake as a key area that needs to be addressed for overall nutritional management of type 2 diabetes.

3.1 Introduction

3.1.1 Dietary salt intake in T2DM population

There are limited number of studies quantifying salt intake in diet of Type 2 diabetic population, but the available evidence confirmed poor compliance to the recommended daily salt limit (see table 3.1) in this population. The reported mean salt intake is above the ‘6g’ of daily limit across the type 2 diabetic population in different parts of world, irrespective of methods used for estimating daily salt intake and study sample’s characteristics as duration of diabetes, presence of diabetes related complications and different BMI levels. Also, prospective longitudinal studies in T2DM concluded that there is less likelihood of adherence to dietary salt guidelines over time in type 2 diabetic group, as dietary salt intake remained high (Baqar et al., 2020; Ekinci et al., 2011). The possible explanations and risk factors associated with non-adherence to dietary guidelines in general and specific to dietary salt intake, needs careful consideration, due to the central role of dietary management in managing this chronic condition.

Table 3.1: Dietary salt intake in participants with T2DM

Author, Year of publication	Study design and sample	Sample Characteristic	Method used for estimating dietary salt intake	Estimated salt Intake
Takahashi et al., 2021	Cross-sectional study, n=300 Country- Japan	• Male (55.7%) • Mean age (years) 65.7 (SD 10.7) • Mean duration of T2DM (years) 13.7 (10.0) • Presence of HTN (62.7%) • Mean BMI (kg/m^2) 24.5 (4.4)	Urine spot samples to estimate urinary sodium excretion	Mean daily salt intake 9.4 (2.4) g/d
Baqar et al., 2020	Prospective cohort study, n=904 Country- Australia	• Male (60.9%) • Mean age (years) 60 (13) • Mean duration of diabetes (years) 31.4 (SD 6.7) • T2DM (81%), Type 1 diabetes (15.9%) and latent autoimmune diabetes (1.1%) • Presence of HTN- NA • Mean BMI (kg/m^2) 31.4 (SD 6.7)	An average of four 24h urine sodium excretion per participant for a median of 7 years.	Yearly mean daily salt intake (g/d) 10.4 (SD 4.2)
Guastadisegni et al., 2020	Cross-sectional survey, n= 502* Country- Italy	• Male (61.3% • Age 35-79 years • Mean BMI (kg/m^2), Men 29.8 (SD 4.3), Women 32.1(SD 5.7) *Data for people with diabetes from data from the Cardiovascular Epidemiology Observatory/Health Examination Survey, conducted in 2008–2012 is presented here.	24h urinary salt excretion	Mean salt intake, men 10.9 (SD 3.6), women 9.2(SD 2.8) g/d
Smina, Kumptla and Viswanathan; 2019	Cross-sectional study, n=50 Country- India	• Male (55.5%) (n=200) • Mean age (years) 54.3 (8.6) • Mean duration of T2DM (years) - NA • Presence of hypertension 100% • Mean BMI (kg/m^2) 28.3 (SD 6.2) *The study included four different groups, with 50 members each, designated as control (group I), T2DM (group II), chronic kidney disease CKD (group III) and HTN (group IV)), the data here is shared for group IV only (T2DM +HTN)*	24h urinary sodium excretion method	Mean daily salt intake (g/d) 13.3 (SD 4.7)

Author, Year of publication	Study design and sample	Sample Characteristic	Method used for estimating dietary salt intake	Estimated salt Intake
Gant et al., 2017	Prospective cohort study, n=450 Country- Netherlands	• Male 58% • Mean age (years) 63 (SD 9.0) • Mean duration of T2DM (years) 11 • Mean BMI (kg/m^2) 32.9 (SD 6.2)	24h urinary sodium excretion method	Mean daily salt intake (g/d) 10.9 (SD 4.7)
Provenzano et al., 2014	Baseline data of single centre RCT is reported in this study, n= 251 Country- USA	• Female 66.9% • 67.7% in age group of 45-64years • Duration of T2DM, 60% with $\leq$ 5 years,70.5% on anti-hypertensive medications.	Three-day diet diary	Mean daily salt intake (g/d) 8.0 (SD 2.8)
Afsar and Elsurer, 2014	Cross- sectional study, n= 146 (T2DM +HTN) n= 238 (HTN) Country- Turkey	• Female 81.5% • Mean age (years) 60.8 (SD 10.9) • Duration of diabetes (years) 9.8 (SD 4.8) • Duration of HTN (years) 7.7(SD 1.4) • Presence of coronary artery disease (CAD) 34.2% • Presence of cerebro-vascular accident (CVA) 5.5% • Mean BMI (kg/m^2) 28.2 (SD 5.7)	24h urinary sodium excretion	Mean daily salt intake (g/d) 9.6 (SD 4.4)
Villani, Clifton and Keogh, 2012	Cross- sectional survey, n=88 Country- Australia	• Male 59.1% • Mean age (years) • Male 61.9 (SD 8.3), Female 59.4 (7.9) • Mean BMI (kg/m^2) Male 34.5 (SD 4.8), Female 35.9 (SD 4.9)	Single 24h urinary sodium excretion Four day weighed food records	Mean dietary salt intake (g/d) using 24h urinary sodium excretion; Male 11.2 (SD 4.3), Female 8.3 (SD 2.4) Using weighed food record Male: 7.1(SD 1.6) Female: 5.7 (SD 1.2)
Ekinci et al., 2010	Cross-sectional study, n=782 Country- Australia	Male 57.8%	Single 24h urine sample	Mean dietary sodium intake (g/d) Male 11.9 (4.7) Female 9.5 (4.1)

3.1.2 Barriers in adherence to dietary guidelines in T2DM

The World Health Organisation, WHO defined adherence as the extent to which a person's behaviour as taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider (WHO, 2003). Although adoption of heathy eating practices is one of the most important lifestyle changes, it is most challenging for patients with T2DM (Chester et al., 2019). Since these patients have several competing care regimens as diet, exercise, stress, medication, in practice specific areas of patient self-management (diet and exercise) are often neglected (Hessler et al., 2019). The findings of various research studies have established that type 2 diabetic patients demonstrated high level of non-adherence to dietary advice (Ganiyu et al., 2013; Parajuli et al., 2014; Grammatikopoulou et al., 2017; Pandey and Sharma, 2018; Ranjbaran et al., 2020). Adherence to diet is affected by various factors including intrapersonal (education, motivation, time constraint); interpersonal (family support, exposure to dietary counselling, patient- provider relationship) and other factors as availability of multi-disciplinary care and provision of culturally tailored dietary information (Mohebi et al., 2013; Mogre et al., 2017; Dao et al., 2019; Mostafavi-Darani et al., 2020). Dietary knowledge, attitudes, and perceptions related to nutritional management of T2DM, are key predictors of better self-efficacy, and thus for behavioural intention and dietary behaviours (Ahola and Groop, 2013, Didarloo et al., 2014; Ku and Kegel, 2015; Sami et al., 2017).

The research studies reporting dietary adherence scores/ rates for diabetic participants has most included key topics as consumption of fruits and vegetables, frequency of consumption of sweets, consumption of fats, but the information on consumption of salty snacks or other high salt food items has not been captured (Rivellesse et al., 2007; Asaad et al., 2015; Marinho et al., 2018; Han et al., 2020). However, few studies estimating dietary salt intake in diabetes population have discussed the probable reasons or mechanisms attributed to higher salt intake in this group as increased salt appetite, reduced salt taste perception (Isezuo et al., 2008; Gondvikar et al., 2009; Baqar et al., 2020; Catamo et al., 2021), lack of knowledge on salt content and source of food (Baqar et al., 2020), lack of access to nutrition counselling and dietary salt intake not addressed in nutrition counselling (Provenzano et al., 2014).

3.1.3 Knowledge, attitudes, and behaviour related to salt intake in T2DM

Even though there has been great deal of research studies reporting consumer's awareness level and perceptions on role of salt of in health, recommended dietary salt intake limits and lack of understanding on food sources of salt; these studies are conducted mostly in general population. There are only limited number of studies (refer table 3.2) exploring this topic in participants with T2DM, and to the best of author's knowledge there has not been any such study conducted in UK. The findings of these studies confirmed inappropriate practices and/ lack of knowledge related to various aspects of dietary salt intake in T2DM. Also, it was noted that co-existence of hypertension in T2DM did not improve the awareness or behaviours related to salt intake (Gee et al., 2013). Thus, considering the evidence for the increased risk of all cause and cardiovascular mortality in T2DM with concomitant hypertension (Petrie et al., 2018, Climie et al., 2019), and implication of salt reduction on health improvements in this group, this study was designed to assess knowledge, attitudes, and practices (KAP) related to dietary salt intake. To the best of the researcher's knowledge, this is the first UK study aimed at determining baseline knowledge regarding salt intake and assessing sources of salt in diet of hypertensive type 2 diabetic participants.

Table 3.2: Awareness and behaviour related to dietary salt intake in T2DM

Author and year of publication	Study design and sample	Methods	Results
Gee et al., 2013	Cross-sectional survey, n=1170 Hypertensive with comorbid diabetes and n=4965, hypertensive without diabetes. Country: Canada	Questionnaire developed by Bienek et al., 2012	Hypertensive individuals with diabetes were not more likely to have received advice on limiting salt intake. Proportions reporting limiting their salt intake, did not differ significantly between hypertensive participants with or without diabetes.
Gray et al., 2014	Prospective cross-sectional study, n=151 (82% T2DM and rest Type 1 diabetic) Country- Australia	Salt knowledge survey developed by Grimes et al., 2009. FFQ- Electronic version of the Dietary Questionnaire for Epidemiological Studies Version 2 (Hodge et al., 2000). Spot urine samples to measure sodium and potassium excretion.	Only 6% respondents knew the correct maximum daily recommended upper limit for salt intake. 23.9% participants were not concerned with the amount of salt in their diet. Fewer than 30% of people knew that foods such as white bread, cheese and breakfast cereals are high in salt. 51% correctly ranked three different nutrition information panels based on the sodium content. Estimated mean daily salt intake based on urinary sodium excretion was Men: 9.7 (1.8) g/d, Women: 6.6(1.5) g/d.
Breen et al., 2015	Cross-sectional survey, n =124 Country: Ireland	Audit of Diabetes Knowledge questionnaire developed by Speight and Bradely, 2001.	Over 80 % of the participants were aware of the links between salt and blood pressure. Participants were most likely to use nutritional labels to check the sugar content (58·9 %), followed by fat content (49·2 %) and salt content (21%) of foods.
Verma et al., 2019	Cross-sectional study, n=402 diagnosed with metabolic syndrome Country, India	43-item questionnaire to assess knowledge, attitudes and practices related to CVD risks.	About 80% of the participants decreased their sugar consumption and salt intake only occasionally, when there is increase in blood sugar levels or blood pressure, but do not comply with this practice. Though 41% were willing to decrease their sugar consumption, only 18% ready to decrease salt consumption in diet.
Ahsan et al., 2020	Cross-sectional study, n=131 Country: Bangladesh	Interviews using WHO STEPS module.	Though 47.3% of the respondents believed that lowering salt in meal is very important and 77.9% of them believed that excess salt or salty sauce can cause health problems. More than six in 10 of them (62.6%) took added salt while taking meal; and 40.5% took processed foods with high salt. The mean amount of added salt intake among the users was 4.4±1.6gm per day.

3.2 Research aim and objectives

Aim: To determine barriers in adherence to recommended salt intake in patients with type 2 diabetes and comorbid hypertension.

Objectives

- Development of a questionnaire to determine awareness level, attitude and practices related to dietary salt intake in type 2 diabetes patients.
- To determine knowledge, attitudes and practices related to dietary salt intake.
- To review association of knowledge, attitudes and dietary practice score with the estimated daily salt intake, demographics, and health outcomes as HbA1c, blood pressure.

3.3 Methodology

3.3.1 Study design: This research study is a dietary survey aimed at eliciting information on dietary salt intake amongst patients with T2DM and comorbid hypertension and the study design is descriptive and exploratory.

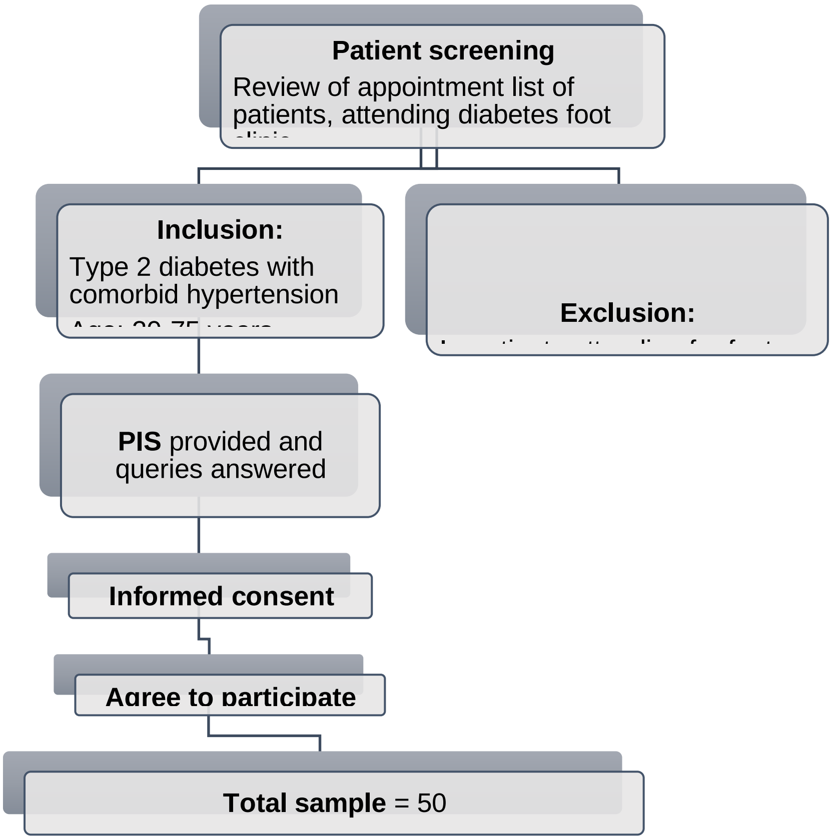
3.3.2 Study settings: The study participants were recruited from Outpatient Diabetic Foot Clinic at Basildon & Thurrock University Hospital, Basildon.

3.3.3 Recruitment process

3.3.3a Screening: The list of patients attending the Diabetes Foot Clinic was obtained from the clinic's secretary. The patient appointment sheet included time of the appointment along with patient's name and hospital number. The clinical records of the patients attending the clinic were reviewed to check following data: date of birth, medical history, and medications. This information was useful to determine if the patients fall under the research study's inclusion criteria.

3.3.3b Enrolment: A diabetic nurse was informed about the list of shortlisted patients, and she informed the patient/(s) that a research student shall approach them to discuss about the study. The researcher approached the shortlisted patients in waiting area and they were given introduction about the study. A copy of participant information sheet, PIS-Phase 1 was handed over to them to read through it and related queries were answered. They were explained that they can also take PIS and discuss with their family/ GP and can consent at the next appointment. The informed consent was obtained, and the form was duly signed by the patient as well as researcher and a copy of consent form was handed over to them.

Figure 3.1: Recruitment strategy



3.3.4 Study participants: A total of fifty participants were recruited using convenience sampling. The patients within the age group of 20 to 75 year; having type 2 diabetes and comorbid hypertension were included. Inpatients referred to the clinic for diabetic foot review/dressings were excluded, as their dietary intake is institutionalized and not reflective of usual dietary practice.

3.3.5 Survey instruments and data collection: For this KAP study, following tools and techniques were used: Questionnaire, 24h dietary recall, anthropometric readings for height and weight, biochemical parameters as HbA1c and total cholesterol and blood pressure readings recorded from electronic medical records (EMR). The data collection period was February 2018 to December 2019.

3.3.5a Questionnaire: The questionnaire developed by Sarmugam et al., 2014 and WHO/PAHO 2010 to determine dietary salt knowledge were referred and further adapted, in relevance to the objectives and the target group of this study. The questionnaire was pilot tested for comprehension as well as face validity and revised before its application with the study group. The research questionnaire (see Appendix H) included following seven sections/ parts: Medical History; Dietary practices related to salt intake; 24h dietary recall; Knowledge of salt intake and its role in health; Attitude towards salt intake; Personal Information and Health Information. Research participant number was allotted to the participants and recorded on the research questionnaire, based on their order of enrolment to the study as RP01 to RP50.The study participants were requested to fill the questionnaire whilst they were waiting for their appointment at diabetic foot clinic or whilst they were in monitoring room after foot procedure/(s) or waiting for X-Ray or blood test prior to foot care appointment. If answers to any sections of the questionnaire was missed or part filled, researcher re-approached the patient during their wait for transport/ scheduling next appointment or at any of subsequent visits to the clinic.

3.3.5b 24h dietary recall: A 24h dietary recall is a retrospective assessment method that captures dietary intake over a 24h period, including a detailed description of the food and beverages consumed such as portion size, brand name, cooking method, recipe, ingredients (Castetbon et al., 2009; Subar et al., 2012; Dietary assessment and physical activity measurements toolkit (DAPA), 2016; Rehm et al., 2016). A 24h dietary recall was obtained from each study participant to elicit complete dietary profile for the sources of salt in their diet. Participants were asked a series of structured but open-ended, non-leading questions about each food or beverage consumed over 24h. Grimes et al. (2017a) also used 24h dietary recall method to determine the food sources of sodium and potassium in the Australian population. A cross-sectional survey conducted by Johnson et al., 2019 to determine the sources of dietary salt in urban and rural population of India, also demonstrated the use of 24h dietary recall method. The multiple pass recall method (MPR) was followed to ensure completeness and appropriateness of dietary information. This method is widely used in diet and nutrition studies (Raper et al., 2004 and Moshfegh et al., 2008) and consists of several passes designed to aid memory including an uninterrupted 'quick list' of items consumed, detailed probes that query food characteristics and amounts, a forgotten food list, and a thorough review.

Face to face interview was used by the researcher to elicit information on the food intake on a previous day. The format of the 24h recall included record of date and day of the diet recall, meal (breakfast/lunch/dinner/mid-morning/evening/any other meal), meal timings, menu along with the ingredients and their respective quantities/amounts. The information on portion sizes was elicited based on household measures; brand names and quantities for ready to eat / packaged food was obtained; use of salt and salt-based seasoning seasonings, sauces, and dressings used in cooking or at table was recorded. The detailed data on the food ingredients for cooked meal, alongside method of cooking was obtained and recorded. The time taken for recording dietary intake was approximately 20 minutes per participant.

3.3.5c Anthropometric measurements: Height and weight measurements were recorded for the study participants, as available in their EMR. BMI was calculated using weight and height data and the participants were classified as underweight /normal weight /overweight /obese based on WHO guidelines for BMI classification (see chapter 2).

3.3.5d Biochemical Parameters and Bio-physical measurements: The blood test results for HbA1c, total cholesterol and blood pressure readings (SBP/ DBP) were gathered based on latest readings available in EMR.

3.3.6 Data Analysis

The raw data from the research questionnaire was entered in Microsoft Excel, Windows version 2013.

3.3.6a KAP score: The questions corresponding to the knowledge, attitudes and dietary practices were scored and the criteria used for scoring is explained in table 3.3.

Table 3.3: Criteria for computing KAP score

Parameter	Scoring criteria	Maximum achievable score
Knowledge regarding dietary salt intake was scored on a set of 22 questions as P4Q1 to P4Q11; P4 Q12.1 to P4 Q12.15	Maximum score of 1 for correct response, zero for incorrect or no response	22
Attitudes regarding dietary salt intake was scored on a set of six statements P5Q1a to P5 Q1f	Maximum score of 2 for response "strongly agree" and score of 1 for response "agree" and zero score for response "don't agree"	12
Dietary practices towards salt intake were scored on a set of two questions pertaining to use of salt in cooking and salt at table	Maximum score of 3 for 'never', 'rare'-score 2, 'sometimes'-score1 and 'always" score 0.	6
Combined KAP score		40

3.3.6b Dietary assessment included input of 24h dietary data into nutrition analysis software, Nutritics (research edition v5.096). The recipes were customized based on the participants dietary recall data and new foods were entered along with their nutrition label information as available online, as per the specified brand name. A total of fifty-eight new recipes and eleven new foods were entered. The batch export report provided the average intake for all the macronutrients energy, protein, carbohydrates, and fat. The other nutrients of relevance to the nutritional assessment of the study's target group were fibre, saturated fat, total sugar, free sugar, sodium, potassium, calcium, and vitamin D also reviewed in comparison to recommended intake.

3.3.6c Anthropometric assessment and health parameters: Based on the ethnicity of the study participant, specific BMI classification was used for the categorisation of participants as normal weight/ overweight and obese (see Chapter 2). The health parameters as HbA1c, total cholesterol and blood pressure readings were analysed in comparison to the treatment goals as defined by NICE 2019; HbA1C $\leq$ 58.0 mmol/mol, blood pressure reading of <140/90 and total cholesterol level <5 mmol/l d.

3.3.7 Statistical analysis

The data was analysed using statistical package for social sciences, SPSS (version IBM SPSS Statistics 26). The study participant's baseline characteristics were stated using descriptive statistics –count and percentages. Mean and standard deviation was computed to describe other characteristics of the study sample. All the study variables were checked for normality using Shapiro–Wilk test along with review of the histogram. If the data variable was not normally distributed, median values were calculated. Statistical test such as t-test, one-way ANOVA test was used to compare the difference in mean KAP scores according to age, income, education, BMI, length of diabetes and level of salt intake at the significance level $p \leq 0.05$. Normality test and diagnostic tests as homogeneity of variance and Levene's test of equality of variance were applied.

3.3.8 Data storage, retention, and disposal: Health and dietary information received from the study participants in form of hand-written questionnaires and consent forms was kept securely and confidential, in compliance to University's Code of Good Research Practice and Data Protection Act 1998. Hard copies of data collected at hospital, was transferred to the university at the earliest possible opportunity and kept in a secure folder in a lockable filing cabinet. Hand-written questionnaire and consent forms were scanned and stored as an electronic file on university computer (allocated for research work) at Faculty of Life sciences & computing in a lockable room. All electronic files were protected by applying a password to record as well to parent folder. The computer was always locked and regular back up of electronic data was taken in memory drive that was locked away securely. The research data shall be retained for ten years, after the completion of study. After retention period is completed, hard copies shall be shredded and disposed of, as per the guidelines of London Metropolitan University's confidential waste disposal service.

3.4 Results

3.4.1 Demographic characteristics

The demographic characteristics of the study sample (n=50) are summarized in table 3.4. The majority of the participants of this study were males (70%), white ethnicity (90%) and retired (46%). The participant's age ranged from 44-75 years (Mean 61.7, SD 9.5 years) and majority (60%) belonged to the age category of 61-75 years. One-third of the participants (33%) are in the income range of £10,400-£25,999 per annum, followed by 30% with an annual income of ≤10,399; 24% in income group of £26,000-£36,399 and only 12% earning an annual income ≥ £36,400. Majority of the participants completed education to the school level (58%); followed by 27% with university degree and only 2% achieved higher qualification as a post-graduate degree. The rest 13% of the participant reported to be school dropouts or had no formal education.

Table 3.4: Demographic characteristics of study participants

Variable	Sub-category	n (%)
Gender	Male	35 (70%)
	Female	15 (30%)
Ethnicity, N=49	White	44 (90%)
	Asian or Asian British	1(2%)
	Black/African/Caribbean /Black British	3 (6%)
	Mixed ethnic group	1 (2%)
Employment status	Un-employed	14 (28%)
	Employed	9 (18%)
	Self- employed	4 (8%)
	Retired	23 (46%)
Income status, N=33	<£5,200-£10,399	10 (30%)
	£10,400-£25,999	11 (33%)
	£26,000-£36,399	8 (24%)
	≥£36,400-£51,999	4 (12%)
Education level, N=48	School	28 (58%)
	University education	13 (27%)
	Post- graduation	1 (2%)
	Other, specify	6 (13%)

3.4.2 Anthropometric status: The group statistics for anthropometric measurements as height, weight and BMI for the study participants are presented in table 3.5a. More than half (55.3%) of the patients are in the obese category, followed by 18.4% percent in the overweight category and the rest (26.3%) in normal weight category. Further categorisation of the obese participants based on severity of obesity grade indicated that 26% of the participants fall into the obese grade I, followed by 13% in grade II and 16% in grade III.

Table 3.5a: Anthropometric status

Parameters	Sample (n)	Mean (SD)	Range
Height (m)	41	1.76 (0.11)	1.52-2.03
Weight (kg)	42	97 (20.7)	60-144.9
BMI (kg/m²)			
Total	38	31.2 (6.4)	22.1-44.0
Male	26	30.2 (6.1)	22.1-42.1
Female	12	33.3 (6.9)	22.7-44.0

Table 3.5b: BMI

BMI	n (%)
Normal weight	10 (26.3%)
Overweight	7(18.4%)
Obese	21 (55.3%)
Obese grade I	10 (26%)
Obese grade II	5 (13%)
Obese grade III	6 (16%)

3.4.3 Bio-chemical and bio-physical parameters: Health profile of the study participants is summarized in table 3.6. The data on achievement of diabetes treatment target indicated that less than third of the participants (32%) had HbA1c ≤58mmol/mol and only 40% achieved the blood pressure goal of <140/90 mmHg. And 76.8% of the participants achieved cholesterol targets of <5mmol/l.

Table 3.6: Health profile

Parameters	n	Mean (SD)	Range	Treatment targets*
HbA1c (mmol /mol)	50	71.7 (22.1)	38-129	≤58mmol/mol
Total cholesterol (mmol/l)	49	3.9 (1.0)	1.7-6.7	<5mmol/l.
SBP (mm/Hg)	50	149 (24.0)	91-208	<140 mmHg
DBP (mm/Hg)	50	80.5 (13.3)	53-122	<90 mmHg

Abbreviations: HbA1c, glycated haemoglobin; SBP, systolic blood pressure; DBP, diastolic blood pressure

Treatment targets defined by NICE guidance

3.4.4 Medical History

Majority (88%) of the respondents, had been living with diabetes for more than a decade. Other ten percent of the participants had been diagnosed with diabetes for last 5-10 years and the rest (2%) was recently diagnosed within a span of year. Sixty two percent had been diagnosed with high blood pressure for more than 10 years, twenty eight percent were diagnosed in the past 5-10 years, six percent within last 5 years and the rest two percent diagnosed with this health condition recently for less than a year. The data on the medical management of both the chronic health conditions-T2DM and hypertension indicated that 78% of the patients had been taking medication for the management of both health conditions. However, twenty-two percent of the patients reported managing hypertension without medication/(s). Seventy per cent of the study participants reported having have a medical condition other than T2DM and high blood pressure. However, only 26% specified the name for comorbidities as renal disease, heart disease, dyslipidaemia, stroke, gastroparesis, and non- diabetes related conditions viz. cancer, spondylitis, fibromyalgia, hypothyroidism, and hemochromatosis. The study participant's responses on the existence of any health conditions in the family are summarised in the table 3.7.

Table 3.7: Family history

Medical condition, n=49	**n (%)**
T2DM	14 (29%)
Hypertension	4 (8%)
Both T2DM and hypertension	9 (18%)
Other	1 (2%)
No family history	21 (43%)

3.4.5 Dietary practices related to salt intake

Majority (82%) of the participants consumed home cooked meal/(s) daily. And nearly a third of the participants (32%) stated frequent consumption of ready meals ranging from daily to 2-3 times a week. The practice of having a takeaway meal or dine in at restaurant on a regular basis, is not common in this group (see table 3.8)

Table 3.8: Patterns of consumption of home cooked, ready meal and takeaway

	Homecooked meals	**Ready meals**	**Takeaway meals**
Frequency of intake	n (%)	n (%)	n (%)
Daily	41 (82%)	8 (16%)	0%
2-3 times a week	4 (8%)	8 (16%)	4%
Once a week	3 (6%)	6 (12%)	18%
Once a fortnight	0%	5 (10%)	16%
Rare	1 (2%)	10 (20%)	42%
Never	1(2%)	13 (26%)	20%

A substantial percentage of participants (44%) confirmed adding salt to their meals during cooking, followed by forty two percent putting salt rarely or not at all and the rest fourteen percent stated that they add salt in cooking sometimes. For the use of salt at table, 26% stated they always sprinkle salt to their food at table and another 22% stated using it sometimes. The most popular salt is table salt (50%), followed by rock/sea salt (34%) thirty-four percent and lo salt (10%). Majority of subjects (52%) perceived their intake as "low", followed by thirty-eight percent reported their salt intake as average. Only eight percent stated their salt intake as "far too much" and one of the participants indicated inability to categorize the level of dietary salt consumption.

A significant number of participants (62%) stated that nutrition label information is not a vital part of their food choices. However, most of the hypertensive- type 2 diabetic patients (78%) regard sugar as most important nutrient on the label, followed by 36% considering total fat content and only twenty four percent reviewing salt content (see table 3.9). Only four percent reported inspecting all the five nutrients on front-of-pack label.

Table 3.9: Reading nutrition label

Nutrient	n (%)
Energy	9 (18%)
Fat	18 (36%0
Saturates	5 (10%)
Sugar	39 (78%)
Salt	12 (24%)
Other	3 (6%)
None	6 (12%)

3.4.5a <u>Measures to control salt intake</u>: The study participants ranked the seven listed measures for reducing salt intake (see table 3.10). The measures that ranked first are 'not adding salt during cooking' (34%) followed by "Not adding salt at table "(32%) and avoid eating out (14%). Second rank was given to "Do not add salt at table" by thirty two percent followed by "avoid eating out "(18%) and "do not add salt during cooking" (14%). The measures that were ranked third by most of the participants were "Reduced intake of processed foods" as indicated by 26% followed by "avoid eating out" (24%) and use herbs & spices instead of salt in cooking (14%). "Compare salt content on nutrition label" and "buying low salt alternative" were least popular measures amongst the study group.

Table 3.10: Measures to reduce daily salt intake

Measures to control salt intake	Rank 1	Rank 2	Rank 3
Avoid eating out	14%	18%	24%
Buy low salt alternative	6%	0%	2%
Reduced intake of processed foods	6%	10%	26%
Compare salt content on nutrition label	6%	8%	2%
Do not add salt at table	32%	32%	4%
Do not add salt during cooking	34%	14%	6%
Use Herbs & spices instead of salt in cooking	6%	6%	14%

3.4.5b Barriers in adherence to recommended salt intake: Only thirty percent of the participants answered the question 'specify the reasons that pose difficulties in controlling your salt intake'. Twelve percent reported no difficulty in controlling their salt intake and the rest eighteen percent stated the following reasons as dependence on ready meal, taste of food is not good without salt and difficulty in comprehension of food label.

3.4.6 Knowledge of salt intake and its role in health

Majority (94%) of the study participants reported receiving advice from the healthcare professional for managing their health condition. The most common topic that was covered as part of health care advice was dietary modification for controlling and managing diabetes and hypertension as stated by eighty-four percent of the study patients. Sixty-four percent of participants reported they were advised to lose weight, followed by fifty-eight percent advised to stay active and thirty-two percent recommended to quit smoking. Other eighteen percent answered that medication management and blood glucose monitoring was emphasized by their healthcare team. The diabetic nurse was focal point of advice as suggested by fifty percent of the study participants, followed by dietitian (46%) and GP (44%). Another, twenty-two percent respondents stated diabetic foot consultant (as other professional who guided them for disease care.

Guidance on dietary modifications: The participants responses on various aspects of healthy eating guidance received by their healthcare team are summarized in table 3.11. Only fifty-eight percent acknowledged receiving advice to watch their salt intake.

Table 3.11: Dietary modification messages

Dietary Advice	**n (%)**
Limit intake of sugar & sugary drink/foods	46 (92%)
Limit intake of fried and fatty foods	43 (86%)
Eat 5 a day -Fruits & Vegetables	34 (68%)
Intake of oily fish	29 (58%)
Limit alcohol consumption	23 (46%)
Limit salt Intake	29 (58%)
Other	2 (4%)
No diet advice	3 (6%)

Health conditions associated with excessive salt intake: Although excessive salt intake is associated with the health ailments: stroke, osteoporosis, high blood pressure, kidney stones and stomach cancer, majority (82%) reported their awareness of the excessive salt intake linked to high blood pressure only.

Awareness of UK government recommendation on dietary salt limits: Although seventy-two percent of the population stated awareness of UK government recommendations to lower salt intake. Only one respondent answered the correct response “<6g/day salt intake”. More than half (53%) of the participants indicated lack of knowledge on daily salt limit.

Table 3.12: Recommended daily salt intake

Daily salt limit	n (%)
<6g/day	1 (2%)
<5g/day	6 (12%)
<3g/day	13 (27%)
Other	4 (8%)
Don't know	26 (53%)

Contributors to daily salt intake: The participants were asked to specify what contributes highest to the daily salt intake and most (80%) referred to the processed foods, followed by salt at table (22%) and salt in cooking (12%) and two percent were unable to provide any response.

Nutrient value on the label corresponding to salt content: Less than a half (42%) of the respondents recognised that both sodium and salt on the food label are related to the total salt content. Eighty-six percent of participants were able to interpret the traffic light label correctly, to determine the low salt food option.

Awareness of salt content in various food items: The food items as bread, smoked fish, pickles, biscuits, and tomato ketchup were not considered “high in salt’ by most of the study participants (see table 3.13). Only 36% of the respondents, referred to cheese as “high in salt”. Take-away meals and crisps were regarded as high in salt by 96% and 92% of the participants in each respective category. Pasta-ready meal was considered as ‘high in salt’ category by 74% of the participants. The processed meats as bacon, salami & sausages were recognised as salted food by 74% and 84% respectively.

Table 3.13: Foods recognised as 'salty'

Food item	High in salt		
	Yes	No	Don't Know
Bread	54%	38%	8%
Tomato Ketchup	64%	18%	18%
Bacon	74%	16%	10%
Pasta- ready meal	74%	22%	4%
Pizza	80%	8%	12%
Soy sauce	68%	14%	18%
Smoked fish	32%	52%	18%
Pickles	50%	34%	16%
Stock cubes	82%	6%	12%
Cheese	36%	48%	16%
Salami & Sausage	84%	8%	8%
Crisps	92%	4%	4%
Biscuits	44%	44%	12%
Cakes	38%	52%	10%
Takeaway meals	96%	0%	4%

3.4.7 Attitudes towards reducing dietary salt intake

The study participant's attitude towards reducing dietary salt intake is assessed through their responses to the six key statements on dietary salt intake as summarized in table 3.14. Majority (94%) of the respondents agreed/strongly agreed that reducing salt intake is important for their health. Similarly, ninety-two percent agreed that they would like to take action to cut down the salt in their diet. However, a significant eighteen percent showed their disagreement for reading salt content on the nutrition label, prior to the purchase. Likewise, twenty percent disagreed that food cooked with less salt and with the use of flavourings as ginger, garlic tastes good. More than half of the participants (54%) disagreed for requesting low/no salt food whilst dining out/takeaway. Eighty-six percent of the participants stated interest in gaining more information about simple ways to reduce salt intake.

Table 3.14: Responses to statements on reducing dietary salt intake

Statement	Participant's response n (%)		
	Disagree	Agree	Strongly agree
Reducing salt intake is important for better control of my health condition	3 (6%)	31 (62%)	16 (32%)
I will cut down the amount of salt I consume on regular basis	4 (8%)	32 (64%)	14 (28%)
I will read salt content on nutrition label prior to purchase	9 (18%)	27 (54%)	14 (28%)
I will request to reduce or avoid adding salt to the dishes when eating out	27 (54%)	15 (30%)	8 (16%)
Food cooked with less salt and with use of flavourings as lemon, ginger, garlic etc. tastes good.	10 (20%)	29 (58%)	11 (22%)
I am interested to gain more information on simple ways of reducing salt	7 (14%)	37 (74%)	6 (12%)

3.4.8 Knowledge, attitude and practice score: The score for knowledge, attitude, practice and combined score for KAP related to dietary salt intake as achieved by this study group is summarized in table 3.15. Only six of the study participants (12%) achieved KAP score above 32 corresponding to 80%.

Table 3.15: Score for knowledge, attitude and practice score related to dietary salt intake

Score	Maximum score achievable	Score Mean (SD)	Range
Knowledge score	22	13.5 (3.7)	4-20
Attitude score	12	6.2 (2.6)	2-12
Practice score	6	3.0 (1.9)	0-6
KAP score	40	22.6 (6.1)	7-38

3.4.9 KAP score and dietary salt Intake: The mean KAP score in the participant group consuming $\geq$ 6g/day salt intake is lower than participant group consuming <6g/d (see table 3.16). The Shapiro-Wilk test and the histograms for KAP score in the study group consuming $\geq$ 6g/day indicated that data was not normally distributed. KAP score between the two groups was not statistically significant as determined by the Mann-Whitney U test (U=184.5, p=0.14).

Table 3.16: Combined KAP score in two study group <6g/day and ≥ 6g/day

Salt intake group	KAP score Mean (SD)
<6g/day, n=36	22.9 (6.3)
≥6g/day, n=14	21.6 (5.4)

3.4.10 KAP score and demographics: The results of independent t-test indicated that the difference in mean KAP score in male and female participant groups (Mean (SD) 22.3 (6.6) and 23.1 (4.6), p=0.7) was not statistically significant. One Way ANOVA test showed that there was no statistically significant difference in mean KAP score on dietary salt intake, by occupation categories, p=0.99. Similarly, no significant difference in the mean KAP score was observed across the age categories, education, and income level.

3.4.11 KAP score and health parameters: A greater percentage of participants in higher KAP score, had achieved targets for HbA1c and vice-versa, but this difference was not statistically significant. No statistically significant difference was observed for systolic blood pressure target achievement and KAP score.

3.4.12 Nutrition composition of diet of study participants: The dietary intake data as gathered through 24h dietary recall was analysed to determine nutrient intake of the study group and is summarized in table 3.17. The dietary salt intake was further analysed for this study group, and it indicated that twenty eight percent of the participants are consuming above the recommended intake of <6g/day, as defined for UK population and for diabetes patients by Diabetes UK guidelines. However, as per the WHO recommendation <5g/day, nearly half of the participant group (48%) is consuming salt above this recommended limit.

Table 3.17: Daily nutrient intake

Nutrient intake per day	**Mean (SD)**
Energy (kcal)	1344 (430)
Protein (g)	66.0 (23.3)
Carbohydrates (g)	152.7 (55.4)
Fat (g)	52.6 (28.6)
% of total calories	35.2%
Saturated fat (g)	19.8
% of total calories	13.2%
Trans fats (g)	0.68 (0.69)
% of total calories	0.004%
Cholesterol (mg)	221.5 (198.1)
Sugar (g)	46.1 (33.8)
Fibre (g)	16.5
	12.3g per 1000 kcal
Salt (g)	5.06
Potassium(mg)	1935.8
Calcium (mg)	519
Magnesium (mg)	190

3.5 Discussion

Overview

This study reviewed the health and nutritional profile of a subgroup of type 2 diabetes participants who have progressed to diabetic foot disease. This condition adversely affects the quality of life and are at risk of premature death. Nutritional management is very important for good glycaemic control, prevention as well as management of CVD and for wound healing in patients with foot ulcers. Majority of the participants had a relatively longer duration of T2DM (more than a decade) and the achievement of health targets for glycaemic control as well as blood pressure was sub-optimal for the group in spite using pharmacotherapy. There was lack of awareness on daily salt limits, food sources of salt and poor interest in reading nutrition label for choosing healthier alternatives. For the nutrition label, majority of the participants prefer to read information on sugar followed by fat, salt and a merely 4% check all the five nutrients on FOP. Such neglect to monitor dietary salt intake is evident in other practices of unwillingness to buy reduced salt food products, requesting for no or less salt in meals whilst eating out and frequent use of salt in cooking/ table. However, it is important to consider that this group of participants indicated poor perception of their actual salt intake as only 8% considered themselves as eating ‘far too much’ as compared to 28% consuming more than 6g/day, based on the data gathered from 24h dietary recall. The findings of this study substantiate the need to address the barriers related to dietary salt intake through a practical tool that could improve awareness around dietary salt as well as help in monitoring salt intake in this vulnerable group.

3.5.1 Study participant characteristic: The research participants had T2DM with comorbid hypertension and advanced to diabetic peripheral neuropathy resulting in diabetic foot disease. The participants were recruited from a diabetes foot clinic, and researcher is aware of the limitation of the lack of diversity of the participant group. At the same time, it is imperative to focus on the relevance of assessing KAP related to dietary salt intake in this high-risk group diabetic patients. Diabetes foot disease is a major disabling complication of type 2 diabetes and poses a great economic burden to health and social care. Foot disease affects nearly 6% of people with diabetes and includes infection, ulceration, or destruction of tissues of the foot (Zhang et al., 2017).

Between 0.03% and 1.5% of patients with diabetic foot require an amputation (Lazzarani et al., 2015). Diabetes patients with foot complications have a poor quality of life affecting their social participation, livelihood and even are more likely to have a higher risk of premature death (Jeffcoate and Bakker). The regulation of blood sugar levels is key to effective wound healing in patients with diabetic foot disease (Marston, 2006; Christman et al., 2011; Mishra et al., 2017). Adherence to the dietary recommendations including lowering dietary salt intake is paramount to good glycaemic control (Brown et al., 2016; Sami et al., 2017) and for prevention and management of diabetes related complications (Heerspink et al., 2012; Horikawa and Sone; 2017). Therefore, review of KAP regarding salt intake in this diabetic sub-group, provided in depth understanding of dietary challenges faced since T2DM diagnosis till their pathway to managing the foot disease. The information on strategies to overcome such barriers can be translated for all patients with diabetes and may act as a deterrent for progression to this stage. This study's data on gender distribution (70%, male) compared well with the higher proportion of male patients reported in National Diabetes Foot Audit, NDFA 2014-16 (Jeffcoate, et al., 2017). The study conducted by Hasan et al. (2013) also reported that male patients had greater risk of diabetic foot ulcer compared to their counterparts with no foot ulcer. The results of the present study confirmed preponderance of white ethnic descent (90%) and such findings of predominance of diabetic foot ulcer in white ethnic population was highlighted in NDFA report as well. Similar observation was also published by another study conducted in patients with diabetic foot in UK (Abbott et al.,2005). Another important consideration with respect to ethnicity, is the proportion of minority ethnic group at the research site (Basildon) is lower than national average as 6.2% of people are from minority ethnic background compared to 13.6% in England (Public Health England, 2019). The socio-economic status of the study sample as determined by the employment status showed that only less than a third of the participants were in employment, owing to retirement age and unemployment possibly due to diabetic foot related disability. The lower rate of employment also signifies the lower income status of the significant proportion of participants. The employment and income deprivation are one of the factors associated with increased risk of developing diabetes related foot complications (Riley et al., 2021). Poor socioeconomic factors have been empirically accepted as a risk factor for the development of diabetic foot problems (Apelqvist and Larsson, 2000; Peters, Lavery and Armstrong, 2005; Leese et al., 2013).

The data on body mass index (mean BMI, kg/m^2 31.2 (SD 6.4) of the study sample suggested prevalence of obesity in study participants. These findings are consistent to that reported for T2DM patients with average BMI of 31.1kg/m2 in NDFA report. The case-control study conducted by Ganz et al. (2014) concluded that overweight and obesity was statistically significantly associated with the risk of being diagnosed with type 2 diabetes. The strength of this association increased with BMI category (RR [95% confidence interval]: overweight, 1.5 [1.4–1.6]; Obesity Class I, 2.5 [2.3–2.6]; Obesity Class II, 3.6 [3.4–3.8]; Obesity Class III, 5.1 [4.7–5.5]). Observational data from the other studies also suggested that weight gain and obesity are among the most important predictors of developing type 2 diabetes (Manson et al., 2001; Naryan et al., 2007). The mechanism underlying these associations likely involves inflammatory activation of adipose tissue resulting in insulin resistance. Other identified “links” between obesity and type 2 diabetes are pro-inflammatory cytokines (tumor necrosis factor and interleukin 6), deranged fatty acid metabolism, and cellular processes such as mitochondrial dysfunction and endoplasmic reticulum stress (Eckel et al., 2011; Zatterale et al., 2020).

3.5.2 Health profile

Most of the study participants had T2DM for more than a decade. This observation is linked to the progressing age and relatable to the presence of foot complications as one of the chronic complications of uncontrolled diabetes. The similar findings were reported in NDFA stating average length of diabetes as higher in those presenting with diabetic foot ulcer in comparison to the participants of National Diabetes Audit, NDA (Health and Social Care Information Centre, 2016). There is enough scientific literature suggesting the risk of microvascular complications as diabetes foot disease increasing with age as well as duration of diabetes (Ramanathan, 2017; Al-Rubeaan et al., 2015; Assaad-Khalil et al., 2015).

The results of this study suggested poor glycaemic control in majority of the participants as merely 32% of the participants achieved HbA1c treatment target in comparison to higher target achievement (63.4% and 47.8%) for the participants of NDA 2020-2021 (NHS Digital, 2020) and NDFA 2013-14 (Health and Social Care Information, 2016). These findings are upsetting as meeting HbA1c target is vital for wound healing for patients with diabetic foot disease (Xiang et al., 2019) as well as prevent development of other complications related to T2DM in general. Similarly, the rate of achievement of blood pressure targets were lower for this study's participants group compared to those in NDA audit (40% and 66.7% respectively). Several studies have reported poor glycaemic control and hypertension as risk factors associated with diabetic foot complications (Elbarsha et al., 2019; Gupta et al., 2019; Rossbath et al., 2021).

3.5.3 Nutritional intake: The nutritional intake for this study's participant group suggested sub-optimal intake and poor compliance to the dietary guidelines as represented by higher intake of total as well as saturated fat (35.2% and 13.2% of total calorie intake respectively) as compared to the recommended intake of <30% and <7% for those at high risk of CVD (NICE, 2014). Also, the intake of fibre is lower (12.3g/1000 kcal) as compared to recommended intake of 15g/1000kcal (Dyson et al., 2018). Although, the mean salt intake at group is within recommended limit, there is likely under-reporting of salt intake related linked to energy under-reporting. The mean intake of potassium is lower as compared to recommended, however it might be related to dietary potassium restriction associated with diabetes related co-morbidities (nephropathy) or use of specific medications.

3.5.4 Knowledge regarding dietary salt intake and its role in health: The mean KAP score of the study group was low, as expected of the characteristic of the patients with diabetic foot owing to poorer metabolic control. The mean score was around 50% with respect to each of the KAP attributes: knowledge, attitudes as well as dietary practice related to salt intake. The lower level of awareness regarding dietary salt intake relates well to the observation that most of the participants reported receiving advice on limiting sugar and fat as compared to lowering salt intake. Also, majority of the participants perceived sugar as most important nutrient for determining their food choice/ selection. Another significant finding is that most of the participants of the present study were unable to identify the association of excessive salt intake beyond raised blood pressure, such as stroke, osteoporosis, stomach cancer and kidney stones. The similar results were observed in KAP study carried out by Grimes et al. (2017b) that indicated the awareness on the relationship between excess salt and stroke, kidney disease, stomach cancer was lower compared to that of hypertension. The dietary recommendation for lowering salt intake as advocated by diabetes care recommendations (Dyson et al., 2018); needs to be advocated in patients specifically with dual burden of type 2 diabetes and hypertension. It also, seems that the burden of the comorbidities and day to day management of diabetes foot disease might be the reason for poor attention to this aspect of dietary modification. In view of the poor knowledge in this aspect, the study patient group is unlikely to have the ability to accurately estimate their daily salt intake and thus majority perceived their intake as average.

3.5.5 Declarative and procedural knowledge: The level of awareness regarding dietary salt intake recommendation is significantly poor as only one respondent correctly answered the recommended amount of salt intake per day. Grimes et al. (2017b) stated that only 28% could correctly identify the maximum recommended daily intake for salt. A review of literature of thirteen studies also reported that majority (70%) of the participants were unable to correctly recall or identify the recommended amount of salt intake (Sarmugam and Worsley, 2014). Although, above studies were conducted in healthy adult population, their awareness level with respect to the daily allowance of salt was better compared to present study's patient group. An Australian study conducted with diabetic participants (82% with T2DM) also reported poor level (6%, n=9) of awareness on daily salt limits guidance.

The results of present study indicated that less than half of the participants understood that both sodium and salt equivalent refer to the salt content on the food label. The study conducted by Bhana, Utter and Eyles (2019) in general population of Newzealand indicated that 62% knew the relationship between salt and sodium. Although, this information might not be meaningful in context of UK manufactured products, that are required to state salt content as mandatory nutrition declaration (Population Health Division, 2016), it stands important in times of increasing popularity and market of food available through e-commerce. Many countries still represent sodium content on the nutrition label as US FDA regulations.

One of the positive highlights of the study is that majority of the participants correctly stated processed foods as the predominant contributor to salt in diet of UK population, and thus, consistent with the results of studies conducted in other developed countries. Grimes et al. (2017b) stated that three quarters of respondents identified most salt in Australian diet comes from processed foods. Majority (87%) knew the processed food is the primary dietary source of salt in diet of New Zealand population (Bhana, Utter and Eyles, 2019). The awareness on the salt contribution of processed foods relates well to the observation that "reduced use of processed foods" ranked third, as an important measure to control salt intake by hypertensive diabetic group in the present study.

3.5.6 Dietary sources of salt: Take-away meals, crisps, salami & sausage, stock cubes, pizza, pasta ready-meal and bacon were correctly recognised as 'high salt' by most of the respondents. This correlates well with their awareness of processed food as major contributor to salt content in diet of UK population. However, the food items as cheese, smoked fish and cakes were recognised as 'high salt' by substantially lower percentage of the participants (around one-third of the participants).

As per the findings of NDNS, cheese is one of the top ten contributors of salt intake and is widely consumed in UK (NDNS, 2009). The understanding of food sources of salt was checked for this study participants, and the notable finding was cheese is considered high in salt by merely 37% of the respondents. On the contrary, other studies conducted with general population in Korea and Australia respectively indicated a significantly higher number of participants that identified cheese as "high salt" (Kim et al., 2012 and Sarmugam et al., 2014). Only half of this study's participants regarded bread as high in salt. A large -scale survey led by Consensus Action on Salt and Health in UK suggested that fewer than 15% of the participants could correctly identify bread as the major contributors of salt to British diets (Action on Salt, 2014). A greater percentage of respondents in our study, were aware of the salt contribution from this staple food, as compared to knowledge level reported by general population in UK based study. Since bread is such a large part of diet in UK and biggest contributor to salt in diet, it is a matter of concern to the have a significant 46% of the study participants unable to identify bread as a contributor to salt. However, the findings of Gray et al. (2014) highlighted comparatively lower rate of awareness of salt contribution from cheese and bread, in diabetic participants (<30%).

Only half of the hypertensive diabetic participants in present study were able to identify pickles as 'high salt' as compared to other study conducted by Kim et al. (2012) in general population where more than 70% of participants correctly identified pickles as high in salt. Nearly one-third of the hypertensive diabetic participants were not aware of salt content/contribution of sauces such as tomato ketchup. This observation is notable in view of the findings of the recent survey of salt content of sauces in UK

(Action on Salt, 2019). Over a third (38%) of sauces with salt targets as set by government to be achieved by 2017 currently exceed their respective maximum target. Thus, it is vital that public health campaigns shall put greater efforts not only on keeping the saltshakers off the table but for sauces in restaurant and families to keep the sauces off the table at home. The survey done by "action on salt" also revealed that only 1 in 5 of sauces displayed colour coded nutrition information on front of pack. The lack of mandatory FOP labelling could be one of the barriers in adoption of healthy shopping practice, despite good procedural knowledge of label reading amongst the study participants. It is important to note that UK's FOP nutrition labelling scheme introduced in 2013 is still voluntary and only adopted by two- thirds of packaged food and drinks market in UK (Skotarenko, 2018).

3.5.7 Attitudes towards reducing dietary salt: A majority of the participants showed positive attitude towards reducing their dietary salt intake by stating their agreement on these five measures: acknowledging the role of salt reduction in health; reducing salt consumed, reading nutrition labels, cooking with use of flavourings/ herbs and interest in gaining more information. Ninety four percent of our study participants agreed that reducing salt is important for health as compared to 41% of the adults as reported by Australian study conducted by Grimes et al. (2017b). The study carried out by Bhana, Utter and Eyles (2019) reported less favourable attitudes towards dietary salt reduction among New Zealand adults.

However, more than half of the participants stated their disagreement for requesting low or no salt food, whilst dining out. The hesitation to ask for salt modifications as their dietary requirements at restaurant seems to be related to "avoid eating out" as one of preferred method of reducing salt intake. The salt survey conducted by Action on salt (2018) indicated lack of consistent and clear nutrition labelling on menus, despite high salt content in food items served at restaurants in UK. Thus, it is imperative that restaurant menus provide color-coded labelling on their menus and display arrangement to cater to low salt dietary requirements, for consumer to make healthier food choices.

3.5.8 Dietary Practices: The findings of our study suggested that practice of consuming home-cooked meals on daily basis is common in the present study group, as reported by 82% of the participants. The cross-sectional analysis of UK based cohort study also indicated that 61.5% of the participants had home cooked meals more than 5 times a week and such practice was more prevalent in older, not working or working reduced hours (Mills et al., 2017). The higher proportion of the present study participants, consuming home cooked meals seems to be related to the personal characteristics as being retired, older age group, reduced social participation owing to foot disease related disability. The practice of having a takeaway meal or dine in at restaurant on a regular basis, was also not common. The practice of homebased cooking in this study group doesn't seem to have particular benefit in reducing salt consumption, in view of frequent addition of salt in cooking and even at table, as reported by the study participants. The practice of discretionary salt use has implication on the total salt intake. The data on mean dietary salt intake of this study group indicated the dietary intake levels were above 5g/day, above the dietary salt targets set by WHO.

Another important observation related to dietary practices in this study group suggested that the nutrition label reading is not popular amongst majority (62%) of the participants. Such practices may affect the diet quality of the participants irrespective of the efforts placed in homebased cooking. Similar findings of higher rate of non-participation (45%) in food label reading amongst type 2 diabetes patients was reported in a case- controlled study conducted by Samuel et al., 2016. This intervention study provided dietary education through community health workers and emphasized that food label use results in consumption of diets of higher nutritional quality and, in turn, aimed for good HbA1c control among individuals with type 2 diabetes. Other multi-ethnic studies also confirmed the important role of food label in improving diet quality (Carter et al., 2013; Bajorek and Morelleo, 2010).

Less than a third of participants reported reviewing salt content on the food label as compared to higher interest for sugar on the label (78%). Similar results were reported in a cross -sectional analysis of diabetes related nutrition knowledge in hypertensive type 2 diabetic participants, where sugar was most frequently checked nutrient on label (59%) as compared to salt (21%) (Breen et al., 2015). Another study conducted with hypertensive participants reported 50% of the study group reading salt content on label (Elfassy et al., 2015). This signifies the priorities of patients handling dual burden of T2DM and hypertension; and thus, concerted efforts to address dietary salt reduction messages with this group. Such practice of neglect to the salt content on the label is likely one of the potential barriers, in adherence to recommended daily salt limit in this group.

The findings of this study suggested a mismatch between the self-perception and estimated dietary salt intake through 24h dietary recall method. Although merely 8% of the respondents considered their salt intake as “far too much”; the results of nutritional analysis of 24h dietary recall indicated 28% of the participants consuming >6g/day and nearly half of the participants consuming >5g/day. Similar findings were reported by a cross-sectional study conducted by Bhattacharya, Thakur and Singh, 2018 suggesting that majority of the participants (75%) perceived that they are taking right amount of salt even though the study participants were not aware of the recommended amounts. A descriptive cross-sectional survey led in healthy adults also stated that an overwhelming number of participants (82%) believed that their level of salt consumption was appropriate. Another international study that recruited participants across eight countries reported similar results, that most of the respondents perceived their salt intake as ‘satisfactory’ although their actual intake was above the recommendations (Newson et al., 2013).

3.5.9 KAP score and dietary salt intake: The difference in the KAP score between the two-participant group (consuming ≥6g/day and <6g/day) was not statistically significant. It is important to keep in mind the limitation of a single 24h dietary recall in estimating usual dietary salt intake. The urinary sodium excretion method is considered gold standard for assessing dietary sodium intake. However, the use of multiple urine sodium excretion assay with the study group was beyond the scope and resources of this study. The key objective of this study is to assess KAP and determine the dietary sources of salt in diabetics, for the development of an educational tool to monitor salt intake. Though, 24h diet recall tends to underestimate intake, a high-quality 24h diet recall improves accuracy, and may be used if 24h urine sodium excretion method is not feasible (McLean et al., 2019). Also, no substantial and significant difference in KAP score across the demographic as well as health parameters as glycaemic control and blood pressure was observed in this group.

Study limitation and strengths: This study has a limitation due to small and homogeneous sample of participants recruited from Diabetic foot clinic service. Although, this study findings reported useful data on dietary practices and nutrition intake of this vulnerable group. Notably, this is the first study identifying the barriers faced by Type 2 diabetes group in adherence to dietary salt intake irrespective of multiple interfaces with health professional/(s), this group might have had, in view of length of diabetes and management of foot complication.

3.6 Conclusion

The findings of our study indicate low level of awareness related to dietary salt amongst the hypertensive diabetes participants and describes the specific barriers in adherence to the recommended salt level in this group. The knowledge regarding the role of salt in health and its association with high blood pressure is optimum in this group. Understanding of quantitative aspect as recommended daily salt intake and food sources of salt is poor amongst the study group. Although understanding of salt content on FOP label is good, it did not translate in to practice of reading nutrition label. Unlike the trends in UK general population, consumption of home cooked food is popular. However, the frequent use of discretionary salt in cooking, at table and choice of the ingredients bought without reading label, might negate the benefits of nutritious meals that can be cooked at home. The participants reported poor attitudes for requesting for low or no salt meals in restaurant and considered avoiding dining out as a measure to reduce their salt intake. This finding calls for public health action, for the restaurants business to take responsibility to provide appropriate nutrition information in their menu and accommodate low salt dietary requirements in an open and convenient manner. The most common barriers such as poor self-perception of salt intake owing to lack of knowledge of high salt foods, non- practice of label reading and practice of using salt in home cooked meals needs to be managed for this group. The measures to overcome these barriers could be an important aspect for improving the health targets such blood pressure as well as glycaemic control amongst this patient group. There is need for development as well as dissemination of appropriate educational resource on dietary salt reduction in T2DM.

Chapter 4: Development of a novel dietary salt monitor

Overview

Most of the salt in UK's population diet is contributed by processed foods, and there are wider variety of food additives other than table salt that contributes to the salt content of these food products. Also, the amount of salt in similar product varies across different brands and this makes it difficult to monitor one's salt intake. Amongst varying dietary assessment, food frequency method has an advantage of assessing longer-term nutrient intake and poses less burden on respondent. Previous research studies conducted globally including UK have developed sodium (salt) specific FFQ based on the consumption patterns of general population. This research study had gathered data on the food sources of salt based on the consumption pattern of fifty participants with type 2 diabetes participants using 24hr dietary recall method. The food items high in salt were identified based on nutrient threshold of ≥1.5g/100g and pivot table method was used to determine the top contributors of salt. These food items were further categorised to make twenty broad categories and assigned salt content per portion, for finalizing a short salt specific FFQ namely 'Dietary Salt Monitor'.

4.1 Introduction

4.1.1 Historical context to use of salt in food

It is believed that the relatively high salt usage of virtually all societies today became common beginning between 5,000–10,000 years ago (He and MacGregor, 2007; MacGregor, 1998). Seemingly, food preservation was the reason for excessive salt use for years (Multhauf, 1978; MacGregor and De Wardener 1999) and this probably was the origin of current practice of high salt consumption. Although it is tough to know how much salt was consumed by humans prior to recent times, the estimates have been made based on historical records. In an estimate of early usage, the average daily sodium intake in certain parts of China in 300 B.C. was reported to be nearly 3,000 mg/d for women and 5,000 mg/d for men (Adshead,1992), in France and Britain in 1850, the human culinary intake of sodium was estimated to be 4,000–5,000 mg/d

(Multhauf 1978). These numbers, if reliable, are within the range of the amounts consumed in many societies today (Intersalt Cooperative Research Group, 1988). Thus, high salt intake by humans does not have its origins in twentieth-century food processing, but instead likely reflects food processing needs, especially preservation of food, that originated thousands of years ago. Humans generally consume far more salt than is necessary and continue to enjoy salty foods even when physiological needs are met.

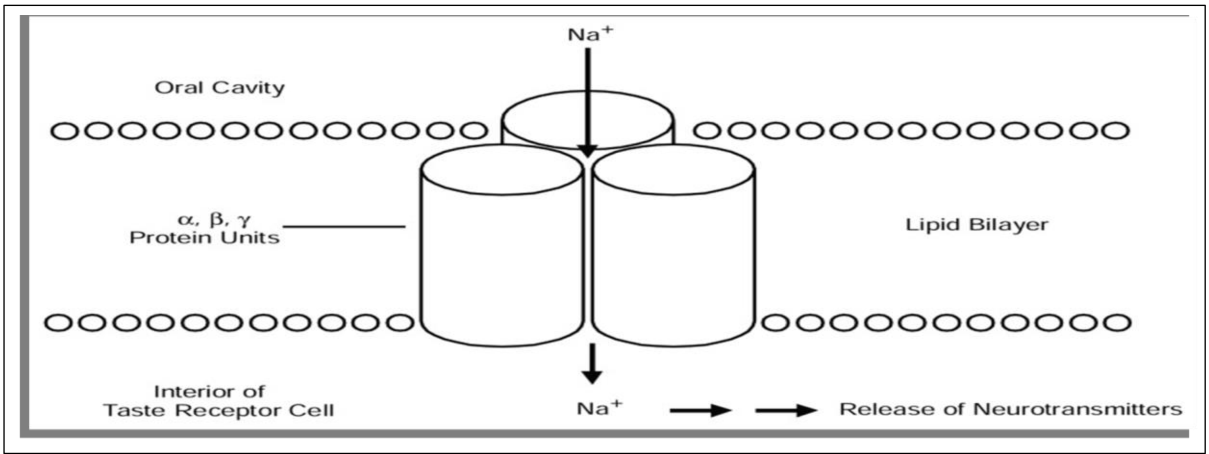
Thus, it appears that salt preference rather than a true physiological need drives salt intake in human populations (Geerling and Loewy 2008; Morris et al., 2008).

Salt also had an important mention in history as 1930's 'Salt Satyagrah' or 'Dandi March' that had been quintessential in India's independence movement. Gandhi organised this movement chiefly to defy the monopoly on salt imposed by the British Raj, and by collecting naturally occurring salt from the seashore (Sellars and Oltvai, 2016).

4.1.2 Evolutionary perspective of salty taste

Human taste abilities have been shaped, in large part, by the ecological niches our evolutionary ancestors occupied and by the nutrients they sought (Breslin, 2013). Man's innate appetite for salt may be related to his evolution of food habits, as omnivorous ate lots of small live animals – insects, rodents and fish or shell fish on coast and scavenged. It is notable that those people who lived mainly on protein and milk or who drank salty water did not generally salt their food, whereas those who lived mainly on vegetables, rice and cereals used much more salt (Denton, 1982). Taste-stimuli are typically released when food is chewed, dissolved into saliva, and pre-digested by oral enzymes (Pedersen, 2002). Humans perceive nutrients and toxins qualitatively as sweet, salty, sour, savoury, and bitter tasting (Breslin, 2013). Simple carbohydrates are experienced as sweet, the amino acids and selected ribonucleic acids are experienced as savoury, sodium salts are experienced as salty, acids are experienced as sour, and many toxic compounds as bitter. The sense of taste is stimulated when nutrients or other chemical compounds activate specialized receptor cells within the oral cavity. For salty stimuli there is growing evidence that the epithelial sodium channel (ENaC), in part, transduces salty taste (figure 4.1). This channel is thought to form a tunnel through the taste receptor cell that allows Na^+ ions outside the cell to move inside the cell. Once sodium is inside the taste receptor cell it causes a cascade of biochemical reactions that result in the release of neurotransmitters that signal salt taste to the brain (Henney et al., 2010). The evolved taste abilities of humans are still useful for those living in parts of world with very low food security. But in a developed world where there is abundance of energy-dense foods, our sensitivities for sugary, salty, and fatty foods have led to increase in prevalence of nutrition-related diseases such as obesity, hypertension, and diabetes.

Figure 4.1 An epithelial sodium channel (ENaC)



4.1.3 Types of dietary salt and its uses

The common sources of salt for consumers can be classified into refined salt, less processed salts as sea salt. The less processed salts usually do not contain additives and the main distinction is texture, grain size and flavour (Drake and Drake, 2011). Salt contains only trace amounts of minerals and the mineral content of different salt used in food is stated in table 4.1.

Table 4.1: Mineral content of different type of salts

Categories	**Calcium**	**Potassium**	**Magnesium**	**Iron**	**Sodium**
Table salt	0.03%	0.09%	<0.01%	<0.01%	39.1%
Maldon salt	0.16%	0.08%	0.05%	<0.01%	38.3%
Himalayan salt	0.16%	0.28%	0.1%	0.0004%	36.8%
Celtic salt	0.17%	0.16%	0.3%	0.014%	33.8%

4.1.4Uses of salt and sodium-based additives in food processing

Salt is one of the most widely used additives in food industry, as a flavour and palatability enhancer, and for food safety as an effective agent for preservation (Albarracin et al., 2011). Since sodium plays different roles in specific food types, it is relevant to review the functions of sodium in the context of food categories (Henney et al., 2010) and is summarized in table 4.2. The sodium salts of organic acids, sodium nitrite, and sodium phosphate compounds (see table 4.3) are added to foods to prevent microbial growth and improve texture, thus product reformulation as part of sodium reduction strategies, must also consider these sources of added sodium (Doyle and Glass, 2010; Reig et al., 2012).

Table 4.2: Functions of sodium in different food categories

Food Categories	**Function of sodium/ sodium-based additives**
Grains	
Ready to eat cereals	Improve flavour and texture
Bread & Baked Goods	Sodium bicarbonate and sodium salts of leavening acids to improve texture and flavour, control fermentation and yeast activity. Sodium metabisulfite as dough softening agent.
Meats	
Processed Meats	Salt, sodium nitrite, and the reductants as sodium ascorbate and sodium erythorbate are commonly used in processed meats to impart flavour, texture, and characteristic pink colour; improve tenderness and for preservation.
Dairy products	
Cheese	Salt by brine solution or dry rub: to remove additional water by osmosis to reach desired moisture levels and alters the texture. Cheese with lower salt content is softer and vice-versa. Sodium phosphates and sodium citrates, as emulsifying agents are important to the final texture of cheese products.
Butter	Flavour and taste development
Other dairy products (ice-cream, pudding & yogurt)	Additives as sodium alginate and carrageenan (both thickening agents).
Fruits, Vegetables, Beans and Legumes	
Sauces, Gravies, Stocks, Salad Dressings, and Condiments	Reasons for sodium use include flavour, preservation, and improving the stability of emulsions. Salt is added to soy sauce to control fermentation process.
Canned fruits, vegetables, beans, and legumes	A salt brine is generally used to enhance consistency and flavour.
Pickled vegetables	For the fermentation process and maintain a crisp texture.
Mixed dishes	
Pizza	As leavening agent and for dough stickiness.
Soup	As flavour enhancer.

Frozen meals	To prevent or mask warmed up flavours.
Savoury snacks	
Crisps, Nuts, Pretzels, Chips, Popcorns, and extruded products	Salt is added primarily to impart flavour and to some extent modify texture and colour.

Table 4.3: Amount of sodium contributed by some common sodium-containing additives, (Source: Henney et al., 2010)

Sodium compound	Typical use	% Sodium in compound	mg of Na/100 g food
Chloride	1.5% to 2%	39.34%	590- 790
Benzoate	0.1%	15.95%	16
Diacetate	0.1% to 0.4%	16.18%	16- 65
Lactate	1.5% to 3%	20.51%	310- 620
Propionate	0.3%	23.93%	70
Sorbate	0.3%	17.14%	50
Nitrite	0.012%	33.32%	4
Acid pyrophosphate (SAPP)	0.35%	20.72%	100
Tripolyphosphate (STPP)	0.35%	31.24%	160
Pyrophosphate (TSPP)	0.35%	34.57%	170
Hexametaphosphate (SHMP)	0.35%	22.55%	110

4.1.5 Dietary sources of salt in foods: global perspective

In a typical western diet, only 10% to 12% of dietary sodium occurs naturally in foods and the major contributors of dietary salt intake are processed foods and foods eaten out of home (Hasenegger, 2018). The term "processed foods" includes all foods that have undergone manufacturing methods and not only convenience foods but also products like bread, cheese, and meat products (Monteiro et al., 2019). The consumers are not aware of how much salt is added at the stage of manufacturing and this contributes the most to their salt intake level (James et al., 1987). In non-industrialised countries, the main contributors of daily salt intake (up to 75%) are salt added during preparation, at the table at home, or in condiments (e.g., soy sauce, fish sauce) used for the seasoning of foods in countries such as China (Brown et al., 2009). A systematic review of the sources of sodium included 80 studies conducted in 34 countries between 1975 and 2018.

There is marked variation in discretionary salt use around the world that is highly correlated with the level of economic development. Populations in Brazil, China, Costa Rica, Guatemala, India, Japan, Mozambique, and Romania received more than half of their daily salt intake from discretionary sources. Bread products, cereal and grains, meat products, and dairy products were the major contributors to dietary salt intake in most populations (Bhat et al., 2020). According to data from the National Diet and Nutrition Survey, most of the salt in the diet of UK population comes from salt added to foods in the production processes. The discretionary use of salt as added to foods by individuals during cooking or at table contributes approximately 15-20% to dietary salt intake (Wyness, Butriss and Stanner, 2012 and He, Brinsden and MacGregor, 2014).

4.1.6 Assessing dietary salt intake at population level

Consumer education and knowledge empowerment for identification of food sources of salt, needs to be part of comprehensive approach for salt reduction strategies (He, Brinsden and Macgregor, 2014; Bhana, Utter and Eyles, 2018) and more importantly for at risk population as type 2 diabetics with or without hypertension. The results of KAP study (see chapter 3) indicated poor level of knowledge related to daily salt limit as wells as food sources of salt (Babber and Bhakta, 2020) and were consistent with other research studies (Gee et al., 2013; Gray et al., 2014). Healthcare professional's (HCP) advice to reduce salt is associated with patients taking action to reduce their salt intake. HCP should emphasize product selection with their patients as a primary means to reduce dietary sodium (Jackson et al., 2018).

The methods for accurately estimating salt intake as 24h urinary sodium excretion is expensive, have high burden rate and in-appropriate for public health interventions aiming at nutrition education (Tangney et al., 2016; Santos et al., 2019). Self-reported measures such as 24h recall, food record, weighed diet records are usually complex, time-consuming and requires a trained healthcare-personnel for the assessment and potentially more useful in research settings (Hawkes and Webster, 2012; McLean et al., 2017). Food frequency questionnaires are widely used for determining dietary salt intake over an extended period (Cade et al., 2004; McLean et al., 2017). However, when a single nutrient or food group is of interest, short FFQs may be enough to assess the intake (Lillegaard, Overby and Andersen, 2012). Although a short FFQ may underestimate the true variation in dietary intake, but a very long and detailed one can be time and resource consuming and the burden on the responder may jeopardize data quality (Naska, Lagiou and Lagiou, 2017).

There are only limited number of short food frequency questionnaire available for estimating salt intake, all of them are developed for non-diabetic population (see chapter 5). Arcand et al., 2014; Cooper et al., 2020 and Gallani et al., 2020 has developed short FFQ to estimate salt intake for Canadian population. Other published studies described a 26- item sodium screener developed for US population (Norris, Block and Block, 2012); a short food frequency questionnaire based on 42 categories to assess habitual dietary salt intake in South Africans (Charlton et al., 2008) and a short dietary questionnaire on salt use and salt preferences of individuals in Finland (Pietinen, Tanskanen and Tuomilehto, 1982). The research study conducted by Day et al. (2001) mentioned the use of detailed 130 item FFQ that was modified version of the one used in US Nurses Health Study, with a food list that was adapted to include foods that were commonly consumed in UK. Other two UK based salt monitors Derby Salt Questionnaire and 'Royal Free Salt Questionnaire' are both validated for use with CKD cohorts (Amalia & Davenport, 2019). Based on literature review, there is no salt specific FFQ developed for estimation of salt intake in type 2 diabetics in UK. Thus, an easy-to-use dietary assessment tool that is designed for this group for improving awareness on top sources of salt in their diet and to monitor improvements in dietary salt intake is needed. Thus, the aim of proposed study is to develop a dietary salt monitor for estimation of dietary salt intake. This shall be very useful to overcome barriers in knowledge as well as practices related to adherence to dietary salt intake recommendations in participants with T2DM who can benefit highly from reducing salt intake.

4.2 Research aim and objectives

Aim**:** To develop a novel dietary salt monitor as an educational tool and monitoring dietary salt intake in type 2 diabetic patients.

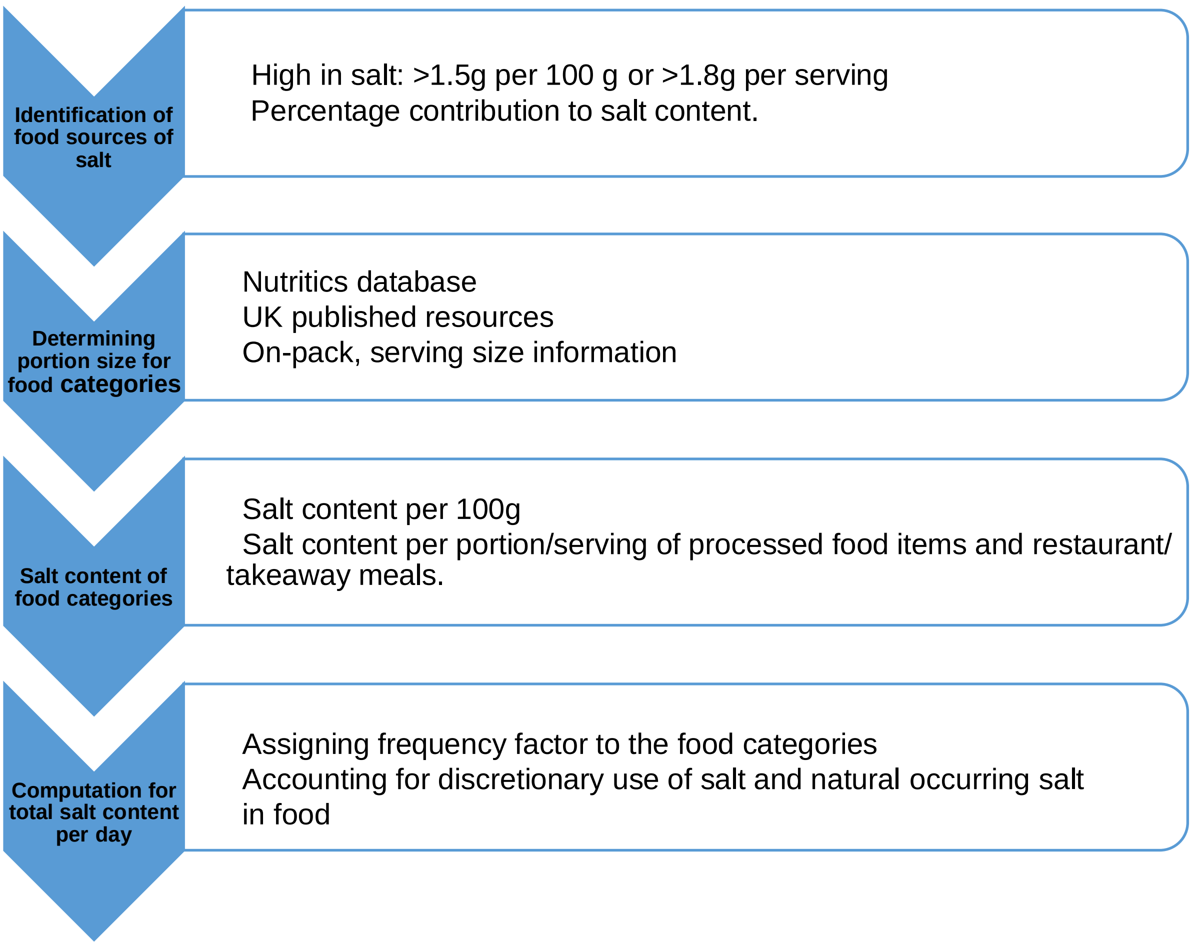
Objectives

- To develop a short food frequency questionnaire consisting of standardized list of food categories representing sources of salt in diet of participants with type 2 diabetes.
- To develop a database assigning portion weight and salt content for the food categories, for dietary salt monitor.

4.3 Methodology

The figure 4.2 explains the step-by-step process involved in the development of a novel UK salt monitor for use as nutrition education tool for type 2 diabetics.

Figure 4.2: Steps for development of dietary salt monitor



4.3.1 Identification of food sources of salt in the diet of type 2 diabetes participants

For determining the food sources of salt in the diet of type 2 diabetes participants, two approaches were chosen, inclusion of high salt foods and top contributors of salt. Willett, 1998 described these two approaches as common procedure for selecting food items for Food Frequency Questionnaire. Thus, a simple procedure identifies food items with a high nutrient content from published food composition tables. The second procedure uses open-ended food intake data from a population, such as those obtained by food record or 24h recall. Food items are selected based on their percentage contribution to nutrient intake in a population (Block et al., 1986).

An in-depth dietary intake data based on 24h dietary recall was obtained from hypertensive and type 2 diabetes patients (see Chapter 3). Nutritics software generated detailed nutrition analysis report, that included recipes, ingredients, and their nutritional content including sodium. Each participant's detailed dietary report was reviewed to identify foods that are 'high in salt', as per nutrient threshold (i.e. >1.5g/100g or >1.8g per serving) defined by Department of Health (Skotarenko, 2018). Since the report stated sodium content, these values were converted to salt by multiplying it with 2.5. The salt content specified in the report generated by Nutritics, was based on the actual portions consumed by the participants. Thus, the salt content per 100g of food item/(s) was computed via unitary method. The recipes that were entered from Nutritics database did not have list of ingredients, therefore salt content per serving was checked if the weight of the recipe was more than 100g. In view of industry's product reformulation strategy to gradually lower salt content, certain food categories have shifted from red (>1.5g/100g) to amber (>0.3g to ≤1.5g/100g). The food items that were on upper limit of amber threshold i.e., between 1.4-1.5g per 100g or 1.5-1.8g per serving of food item/ recipe were reviewed as well. The brand of crisps popularly consumed by the participants, did not appear as high salt threshold but were towards upper limit of amber threshold, for example: Walkers Marmite Crisp (1.4g per 100g), Walkers ready salted (1.4g per 100g), Walkers Prawn Cocktail (1.3g per 100g), Walkers Cheese and Onion (1.2g per 100g).

4.3.2 Top ten contributors of dietary salt: Pivot tables were used to determine the top contributors of salt in the diet of hypertensive type 2 diabetes participants. Pivot tables are one of Microsoft Excel's tabulation function that permit users to summarise and cross-tabulate data, create tables in several dimensions, offer a range of summary statistics (Grech, 2018). Pivot tables have been mentioned as statistical tool in many nutrition and food related research (Hare, Kirk and Lang, 2001; Eyles et al., 2013; Geci et al., 2020). Nutritics detailed dietary intake report was further analysed using Microsoft excel 2011 function for pivot tables and charts, to ascertain the percentage contribution of different food categories to total day's salt intake. The food description of each food category was further studied, to review food items and determine if the food categories are representing the food items correctly. The food categories were based on the auto-configuration of Nutritics software, and thus correction in the name of food category were made, for example ham, pork haslet, pork sausages were all under bacon category; chicken based ready meals appeared under poultry dishes were re-categorized into ready meal category. Some of the food items from Brand B data appeared blank under the column-food category, were re-categorized and the final Pivot table were generated. The top fifteen food categories enlisted by Public Health England, for salt reduction targets 2017 were referred, to finalise the food categories for inclusion in our research's dietary salt monitor.

4.3.3 Definitions

4.3.3a Portion size and serving size: The amount eaten on any one occasion (i.e., first plus subsequent serving) whereas serving refers to the amount of food served in a single helping (Nelson,1998). Almoin-Roig (2018) defined 'portion' as the amount a person eats on one occasion and 'serving' as the suggested amount to be eaten on one occasion. Faulkner et al. (2012) conducted a review study, on the effectiveness of serving size guidance and indicated the use of definitions of portion size (PS) and serving size (SS) based on those cited in the UK by Institute of Grocery Distribution, 2008. PS is the amount of food intended to be consumed by an individual in a single eating occasion and SS is the quantity recommended to be consumed in a single eating occasion.

However, meaning of portion/serving size varies depending on its applications such as actual portion consumed and reported in dietary survey, recommended portion, serving size for dietary advice by HCP, serving recommendation by industry and analysing dietary intakes (Lewis, Ahern and Jebb, 2012). In UK, there is an absence of national serving size (SS) guidance which has led to public confusion (Faulkner et al., 2016). However, while the UK Eatwell Guide includes portion size information for fruit and vegetables, fruit juice, fish and some information on the amounts of red and processed meat to consume, it does not include information on portion or serving sizes for foods from all the groups included in the guidance, and this is a potential 'missing link' in translating the proportions of the food groups shown in the guide into practice (Benelam and Wiseman, 2019). It is imperative that universally agreed definitions of both PS and SS are established and communicated effectively to the consumer. For this research's dietary salt monitor, portion or serving is used interchangeably in view of lack of universal definition for portion size/ serving size.

4.3.3b Portion Size Estimation Element (PSEE) is defined as a component of the dietary instrument designed to help quantify the amount of food reported as consumed, including portion size estimation aids (PSEAs) (e.g., photos, everyday reference objects, household utensils, food models), categorical size estimates, household utensil measures, unit food amounts (e.g. 1 slice, 1 egg), standard units of measurement (grams, ounces, millilitres), and any other quantifying component (Almiron-Roig et al., 2017).

4.3.4 Published resources on portion size guidance

4.3.4a Food Standard Agency, FSA (2002) - Food portion sizes UK, 3rd edition: This publication is the basis of UK government recommendation for portion sizes and has been used for estimating intake in National Diet and Nutrition Survey (NDNS). The portion sizes here are based on average portion data for generic foods as derived from the 1986/7- Dietary and Nutritional Survey of British Adults (Gregory et al., 1990). The brand level information was obtained directly from food manufacturers and might have changed over the time.

4.3.4b British Nutrition Foundation (Benelam and Wiseman, 2019): British Nutrition Foundation's (BNF) guide on portion size information 'Get portion wise' includes suggested portion sizes for healthy adults for a range of food and drinks from each of the main food groups of 'Eatwell guide'. For the development of this resource, portion size estimates were derived based on review of UK data from the NDNS (Public Health England, 2018a) and its comparison with information on portion sizes from major retailers. A series of 7-day test diets was developed to investigate how portion sizes of different foods could fit into a diet. The results of modelling the effects of following this advice in different ways on energy intakes, indicated that the energy values calculated at extremes for portion size and frequency of intake, were within estimated average requirements for adults. A series of focus groups were conducted to finalize the portion size information and its presentation as a practical and user-friendly resource.

4.3.4c EPIC-Food Frequency Questionnaire**:** This questionnaire is a modified version of the FFQ in the US Nurse's Health Study (Willet et al., 1985; 1988) with a food list that was adapted to include foods that were commonly consumed within the UK. The food list was compiled from national dietary intake data and was based on 130 main food items. For each food item, participants were asked to indicate their usual consumption from nine frequency categories, ranging from never or <1/month to ≥6 times per day. The FFQ did not include specific questions on portion size but rather specified medium servings, defined by natural or household units. Various software including Data into Nutrients for Epidemiological Research, DINER (Welch et al., 2001); Compositional Analyses from Frequency Estimates, CAFE (Welch et al., 2005) and FFQ EPIC Tool for Analysis, FETA (Mulligan et al., 2014) are used for analysing the dietary data from the food frequency questionnaire used by the EPIC-Norfolk and automatically generates a spreadsheet containing energy, nutrient and food group intakes. A booklet developed by Lanigan, 2013 also describes the average weight of standard portion sizes used in EPIC-FFQ.

4.3.4d Food-based dietary guidance (FBDG), from countries such as Ireland, US and Australia, includes comprehensive advice on portion sizes for each of the main food groups. However, UK Eatwell Guide includes portion size information for fruit and vegetables, fruit juice, fish, and some information on the amounts of red and processed meat to consume, it does not include information on portion or serving sizes for foods from all the groups included in the guidance, and this is a potential 'missing link' in translating the proportions of the food groups shown in the guide into practice.

4.3.4e Various UK Schemes: A review study conducted by Lewis, Ahern and Jebb (2012) collated and compared suggested portion sizes from selected UK schemes intended both for general advice and weight-loss advice. Included schemes were from the food industry, non-governmental organisations, and health-care professionals such as Confederation of the Food and Drink Industries of the EU, CIAA; Diabetes UK; Dietetic Association; Dietitians in Obesity Management UK, DOM UK and World Cancer Research Fund, WCRF. As many schemes mentioned in the Institute of Grocery Distribution (Institute of Grocery Distribution, 2008) report were not obtainable or applicable, the British Dietetic Association (BDA) and British Heart Foundation (BHF) schemes were also included.

4.3.4f Irish food portion sizes database: The information on Irish food portion sizes is published in a report available online at http://www.iuna.net (Lyons, 2013). The data for this resource was derived from three large, cross-sectional food consumption surveys as National Children's Food Survey, NCFS (2003–2004), National Teens'

Food Survey; NTFS (2005–2006) and National Adult Nutrition Survey; NANS (2008–2010). Median, 25th and 75th percentile portion weights are described for a total of 545 items across the three survey groups, split by age group or sex as appropriate. For all groups, food portion size was defined as the weight of food consumed per eating occasion. On all surveys, food intake was quantified, as ‘weighed by participants’, ‘assigned a manufacturer’s weight’, ‘Photographic Food Atlas’ (Foster, et al., 2010; Nelson, Atkinson, and Meyer,1997), ‘Food Portion Sizes’, (FSA,2002) and household measures. For most foods examined, the UK median weights were slightly (5–10 %) smaller than the Irish median weights; however, this may be partly attributable to the fact that the Irish group consisted of adults aged 18–64 years only, while the UK group included ‘elderly adults’, whose reduced energy needs might be expected to reduce the overall median portion weights of the group (Lyons, Walton and Flynn, 2013).

4.3.4g Food4Me research study: The Food4me study was a multicentre, web-based study designed to investigate the potential for standardising portion sizes for specific foods, thereby ensuring complementarity across countries. It compared portion size for 156 food items measured using an online food frequency questionnaire across the seven countries including UK. For each food item of FFQ, the 25th, 50th and 75th percentiles of daily intake were estimated from the 2008–2010 National Adult Nutrition Survey database, and classified as small, medium, and large portion sizes, respectively. The probability of consuming a food and the frequency of consumption differed across countries for 93% and 58% of the foods, respectively. However, the individual country’s mean portion size differed from the average across countries in only 16% of comparisons. Thus, although dietary choices vary markedly across countries, there is much less variation in portion sizes (Kirwan et al., 2016).

4.3.4h Reference amounts customarily consumed (RACC) defines the portion size in the United States. RACCs were established by regulation in 1993 in response to the Nutrition Labelling and Education Act and represent the amount of food customarily consumed per eating occasion (21 CFR 101.12—Reference amounts customarily consumed per eating occasion, 1993). They were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the US Department of Agriculture and updated with data from the National Health and Nutrition Examination Survey, 2003-2004, 2005-2006 and 2007-2008 conducted by the Centres for Diseases Control and Prevention, in the Department of Health and Human Services.

4.3.4i <u>Reference Amounts, Health Canada</u>**:** Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. It published a document that sets out reference amounts for different categories of foods, for food industry and other stakeholders. Reference amounts represent the amount of food typically consumed in one sitting, are used to determine what is a single-serving container, serve as the basis for determining the serving size to be shown in the nutrition facts table of multiple-serving packages of foods and serve as part of the criteria for making nutrient content claims (Health Canada, 2016).

4.3.5 <u>Method for portion size computation for dietary salt monitor</u>
Nutritics database on portion size is collated from various sources as UK publication on food portion sizes by FSA, manufacturer's data and from direct weighing by their trained staff. Demographic servings are based on four national surveys including National Adult Nutrition Survey (NANS) 2008-2010 and defined by age and gender (Lyons, Walton, and Flynn, 2013). Although Nutritics software has a collection of nineteen food databases, GB15 database is used exclusively (2015 COFIDS including McCance and Widdowson 7th edition, 2015) for most of the food categories of dietary salt monitor. However, for categories where GB data was not available Brand B data, that is the foods that are sourced from manufacturers and Nutritics sourced foods was included as well. For any food item, GB 15 data provided average values for the portion as well as nutrient content, based on the number of samples analysed under it. The portion size data used in Nutritics was reviewed and compared with varied other national and international published sources listed above in section. The serving size data available on the UK retailer's website is considered and applied for some of the food categories as ready meals, meat substitutes and salt-based rubs & seasonings. Since the values for portion size of food items under each category is highly variable due to a wide range of food items included, median values for standard portion were calculated. The use of median values for portion size has been cited in various research papers including dietary databases (Wreiden et al., 2008; Lewis, Ahern and Jebb, 2012; Lyons, Walton and Flynn, 2013; Zheng et al., 2016) and for development of dietary assessment tools such as food frequency questionnaires (Gibney et al 2018;

Cooper et al 2020). The PSEA used for the study's dietary salt monitor is described as standard portion such as 1 slice for bread, 1 bag for crisp.

4.3.6 Determination of salt content of food categories for dietary salt monitor

The sodium content per 100g of food items selected under each of the twenty food categories, for the dietary salt monitor was collated from the Nutritics software. It used the 2015 COFIDS including McCance and Widdowson 7th edition, 2015 nutritional composition database. For certain categories as ready meals, salt-based seasonings, meat substitutes not available in food composition database, the manufacturers/ retailer's nutrition information data on back of pack label was available under Brand B data of this software. The nutrient profile report was generated for each food category using the 'batch jobs' function and the report was downloaded as an excel file. The sodium content was converted to salt by multiplying the sodium value to 2.5. and median sodium content and IQR was computed for all the twenty categories. For the dietary salt monitor's working sheet (Appendix K), the salt content per standard portion of each food category was calculated using unitary method. This study's dietary salt monitor also aimed to capture the salt content of meal/ (s) eaten out of home -at restaurants/ take-aways. For this purpose, the researcher reviewed the published literature and referred the salt content of restaurant meals as available in a cross-sectional survey conducted by Theis and Adams, 2019. This survey sourced nutritional information on 9605 menu items from 42 UK restaurant's website. The median values for salt content for categorisation as Appetizers/ starters, main meal and desserts were reported in this survey and further used for analysing the salt content of meal eaten away from home, for dietary salt monitor's working sheet.

4.3.7 Estimation of total daily salt using dietary salt monitor: For calculating salt content for each of the food category, the salt content per standard portion of each food category is multiplied by frequency factor (see table 4.4).

Table 4.4: Frequency Factors

Frequency of consumption	Frequency Factor
Daily	1.0
Weekly	0.14
Monthly	0.03
Never	0.0

4.3.8 Accounting for other sources of salt in dietary salt monitor

The dietary salt contribution from sources as natural sodium in foods and discretionary salt needs to be accounted for estimating overall daily salt intake. For this purpose, the percentage contribution of sodium from these two sources (21% and 18% respectively) as stated in NDNS year 7/8 dataset was considered. The percent contribution for these two sources was then multiplied by the average salt intake for UK adults (8.3g/d and 6.8g/day for men and women respectively), as reported by NDNS urine sodium assessment for UK adults in 2018/19 (Ashford et al., 2020).

All the computations including weight against portion, salt content of categories and factor accounted for discretionary and natural salt in food were entered as formula's in excel sheet for developing dietary salt monitor working sheet for analysing the responses of the participants and is illustrated in Appendix K.

4.4 Results

4.4.1 Food categories shortlisted for SFFQ

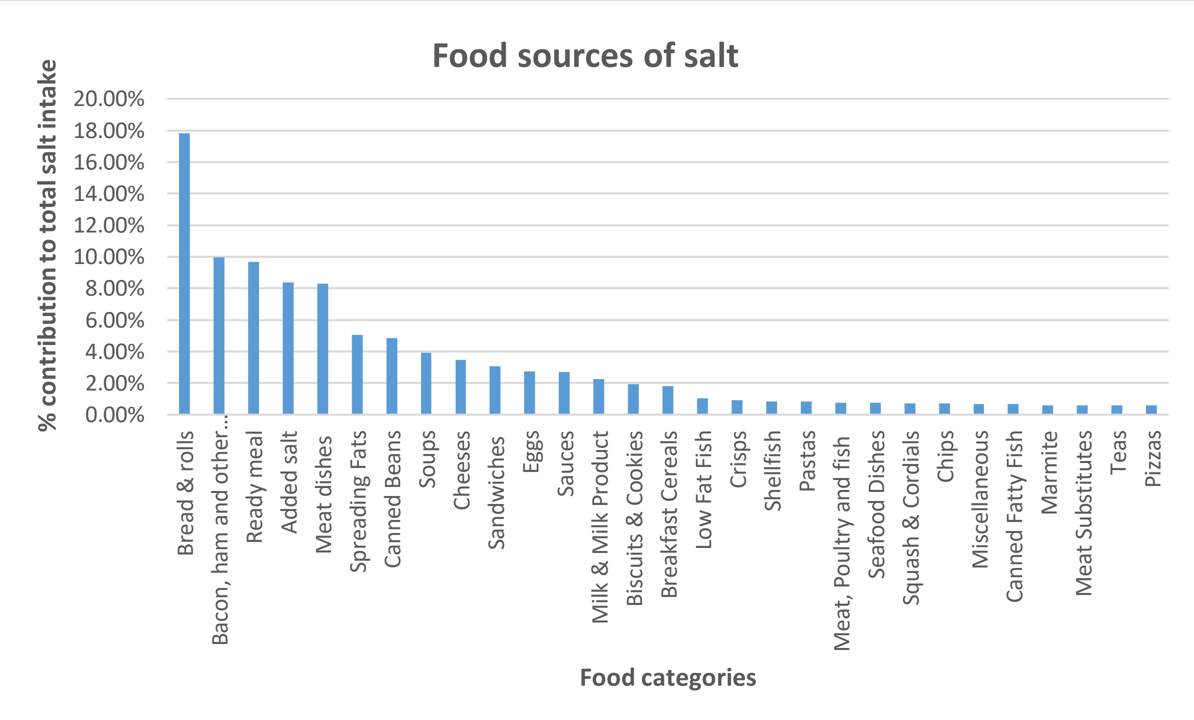
The food items high in salt (>1.5g /100g) as identified from the dietary intake data of hypertensive type 2 diabetes patients are listed in table, alongside data on average portion consumed. The recipes found to be high in salt, based on salt threshold of >1.8g/per portion were ready meals as traditional sausage and mash, chicken and pasta bake, roast beef dinners, chicken tikka curry, Chinese chicken curry and rice and burger meals); meal centres as sausage roll, chicken roll, fish fingers; homemade soups with stock cubes and tinned soups, shop bought sandwiches and home-made sandwiches with high salt fillers like ham, bacon, tuna mayonnaise and table sauces; meat substitutes as Quorn fillets and home prepared meals such as stir fried/ steamed or boiled vegetables with added salt.

Table 4.5: Salt dense food items identified in the diet of hypertensive type 2 diabetes participants

Food items with >1.5g of salt/100g	Average portion (g)
Bacon rashers	43
Ham, sliced luncheon	33
Ham, gammon rashers, grilled	180
Pork sausages	110
Pork Haslet	16
Cheese (Cheddar, stilton, edam)	32
Butter, salted	19
Margarine	13
Marmite, yeast extract	14
Crumpets	78
Tortilla Wraps	80
Tomato ketchup	13
Brown Sauce	23
Colman's Mustard sauce	16
Mayonnaise	10
Salad Cream	29
Crackers	18
Mini Cheddars	50
Boiled duck egg salted	66
Winkles, boiled	110

Top contributors of salt identified using Pivot tables are shown in the figure 4.3.These include bread and rolls (17.8%), processed meats (10%), added salts (8.4%), ready meals (8.4%), meat dishes (8.3%), spreading fats (5%), canned beans (4.8%), soups (3.9%), cheese (3.5%), sandwiches (3.65%), eggs (2.75%), sauces (2.7%), milk & milk products (2.3%), biscuits (1.92%), breakfast cereals (1.79%), low fat fish (1.03%) and crisps (0.9%). The category meat-dishes or eggs were not included as a separate category in SFFQ as the recipes under this category were either home cooked or takeaway and the salt from such recipes was either accounted in discretionary salt or eating out section of SFFQ.

Fig 4.3: Top sources of salt in diet of hypertensive type 2 diabetic participants



The identified high salt food and top contributors were classified into twenty main categories, to finalise the categories under processed food section of SFFQ (see table). Most of the top 15 contributors of salt as per year 7 and 8 dataset for NDNS except sweet biscuits, breakfast cereals and stock were common to the finalised food categories of research's SFFQ. Sweet biscuits were not evident in dietary intake pattern of the study participant's dataset, probably due to their diabetes status. Also, sugar was regarded as most important nutrient to watch, on nutrition label by research participants as per the KAP study findings (detailed in chapter 3). Breakfast cereals contributed only 0.9% of total dietary salt intake amongst our study participants and this category met PHE's 2017 salt target (average salt content of products analysed was 0.44g against average target of 0.55 g/100g of product (Public Health England, 2018b). Also, the review of choice of the breakfast cereals amongst the study participants indicated uptake of healthier cereals such Weetabix, Oat-a-bix, shredded wheat, porridge more common amongst the participants. Other additional categories such as meat substitutes were included in view of increasing popularity of vegan and flexitarian food habits in UK (Mintel, 2020). Salt based rubs and/ seasoning was also included as it was identified as salt dense in dietary intake data of the research participants and keeping in view increased home-cooking experienced by many as positive changes to household food behaviours as reported by FSA's COVID-19 consumer research (Ipsos Mori and Food Standard Agency, 2022).

Table 4.6: Final food categories of SFFQ and rationale for the selection

Food Category	**Based on dietary intake data of diabetic participants***		**NDNS 2014/15-2015/16 Rank based on top 15 salt contributing categories**	**Achievement status of PHE's 2017 salt targets**
	High in salt, as per salt threshold	**Top contributors of salt intake**		
Bacon	Yes	Yes	2	No
Ham	Yes	Yes	7	No
Sausages	Yes	Yes	9	No
Cheese	Yes	Yes	4	Yes
Salted butter and buttery spreads	Yes	Yes	8	Yes
Marmite	Yes			
Bread and rolls		Yes	1	
Breakfast items	Yes			
Baked beans in tomato sauce	Yes	Yes	10	
Soups	Yes	Yes	6	
Ready meals	Yes	Yes	3	
Pizza	Yes		5	Yes
Bought sandwiches	Yes			
Pasta Sauces	Yes		14	Yes
Table sauces	Yes	Yes		
Crisps			13	Yes
Salted nuts				
Savoury biscuits/ crackers	Yes	Yes		
Meat substitutes				
Salt based rubs/seasonings.	Yes			

Abbreviations: NDNS, National Diet and Nutrition Survey; PHE, Public Health England, *24h dietary recall data collected for hypertensive type 2 diabetic patients enrolled from Basildon Hospital, n=50 (see Chapter 3)

4.4.2 Computation for serving size and salt content of the food categories for SFFQ

The median values for a standard serving of each food category and corresponding salt content is compiled in table 4.7

Table 4.7: Standard serving size and corresponding salt content of food categories of SFFQ

S. No.	Food categories	Standard serving (g)*	Salt content (g) per 100g of food item*	Salt content per standard serving (g)
1	Bacon	65 (17)	2.8 (0.4)	1.8
2	Ham	20 (6)	2.6 (3)	0.5
3	Sausages	64 (31)	1.8 (0.9)	1.2
4	Cheese	30 (0)	1.7 (0.5)	0.5
5	Salted butter and buttery spreads	10 (1.3)	1.6 (0.6)	0.2
6	Marmite	9 (0)	10.8 (0)	1.0
7	Bread and rolls	39 (22)	1 (0.7)	0.4
8	Breakfast items	68 (22)	1 (0.7)	0.7
9	Baked beans in tomato sauce	205 (0)	0.7 (0)	1.4
10	Soups	220 (0)	0.7 (0.6)	1.5
11	Ready meals	350 (225)	0.6 (0.3)	2.1
12	Pizza	300 (21)	1 (0)	3.0
13	Bought sandwiches	173 (19)	0.9 (0.4)	1.6
14	Pasta Sauces	114 (39)	0.8 (0.2)	0.9
15	Table sauces	15 (5)	1.9 (2)	0.3
16	Crisps	35 (6.2)	1.7 (0.4)	0.6
17	Salted nuts*	30 (15.2)	1.1 (0.4)	0.3
18	Savoury biscuits/ crackers	8.5 (4.2)	1.1 (0.5)	0.1
19	Meat substitutes	85 (50)	1.2 (0.5)	1.0
20	Salt based rubs/seasonings.	7.4 (5.7)	18 (17.3)	1.3

Values presented as median (IQR)

The serving size and salt content for each food category is discussed as follows:

Bacon: The median values for a unit of bacon is 32.5g (IQR 8.8) and a standard serving is considered as 2 rashers, based on review of serving suggestions for bacon rashers by majority of UK supermarkets (see table). The median value computed for standard portion of a bacon is based on four sub-types of raw, bacon rashers in the Nutritics database. The median salt value computed for 100g of four bacon sub-types based on GB15 Nutritics database is 2.8g (IQR 0.4). The salt density of streaky bacon is highest (3.2g/100g) and the bacon back, fat trimmed has lowest salt density (2.5g/100g).

Table 4.8a: Computation for standard unit for a bacon rasher

Nutritics database code	**Cuts of bacon**	**No. of product samples in sub-categories**	**Average weight in grams (g) per unit**
GB15/62740	Bacon rashers, back raw	10	35
GB15/62750	Bacon rashers, streaky raw	10	20
GB15/62747	Bacon rashers, middle raw	9	40
GB/62736	Bacon rasher, back fat trimmed, raw	24	30
Median (IQR)			**32.5 (8.8)**

Table 4.8b: On-pack serving size recommendation for Bacon by UK supermarket's own brand.

UK Retailer Brand	**Serving size suggestion**
Asda Butcher's Selection 12 Unsmoked Back Bacon Rashers	2 rashers
Tesco Finest Unsmoked Wiltshire Cured Bacon 240G	2 rashers
Morrisons Smoked British Back Bacon Rashers 250g	1 rasher
Sainsbury's Unsmoked British Back Bacon Rashers x8 250g	2 rashers
ALDI Bacon rashers	-NA-
Essential Smoked British Bacon 10 Rashers 300g	2 slices
M&S British 6 Unsmoked Bacon Rashers Made Without Nitrites 200g	2 rashers
Co-op British Smoked Rindless Back Bacon 8 Rashers	2 rashers

Ham: The median portion of a unit, one slice of ham weigh as 20g (IQR 6) (see table). There is great variability in serving size recommendation across different varieties and brands of ham and due to lack of portion size guidance from any latest UK schemes; one slice is considered as standard portion as stated in MAFF handbook (FSA, 2002). The median value for salt content of varying varieties of ham was 2.6g/ 100g (IQR 3.0). The salt density of prosciutto and parma was highest (5g/100g of ham) and lowest for luncheon/ denny slices (2g/100g).

Table 4.9a: Computation for standard portion size for Ham

Nutritics food code	Varieties of Ham	No. of product samples in sub-categories	Average weight in grams (g) per standard unit
GB15/63956	Ham sliced/luncheon	10	20
GB/65723	Ham premium	10	20
N/8728	Ham Denny slices	1	20
N/6843	Ham Prosciutto	1	14
GB15/65722	Ham Parma	1	14
Median (IQR)			**20 (6)**

Table 4.9b: On pack serving size suggestion for ham by UK retailers

UK Retailer Brand	Serving size suggestion
ASDA Cooked Ham Slices,125g	One serving =¼ pack (31g)
TESCO British Pork Cooked Ham, 125g	6 servings per pack One serving= 1 slice
Morrison's Savers Cooked Ham, 400g	32 servings per pack One serving = 1 slice
Sainsbury's British Cooked Ham, 240g	14 slices per pack One serving = 2 slice
ALDI British Pork Cooked Ham, 115g	10 slices per pack One serving = 1 slice
Essential Waitrose British Roast Ham slices, 80g	7 slices per pack One serving = 1 slice
M&S British Sliced Ham, 300g	20 slices per pack 2 slices per serving
Co-op Irresistible Outdoor bred Wiltshire Cooked Ham, 120g	5 slices per pack One serving = 1 slice

Sausages: The median value for a unit of sausage, based on ten categories of raw and heat processed sausages is 32g (see table 4.10). For standard portion size estimation for this research study's SFFQ one serving is considered as 2 sausages weighing 64g.The median salt content for the sausage's varieties is 1.8g/100g (IQR 0.9). The salt content of different type of sausages varied; knackwurst sausage was highest in salt density(3g/100g) followed by both kabana sausage and pork plus beef sausage with 2.2g salt/100g and mortadella with 2.1g of salt per 100g and beef sausage had least salt density of 1.0g/100g.

Table 4.10: Computation for median weight for a unit of sausage

Nutritics food code	Varieties of Sausages	No. of product samples in sub-categories	Average weight in grams (g) per standard unit
GB15/65865	Sausage, Knackwurst	1	40
GB15/65870	Sausages, turkey, raw		32
GB15/65164	Sausages, beef, raw	6	32
GB15/65169	Sausages, pork, raw	1	57
GB15/65866	Sausage, Mortadella	1	20
GB15/65744	Kabana	1	30
GB15/65172	Sausages, pork, reduced fat, raw	7	32
GB15/65868	Sausages, pork, and beef, frozen, raw	10	57
GB15/64227	Liver sausage	10	32
GB15/65175	Sausages, premium raw	10	50
Median			32 (15.5)

Cheese: The computation for standard portion size of cheese included thirty types of cheese, from Nutritics GB food database, and the median value was 30g (IQR 10). The median values for different varieties of cheddar and cheddar types (see table 4.11) indicated same portion as calculated for thirty varieties. The serving size recommendation for UK supermarket cheese as ASDA, TESCO, Sainsbury, Morrison, ALDI and Waitrose also indicated consistent recommendation of 30g as one serving. The median salt content for cheese categories included for research's SFFQ Is 1.7g/100g (IQR 0.5). The salt content of cheese varies considerably across the varieties with Roquefort cheese (4.2g/100g) and halloumi cheese (3.0g/100g) with higher salt density than others.

Table 4.11: Computation for standard portion size of cheese

Nutritics food code	Types of cheese	No. of samples in sub-categories	Average weight in grams (g) per standard unit
63263	Cheese, Cheddar, English	20	30
63261	Cheese, Cheddar type, 30% less fat	3	30
63262	Cheese, Cheddar type, 50% less fat	16	30
	Median		**30**

Butter and spreads**:** The search results for 'butter' and 'spreads' in Nutritics food database provided six sub-categories and the median value for weight in grams for standard portion of each of the sub-category was 9.8g (IQR 1.25). The standard portion for this category is finalised as 10g in line with the industry's serving size recommendation for all major brands of butter. The median salt value for the varieties of salted butter and buttery spreads is 1.6g per 100g (IQR 0.5) (see table 4.12).

Table 4.12: Computation for standard portion size for butter and spreads

Nutritics food code	Variety of butter and spread	No. of product samples in sub-categories	Average weight in grams (g) per portion
GB15/63143	Butter, salted	1	7
GB15/63144	Butter, spreadable (75-80% fat)	9	11
GB15/63145	Butter, spreadable, light (60% fat)	11	11
GB15/63769	Fat spread, low fat (26-39%), not polyunsaturated, including dairy type	7	10
GB15/63776	Fat spread, reduced fat (62-75%), polyunsaturated	5	10
GB/63775	Fat spread, reduced fat (62-75%), not polyunsaturated	10	10
Median (IQR)			**9.8 (1.25)**

Marmite**:** The term 'yeast -based spreads' or 'yeast extracts' is less popular amongst the consumers, thus marmite that is fairy popular yeast extract in UK has been used to name the category of yeast extracts. The standard portion of Marmite (yeast extract) equivalent to 9g is considered, for use in development of this study's dietary salt monitor. The portion size guidance 'Food Portion Sizes' by FSA 2002 stated a level teaspoon of marmite weighs 9g. The same is stated in the instruction manual for analysis of EPIC-FFQ (Lanigan, 2013).

Bread and rolls**:** Based on the extensive variety of breads available in Nutritics GB15 databse, the median value computed for a unit of bread, one slice or a roll is 39g (IQR 22). The median value for salt content of this food category is 1g (IQR 0.7).

Breakfast items**:** The median value for standard portion and salt content for breakfast items as pancakes, crumpets, scones, farls derived from Nutritics database is 68g (IQR 22) and 1g/ 100(IQR 0.7) respectively. Crumpets had highest salt density of 2.6g per 100g.

Baked Beans: The computation for standard portion size included two types; canned beans in tomato sauce and canned beans in barbeque sauce from Nutritics database and the median value is 205g. The review of the UK's popular baked bean brands and supermarket own brand showed consistent recommendation of half a can per serving, although the weight of can slightly varied as depicted in table 4.13.

Table 4.13: Serving recommendation for baked beans by various brands

Brand name	Serving Recommendation	Weight (g) of a regular can
Heinz	Half a can	415
Branston	Half a can	410
ASDA	Half a can	410
TESCO	Half a can	420
Sainsbury	Half a can	400
Morrison	Half a can	410
Waitrose	Half a can	400
Aldi Corale	Half a can	420
Lidl Newgate	Half a can	420

Soups: A total of thirty-two sub-categories of soup including lower calorie soup were considered from GB15 database of Nutritics and the median value for standard portion was derived as 220g. The median value for salt content for different varieties of tinned or powdered soups is 0.7g/100g (IQR 0.6 -1.2). The review of serving recommendation of popular UK brands and supermarket own range for canned soups indicated variance in serving suggestion, 'half a can' across most of the supermarket's own brand Asda, Tesco, Sainsbury, Morrison, and Waitrose and 'one can' for brands like Amy's kitchen and Crosse and Blackwell.

Ready meals**:** A total of 54 subactegories from GB15 and UK supermarket and other brands were included from Nutritics fatabase under this category and the median portion is computed as 350g (IQR 225). This category covered pre-portioned chilled meals as well as frozen ready to cook meal centres as breaded chicken/ fish, individual pie and mini ready meals. Since dietary intake data indicated intake of meal centres in dinner amongst the participants of KAP study, this was included and accounts for higher variablity in IQR. The median value for salt content for this category is 0.6g/100g (IQR 0.5-0.8).

Pizza**:** The median values for average portion for traditional varieties of pizza available in GB15 database of Nutritics, was calculated as 300g (IQR 300-321) and is depicted in table. The review of information on websites for serving suggestions for Pizzas from popular retailers and supermarket suggested consistent suggestion of ½ pizza as one serving although the net weight of pizza varied amongst brands and for different variety of pizza offered under any brand. The median values for salt content of pizza with varying toppings is 1g/100g.

Table 4.14: Portion size computation for Pizza

Nutritics food code	Type of Pizza	No. of samples under each type of pizza	Weight of Pizza (g)
GB15/64710	Pizza, cheese and tomato, retail	11	300
GB15/64715	Pizza, cheese and tomato, retail	11	300
GB15/64711	Pizza, chicken topped, retail	9	321
GB15/64713	Pizza, ham and pineapple, retail	10	321
GB15/65819	Pizza, cheese and tomato, French bread, retail	10	300
Median (IQR)			300 (21)

Bought Sandwiches: The median values for the weight of a pack of shop-bought sandwich; based on six varieties available in Nutritics databse is 173g (IQR 19).. The review of on pack – serving size information for the same variety of sandwiches from the website for the eight of UK supermarket's own brand also revealed similar values (see table 4.15). The serving suggestion across all supermarket brands were same i.e. one serving as one pack, however net weight of the pack varied based on the sandwich variety. The information on the weight of pack was not available online and was computed based on calorie per 100g available on BOP nutrition. The median values for salt content of this category is 0.9g (IQR 0.4).

Table 4.15: Weight of sandwiches available from UK's popular retailers

UK Supermarket own brand	Types of Sandwiches					
	BLT	Chicken Salad	Ham Salad	Cheese & Pickle	Egg Mayo	Tuna Mayonnaise
Asda	193	224	147	NA	162	142
Tesco	186	224	216	166	211	165
Morrison	-	212	167	154	-	169
Sainsbury	192	326	162	-	185	150
ALDI	175	209	178	190	177	195
Waitrose	186	205	164	148	176	138
M&S	188	-	164	-	176	-
Co-op	164	258	177	161	174	139
Average weight	183	237	172	164	180	157
Median (IQR)					**176 (18.5)**	

Pasta Sauces**:** The median portion for 11 sub-categories of sauces under this category as sourced from GB15 NUTRITICS database is 114g (IQR 39) and the median values for salt content is 0.8g/100g (IQR 0.2).

Table sauces: The median value for a standard portion of table sauce, computed aginst twenty varieties sourced from Nutritics database is 15g (IQR 5) and median values for salt content of this category is 1.9g/100g (IQR 2.0).

Crisps**:** The median values for a standard portion of crisps based on eight sub-categories of potato crisps and related products sourced from GB15 Nutritics database is 35g (IQR 6.2) and the salt content corresponding to the median portion is 0.6g.

Table 4.16: Computation of portion size for crisps

Nutritics food code	Sub-categories for Crisps	No. of product samples in sub-categories	Average weight in grams (g) per standard unit
64887	Potato crisps, low fat	20	40
6433	Potato crisps, thick, crinkle-cut	20	35
64886	Potato crisps, fried in sunflower oil	11	45
65832	Potato crisps, square	20	40
65834	Potato crisps, thick cut	20	35
65830	Potato crisps, crinkle cut	20	35
65831	Potato crisps, jacket	20	30
64896	Potato snacks, pringle-type, fried in vegetable oil	5	40
Median (IQR)			**35 (6.2)**

Salted nuts: The GB15 food databse of Nutritics defined the composition of mixed nut category as peanuts 68%, almonds 17%, cashews 8% and hazelnuts 7% and the average portion considered for this category was 30g. The median value for salt content for salted nuts category is 1.1g/100g (IQR 0.4).

Savoury biscuits and crackers: The median for individual unit of each of four types under this category is 8.5g (IQR 4.2) amd is shown in table 4.17 and the median salt content for this category was 1.1g/100g (IQR 0.5).

Table 4.17: Computation of portion size for savoury biscuits and crackers

NUTRITICS food code	Varieties of Crackers	No. of product samples in sub-categories	Average weight in grams (g) per standard unit
63536	Cream crackers	10	7
65946	Water biscuits	3	3.5
63553	Crispbread, rye	5	10
64434	Oatcakes, plain, retail	10	11
Median (IQR)			**8.5 (4.2)**

Meat substitutes: A total of forty-one vegan and vegetarian meat free commercial recipes sourced from nutritics database were included under this category. The median portion calculated for this category is 85g (IQR 50) and the median value for salt content per 100g is 1.2g (IQR 0.5).

Salt based rubs or seasonings: The median portion calculated for this category, based on the serving size information, avialable on pack and is 7.4g (IQR 5.7g). The serving size information was available for only 41% (12/ 29) and varied greatly amongst different brands selected from brand B database of NUTRITICS. The median value for salt intake is 18g/100g (IQR 17). The higher value for interquartile range for salt content of this category clearly characterise variability in salt content between different brands.

4.4.3 Final version of the Dietary Salt Monitor: A copy of this dietary salt monitor (v.1.2020) in Appendix I.

4.5 Discussion

Overview

This study presented development of a novel dietary salt monitor, for its use as an educational intervention tool in participants with T2DM. This is first UK based SFFQ that has food categories determined by the sources of salt in the diet of type 2 diabetes group. It is a short FFQ including a total of 20 food categories that provides comprehensive measurement of varying sources of salt from food including a computation to account for discretionary salt. Previous research studies on development of salt specific FFQ had used demographic servings for portion estimation and thus are semi-quantitative. However, SFFQ used in this study has provision to input individualised portion alongside frequency of intake against each food category. Although rationale for finalising the food categories was primarily salt density and/ top contributors of salt based on the dietary intake pattern of participants with type 2 diabetes, other criteria as top sources in diet of UK population, lack of achievement of 2017 salt targets, challenges faced by industry for further salt reduction, foods unrecognised as high in salt by consumers, sustainability, change in food and cooking practices during COVID-19 and overall nutritional composition of the food category were considered as well, to fulfil its role as an educational tool.

4.5.1 Suitability for target population: The food categories selected for the SFFQ are identified based on the dietary intake pattern of participants with T2DM, residing in UK. Such an approach of selecting the food list basis the diet consumed by the target population, named as data-based approach has been one of the most frequently used methods to develop a new FFQ (Block et al., 1986) and used by other researchers for development of FFQ measuring overall nutritional intake including sodium in type 2 diabetic participants in Brazilian population (Sarmento et al., 2013) and Korean population (Hong et al., 2010).

4.5.2 Estimation of dietary salt intake: This SFFQ is comprehensive to capture overall salt intake from ultra-processed foods, eating out occasions and accounts for discretionary use of salt intake as well as naturally occurring salt in food. A 43-item SFFQ developed by Charlton et al. (2008) for estimating dietary salt intake in general population of South Africa, reported to considerably underestimate the dietary intake of sodium as it did not consider salt added by individuals at the table. On the other hand, some Canadian studies also reported inclusion of questions on added salt and restaurant foods alongside processed foods for the development of salt specific FFQ designed for general population (Arcand et al., 2014; Cooper et al., 2020 and Gallani et al., 2020).

4.5.3 Food categories of SFFQ: This tool included a short list of twenty food categories, that are either food items or broad category covering many sub-categories. Such an approach made it possible to keep the list concise, for confirming lower respondent burden and practicality for its repeated use for monitoring salt intake.Several researchers reported development of salt specific tool based on a short list of high salt foods such as web-based tool called salt calculator including 23 food categories (Arcand et al., 2014); 44-item semiquantitative FFQ used with Brazilian hypertensive population (Ferreira-Sae et al., 2009); 42 categories SFFQ for classifying individual above or below maximum 6g intake in South-African population (Charlton, et al., 2008). The rationale for selecting food categories of SFFQ is supported with the evidence and discussed for each category in detail.

The processed meats as bacon, ham and sausages were included each as a distinct food category in SFFQ. These food items were identified in diet of hypertensive diabetic participants of KAP study (chapter 3) and ranked as second, fifth and seventh highest contributor of salt in the diet of UK population as per NDNS year 7/8 survey (). None of these food categories achieved the PHE's 2017 salt target (Public Health England, 2020), and often technological difficulties in reducing salt due to its role in product safety (Desmond, 2006; Kloss et al., 2015;) are cited. Other factors for insufficient product re-formulation for bacon category are reduced cooking yield (Puolanne et al., 2001) and commercial slicing yield due to reduced water binding of meat due to reduced salt (Puolanne et al., 2001; Lowell et al., 2017). The market survey for bacon as conducted by Action on Salt, 2020 stated that it is possible to further lower salt content of bacon across the brands based on availability of bacon with lower salt content from some retailers. Despite research trials reporting use of technological advancements as ultrasound application to re-structured ham for reducing salt (Barretto et al., 2018), use of high pressure and organic acids for extending shelf-life of vacuum packed-reduced salt cooked ham (O'Neill et al., 2018), there is very limited availability of reduced salt ham variety. Similarly, recent trials for reducing salt content in sausages concluded 25% reduction in salt content can be achieved through use of encapsulated salt (Beck et al., 2021) and this level of salt reduction did not have a significant impact on the quality, stability, and sensory evaluation of traditional dry cured sausages (Elias et al., 2020). Thus, these categories are included to educate about its high salt content alongside overall nutrition profile of higher fat as well as saturated fat content in bacon and sausages. Its further use as a nutrition education tool shall reinforce uptake of healthier alternatives as unprocessed lean meat and or inclusion of plant-based meat alternatives in their natural or minimally processed form, that are naturally low in salt and have lower total fat and saturated fat content. Capper et al. (2020) also recommended that moving to flexitarian diet is a sustainably viable option as it allows British food production to be suited to the constraints of our land and climate.

Meat alternatives were not popularly consumed by hypertensive diabetic participants of this study (see figure), probably owing to their older age. Several UK based studies have described age as an influencing factor for replacing meat with meat alternatives, where older group reported lower liking for meat alternatives (Apostolidis and McLeay 2019; Michel et al., 2021). The category is included in SFFQ of dietary salt monitor in view of increased market availability of this product due to increased marketing direction towards meat-eaters (Hu, Otis and McCarthy, 2019) and non-achievement of PHE's 2017 salt target for the category. A recent study evaluating the nutritional impact of relacing meat with meat alternatives in UK also confirmed the high sodium content of many meat-alternative products (Farsi et al., 2021).

Cheese was identified in top ten contributors of salt in diet of the present KAP study's participants (see figure 4.3) and the results of NDNS year 7/8 survey reported it as fourth largest contributor of salt in diet of UK population (Public Health England, 2018a). Although majority of samples of cheddar and other hard-pressed cheese met the PHE's 2017 salt target of 1.75g of salt/ 100g of cheese, it still classifies as 'high salt' based on salt threshold criteria. The revised salt targets for 2024 calls for further reduction of salt in this category as 1.66g/100g. Since extension of the shelf life of cheese without salt is unfathomable, food industry is working on various approaches as salt replacers, enhancers, and combinations thereof can be effectively applied to improve the flavour quality of low-sodium cheese (Bae et al., 2017, Bansal and Mishra, 2020). Considering the government's gradual approach for product-reformulation indicated by 2024 salt targets for this category, it is vital to create awareness on its salt content. Keeping in view positive nutritional benefits of cheese as a good source of protein and calcium, there is great commercial focus on marketing of reduced fat cheese (Mohamed, 2015) though it is not necessarily low in salt. Thus, nutrition education using dietary salt monitor shall advocate healthier swaps as reduced fat varieties of cheese that are naturally low in salt such as cottage cheese, ricotta, and mozzarella.

Salted butter and butter spreads ranked as sixth top contributor of salt based on dietary information of hypertensive type 2 diabetic participants of this study and ranked as 8th top contributor of salt in UK population, as per NDNS year 7/8 survey (Public Health England, 2018a).Though introduction of reformulation approaches as 'inter-esterification' have enabled market availability of healthier variety of butter i.e., trans-fat free and with lower saturated fat (Berry et al., 2019), there is seemingly limited availability of unsalted margarine or unsalted blended butter spreads. Nearly a quarter of butter and fat spreads did not meet PHE's 2017 salt target of 1.68g/100g and 1.38g/100g respectively (PHE 2018b). The survey undertaken by Action on Salt, 2013 indicated that gap between industrial action and public health strategy for salt reduction in this category needs to be mended, to improve overall nutritional profile of this category.

Although marmite was neither one of the top contributors of salt in diet of diabetics' participants nor based on NDNS survey. It is particularly relevant to educate consumers on salt content of this category keeping in view its relevance in British food (Wadlow, 2011; Mikkelsen et al., 2018), increased market visibility of the product and exemption from nutrition labelling due to smaller surface area of the regular jar (Population Health Division, 2016). These yeast-based spreads are seldom eaten on its own and can substantially increase the salt content of the dish when used as an accompaniment. This is particularly evident in wide range of marmite products available in market that has markedly higher salt content compared to their counterparts. For example: Peanut butter for brands like Meridian has 0g salt, Whole earth crunchy peanut butter has 1 g salt/ 100g as compared to 2.1g salt/ 100g in marmite butter. Marmite biscuits for cheese has 2.8g salt per 100g as compared to

1.4g/100g in Jacob's salt & black pepper bakes and 1.3g/100g in Jacobs crem crackers (based on nutrition information available on product website, April 2021).

Bread & rolls was identified as largest contributor of salt in diet of diabetic participants of the present study (Babber and Bhakta, 2020) and for the UK population as reported by NDNS survey year 7/8 (Public Health England, 2018a). Although government's 'Health by Stealth' approach was successful in progressively reducing salt content in bread by 20% from 2001 to 2011 (Brinsden et al., 2013), the PHE's 2017 average salt targets for this category were not met (Public Health England, 2018b). Nevertheless, the salt reduction in bread is not easy to apply as salt play important roles in bread-making and its reduction can affect the quality of bread (Nahar et al., 2019). Although gradual reduction is a simple and effective product reformulation strategy, this approach, when used alone, most probably will not be able to achieve levels of salt reduction in bread that meet the current public health needs, on a global scale, and in a timely manner (Ide et al., 2020). In this sense, several salt reduction strategies as use of glasswort, a plant with naturally salty taste as a salt replacer (Lopes, Cavaleiro and Ramos, 2017) and use of soluble dietary fibre as water extractable arabinoxylans (WEAX) to reduce 30% salt in bread (Lin et al., 2021) are being under-taken. Since bread is essentially not recognised as a 'high salt' item solely based on nutrition label as it has relatively lower salt content and appears amber as per FOP traffic light label. This category was not even recognised as source of salt by more than half of the hypertensive diabetes participants in KAP study.

Baked beans category was identified as one of the top contributors of salt in the diet of hypertensive and type 2 diabetes participants in our research study. This observation is well supported by high consumption patterns of baked beans in UK population (Frankowska, Jeswani and Azapagic, 2019). As per NDNS year 7 and year 8 results, it ranks tenth top contributor of sodium in UK population contributing 1.77% of sodium to diet. Since this product is not high in salt as per nutrient threshold of >1.5g/100g thus, it does not appear as red on FOP label. However, a typical serving as half-a-can contributes significant amount of salt on its own and even higher if accompanied with salty accompaniments. Thus, tracking salt contribution of this category is important to reinforce selection of no added/reduced salt and sugar baked beans, of this otherwise healthy food item which is high in protein and fibre content.

Soups were indicated as sixth highest contributor of salt, contributing 2.47% of total sodium to the diet of UK population, based on NDNs survey for year 7-8 (Public Health England, 2016). Although soup consumption is associated with lower energy density, higher diet quality and inverse correlation with obesity (Kuroda and Ninomiya, 2020); it is also associated with higher sodium intake (Zhu and Hollis, 2014). Keeping in view health benefits especially its contribution towards ‘5 A-Day’, the key is to educate consumers on choosing the reduced or no added salt variety.

Ready meals ranked as third highest contributor of salt in diet of diabetic participants of the present study. Their greater reliance on ready meals could probably be due to diabetic foot related disability and older age. Hoffman 2017 also suggested that elderly are major consumers of ready-meals and proposed ready meals might be a solution to deal with micronutrient deficiencies for elderly population. It was also reported as third top contributor of salt in diet of UK population as per NDNS year 7-8 (Public Health England, 2018a). PHE conducted an analysis of 6235 ready meals to review progress of 2017 salt reduction targets for this category and reported that average salt targets were not met (Public Health England, 2018b). PHE published second progress report in December 2020, that highlighted that average salt content of supermarket’s own brand had lower salt content as compared to other manufacturers; ASDA ready meals (0.51g/100g) and Bird’s eye ready meals (0.83g/100g). Thus, the category was included in the SFFQ of dietary salt monitor to draw attention to its salt content other than the convenience proposition of these meals.

Pizza was considered in the research’s SFFQ due to its high salt density based on salt threshold of >1.8g/serving. Also, as per the findings of year 7-8 NDNS survey, pizza ranked as 5th largest contributor of salt in diet of UK population. As per the progress report on achievement of 2017 salt targets, the average salt content of 792 pizza products analysed was 1.05g/100g against the average salt targets of 1g/100g.

Sandwiches ranked as tenth highest contributor of salt in the diet of this study’s participants. Although majority of the sandwiches consumed by our research participants were home-made, probably owing to their retired status, carer-dependent due to foot-disability, older age group and cost effectiveness. These were popularly consumed as lunch meal; ham sandwich was most popular and other varieties included bacon sandwich, cheese sandwich, chicken and sweetcorn, tuna mayonnaise etc. It was noted that table sauces and salt as seasoning was popularly used in sandwiches. Although home prepared sandwiches can be a nutritious meal option, addition of high salt fillings and added salt used can negatively alter their nutrition profile. Since these common high salt ingredients are already part of SFFQ, this category was named shop-bought sandwiches to avoid duplicating data. It is assumed inclusion of this category shall be useful for tracking salt contributed by this convenient lunch item in working class of diabetic population.

Pasta/ cook-in sauces did not appear as major contributor of salt in diet of the present study's research participants but reported as 15th top contributor of salt corresponding 1.2% of sodium in diet of UK population. Thus, it was included in SFFQ for research's dietary salt monitor. Although this category met average salt targets for 2017, nearly a quarter of products under survey did not meet the maximum target of 0.93g/100g of sauce (Public Health England, 2018b). The PHE's second progress report indicated that average salt content of supermarket's own brand was lower than other independent retailers, example average salt content of cook-in and pasta sauce from AB Worlds food Ltd was 0.85g/100g vs 0.66g/100g for ASDA and Morrison products in this category. Lack of awareness on salt levels of this category may increase the salt content of the dish, intended to be otherwise healthy.

Table sauces category was identified as salt-dense item consumed mostly with sandwiches in diet of hypertensive diabetic participants of the present study. As per the PHE's survey, only 38% of tomato ketchup products from manufacturers (branded products) were at/ below maximum targets of 1.7g/100g (Public Health England, 2018b). Government has published new salt reduction targets i.e., maximum salt targets of 1.63g/100g for tomato ketchup and has urged food industry to act on salt reduction in this category (Public Health England, 2020). 'Action on Salt' published a survey in 2019 on 261 products grouped as table sauces and revealed that nearly half (44%) were high in salt with only eleven being classed as 'low'.

Crisps as a category ranked 16th top contributor of salt (0.9%) in diet of the diabetic participants of the present study. The UK government's gradual salt reduction strategy 'health by stealth' (Regan et al., 2017) resulted in a shift of many crisps products from red to amber based on colour coded FOP scheme as average salt target of 1.31g/100g was met (Public Health England, 2018b). However, it is important to be cautious of the salt in it as continues to be on higher side of medium salt threshold (>0.3g-1.5g/100g). Notably, the sub-category salt & vinegar crisps had a higher salt target of 1.88g/100g and that was not met as per PHE's progress report for 2017 salt targets. This category is very relevant particularly during the current COVID pandemic, where the snacking particularly from crisps as markedly increased owing to home working, big night in and less socialising as reported by recent report published in The Grocer (Kantar 52 w/e 27 December 2020).

Based on widely known cardio-protective benefits of nuts (Kumari et al., 2020), its consumption is presumably encouraged in people with type 2 diabetes, hypertension and supported by healthy eating recommendations proposed through UK Eatwell guide. A prospective study in16,217 men and women with diabetes mellitus conducted by Liu et al. (2019) confirmed that higher consumption of nuts is associated with lower CVD incidence and mortality. Although nuts are naturally low in sodium, can unnecessarily lead to an increase in salt intake. Thus, the dietary salt monitor shall play important role for recording salt content from this category as well as encourage use of unsalted varieties.

Savoury biscuits/ crackers did not meet 2017 salt targets since the average salt content of 794 varieties of savoury biscuits was 1.53g/100g against target of 1.3g salt /100g (Public Health England, 2018b). Thus, government carried forwarded 2017 salt reduction targets, to be achieved by 2024.

Salt based rubs/seasonings were also included as a measure to monitor the additional salt usage other than table salt, especially in context of positive behaviour change towards cooking practice during COVID-19 pandemic (Murphy et al., 2020). Also, it can possibly miss the attention of consumer as salt is hidden and this product category is exempted from nutrition labelling as it is popularly sold in small pack size (i.e., less than 25cm ^{2}).

4.5.4 Computation of standard portion size: Unlike the use of 'demographic servings' for portion size estimation in semi-quantitative FFQs (Day et al., 1999; 2001; Charlton et al., 2008; Arcand et al., 2014; Mulligan et al., 2014; Cooper et al., 2020; Gallani et al., 2020), this study's dietary salt monitor provided quantitative estimation of portion sizes for each food categories under processed foods. This provided for precise estimation of portions as per individual preferences, since it could vary as per gender, age, socioeconomic background, number of other items in meal etc. (Benton, 2015). Since UK government guidance on consumed portion sizes has not been updated since last 20 years, there is lack of standardized guidance for on pack serving size (Kirwan et al., 2016; Rippin et al., 2018); and absence of large-scale study on dietary patterns of type 2 diabetes population in UK, this study's SFFQ required respondents to quantify their habitual intake as well as frequency of consumption.

An in-depth review of various national and international food portion size resources suggested that the typical weight of unit or standard portion considered for majority of the food categories of dietary salt monitor varied in comparison to the schemes listed in table. This could be due to methodological differences across various schemes such as sub-categories considered for each food category, varieties or different cuts included under each food item; weight accounted is for raw or cooked item, different time frames of survey period and method of computation reporting median/ average/ weighted average/ weight of unit, demographic averages or recommended portion, different country of origin of produce etc. The weight of standard portion for the categories as butter, cheese, marmite, bread, soups, sandwiches, crisps matched closely with most of other schemes (see table 4.18).

Table 4.18: Typical weight of a standard portion or a unit of each food category of dietary salt monitor, computed from Nutritics and other schemes

Food category	**Nutritics**	**FSA**	**BNF**	**EPIC-FFQ**	**BDA**	**Diabetes UK**	**Health Canada ^**	**FDA ^**	**IUNA**	**Food4me study#**
Bacon 1 rasher (g)	32.5[1]	25[2]	37.5[1]	40[2]	-	-	54	-	23[2*]	30.5
Ham 1 slice (g)	20	23	15	23	-	-	55		30	60.5
Sausages 1 unit (g)	32[1]	30[1]	57[1]	45[2]	-	-	75		25[2*]	120.3
Salted butter/ spreads (g)	9.8	10	-	15	5	10	10	15	10/ 12	15.8
Cheese (g)	30	30	30	40	30	-	30	30	34	40
Marmite (g)	9	9	-	9	-	-	-	-	-	16.7
Bread & rolls 1 unit (g)	39	38	40	30	36	36	37.5	50	36	
Breakfast items 1 unit (g)	68									
Baked beans 1 standard can (g)	205	205	200	135	-	-	300	130	120	17.7
Soups (g)	220	220		220			250		257	279
Ready meals (g)	350									
Pizza (g)	300	295		240			200	195	220	274
Bought sandwiches (g)	173	173					200	195		
Pasta Sauce (g)	114	76		90						147.9
Table sauce (g)	15	20		30					15	23.3
Crisps (g)	40	40	40			20				29.3
Nuts (g)	30	22	20	20	30	50	50	30	40	17.8
Savoury biscuits/ crackers 1 unit (g)	8.5	8.5		7/ 10						
Meat substitutes	85						60[2]			
Salt based rubs/ seasoning	7.4									

[1]raw, [2] cooked, *weighed by IUNA, ^ standard serving size guidance for industry; # average portion size for UK population, n= 207; Abbreviations and references; FSA, Food Standard Agency (Crawley et al., 2002); BNF, British Nutrition Foundation (Benelam and Wiseman, 2019); EPIC- FFQ (Lanigan, 2013); BDA, British Dietetic Association and Diabetes UK scheme (Lewis, Ahern and Jebb, 2012); IUNA, Irish Universities Nutrition Alliance (Lyons, 2013) and Food4me study (Kirwan et al., 2016).

4.5.5 Computation of salt content for food categories: The use of national food composition database has been reported as a potential source of error for dietary estimation of salt intake (Periera et al., 2016) and especially in context of UK Government's food industry driven targeted salt reduction strategy. However, the salt reduction strategy relies on 'health by stealth' a silent approach to reformulation, aimed at very gradual reduction of salt in the food products (Zandstra, Lion and Newson, 2016) and lack of progress in achieving 2017 salt reduction targets, for nearly half of the 15 sub-categories (Public Health England, 2018b) supports the suitability of using the latest national database. The food categories with unmet targets are processed meats, bread & rolls, ready meals, soups, savoury biscuits and thus, same targets or marginally reduced are carried forward to be achieved by year 2024 (Public Health England, 2020). Also, for certain categories as ready meals, meat substitutes and salt-based seasoning, the salt content information was based on the up-to-date nutrition labels from brand specific database of Nutritics.

The PHE's salt targets 2017- progress report published salt content of the categories based on the nutrition label data by Kantar world panel as of September 2017 (Public Health England, 2018b) and are available in Appendix N. But due to difference in methodology as number and types of subcategories included, these values might be inappropriate for direct comparison. Also, the manufacturers had lower rate of progress for the salt reduction as compared to retailers, 52% and 73% respectively (Public Health England, 2018b). The review of salt content of dietary salt monitor's categories with the salt level published in PHE's report suggested the values for salt content for bacon and savoury biscuit/ crackers considered for dietary salt monitor were underestimated. For dietary salt monitor, savoury biscuits and crackers were considered in one category whereas Kantar's nutrition label data considered only savoury biscuits. The categories as ham, sausage and crisps had higher salt content based on COFID database as compared to Kantar's nutrition label data. This could be due to different sub-categories included example; ham category in PHE's food categories did not include ham produced by traditional methods such as parma ham, that had higher salt density. Similarly, PHE survey on salt content of crisps included salt and vinegar as a separate category, and thus depicted lower salt content as compared to the values computed for the dietary salt monitor. However, the salt content for categories as ready meals, pizza, meat substitutes, butter and spreads, cheese and breakfast items matched closely for both methods, supporting the median values computed for dietary salt monitor as valid.

4.5.6 Further application and future use: This tool has several aspects including the SFFQ component, that highlights its use for monitoring salt intake as well as creating awareness for reducing salt intake in diabetes. It reinforces message of 'daily salt limit of less than 6g' applicable for general as well as diabetic population as it was identified as a gap in the research study exploring awareness of hypertensive diabetic participants on dietary salt intake (Babber and Bhakta et al., 2020). Other information as practice of reading nutrition label and buying reduced salt food is captured and such practices can be further encouraged through its regular use for monitoring salt intake.

4.5.7 Limitations of the study: There are certain limitations of this dietary salt monitor that needs to be acknowledged. Due to small sample size and use of single 24h dietary recall, it was difficult to determine a comprehensive list of food sources of salt for type 2 diabetes participants. However, the top categories contributing salt to UK population based on NDNS year 7-8 (Public Health England, 2018a) was considered to finalise the list. Although the discretionary salt usage and salt naturally occurring in food is accounted based on the UK population average, this tool doesn't not directly estimate the actual intake of participants. Gallani et al. (2020) used a separate discretionary salt questionnaire to determine the quantity used for different variety of salt and estimating individual intake based on number of family members in Canadian population. However, adoption of such methodology increases respondent burden, with respect to difficulty in quantifying the salt added in cooking or at table. If the improved trend for positive cooking related practices during COVID-19 in UK (Murphy et al., 2020) continues to last longer, it is imperative that discretionary salt usage needs to be directly captured, and future research studies need to consider it. Due to lack of financial resources for this study, researcher did not procure food purchase volume data for variety of food items under each category. Such data as Kantar world panel are available for purchase and could be used for computing weighted averages for determining salt content for the food categories. A study conducted by Mhurchu et al. (2011) analysed sodium content of processed foods in UK and indicated for some food groups as bread and bakery and processed meat purchase-weighted means were 18–35% higher than unweighted means, suggesting that market leaders have higher sodium contents than the category mean. Thus, weighted means for the salt content based on nutrition label data, shall allow precise estimation of daily salt intake, and needs to be considered for future research. Portions were described as the standard portions and the photographs are not used for portion size estimation. This was further reviewed and amended prior to its its use as an online educational tool (see Chapter 6).

4.6 Conclusion

In conclusion, the study resulted in development of a user friendly, 20-item SFFQ, named dietary salt monitor for monitoring salt-intake from the high salt food categories. Most importantly, it has high potential for use as an educational tool for highlighting sources of salt in the diet of diabetic population and enabling reduction in their salt intake. However, this novel dietary salt monitor needs to be validated prior to its use in intervention study.

Chapter 5: Validation of the novel dietary salt monitor, based on a SFFQ against 24h urinary sodium excretions and a food record.

Overview

24h urinary sodium excretion is considered gold standard for estimation of dietary salt intake and often used as reference method for validation of dietary tools aimed at estimation of salt intake. Previous research studies of varying study design and larger sample sizes have used this method for validation of dietary salt estimation using FFQ of varying length. The results of these validation studies have reported moderate correlation and greater bias based on BA plot as well as high level of misclassification, indicating challenges associated in dietary estimation of salt intake. This study aimed at validation of short salt specific FFQ (named dietary salt measurement with a small sample of 12 student participants from a diverse ethnicity and nutrition background. The Bland and Altman method for agreement between dietary salt monitor and urinary sodium excretion method suggested a bias of 1.5g/ d (upper LOA 7.68 and lower LOA -4.72). and a low level of misclassification (n=1, 11%). The study findings also highlighted some ethnic specific food ingredients, that needs to be included in description of existing food categories of the dietary salt monitor. This shall helpful for wider application of dietary salt monitor as an educational tool for increasing awareness of food sources of salt.

5.1 Introduction

Validity refers to the degree to which an assessment method captures true dietary intake (Willet, 2012). A variety of established self-reported dietary assessment methods exist such as 24h dietary recall, diet history, food frequency questionnaire (FFQ) and food record. The dietary assessment methods are cost effective and are suitable for screening of nutrient intakes at a population level (Kiely et al., 2016). FFQ is a widely used dietary assessment method since it captures the long-term dietary intake of populations, has low administration cost (Carroll et al., 2012; Shim, Oh and Kim 2014) and lower respondent burden (Steinemann et al., 2017). A recent systematic review identifying UK validated dietary assessment tools (DATs) indicated that most of DATs validated on adults were FFQs (Hooson et al., 2020). However, the

FFQ method has its own limitations as recall bias, missing data, and misreporting. These are attributed to reliance on participant's memory, inability to accurately estimate portion sizes and misinterpretation of the questions, or social desirability bias (Satija et al., 2015).

Validation of dietary assessment method is an important step for assessing measurement error and evaluating the accuracy of the tool in comparison to a reference or "gold standard" measure. A reference method should be unbiased and have uncorrelated errors with the errors in the method to be validated (Kaaks et al., 1994). Recovery biomarkers are assumed to meet these requirements because they are objective measure (Jenab et al., 2009; Willet, 2013) and can be of value since no dietary assessment is free of error (Cade et al., 2002). However, they have their limitations, such as the reference time, as they reflect nutrient intake in the short term, i.e., intake at a point in time (Kuhnle, 2012) and also it can be expensive and impractical when conducting a large study (Bingham, 2002; Hedrick et al., 2012).

Measurement of dietary salt, either on a population or an individual level, is fraught with methodological difficulties. Due to day-to-day variation in salt intake, dietary methods raise limitations for precise estimation of salt content in both processed and home-cooked food (McLean et al., 2017). A great deal of discrepancy exists in the salt content of similar food across the brands for processed foods (Champagne and Cash, 2013). Also, there are differences in salt content of foods based on food composition databases as compared with nutritional information provided by manufacturers, due to expanding variety of food products in national food supply. The lack of feasibility to capture salt content of all foods in market and update database is considered a potential source of measurement error for precise estimate of dietary salt intake (Carter et al., 2016).

A systematic review conducted by Perin et al. (2020) reviewed the literature on the methods used to estimate salt intake in different study designs and reported the FFQ predominant self-report measure. In another meta-analysis of prospective studies examining salt intake and cardiovascular outcomes, four of the thirteen included studies used FFQs in their assessment of dietary salt intake (Strazzullo et al., 2009).

Approximately 85% to 90% of sodium ingested over a 24-hour period is excreted in the urine, with the remainder excreted in sweat and faeces (Weilgosz et al., 2016;

McLean 2017). Thus, twenty-four-hour urinary sodium excretion method is advocated as a gold standard method to estimate sodium consumption in the population. It is the most suitable reference method or calibration instrument for comparison in validation studies of dietary assessment methods (Freedman et al., 2011) specifically for validating salt specific FFQ in several studies (Day et al., 2001; Charlton et al., 2008; Ferreira-Sae et al., 2009). But the method places considerable burden on participants, and both under-collection as well as over-collection have been reported. The multiple collections over several days are recommended as most appropriate approach for validation of FFQs. Since this method is costly and has high respondent burden (Hawkes and Webster, 2012), researchers are often left with the option of examining relative validity by comparing one dietary assessment method with another method that has a different error structure (Tabacchi et al., 2014).

Validation studies of specific FFQ design to estimate dietary salt intake are needed (Bush et al., 2019) especially for a diabetic population that has higher health risk due to excessive salt consumption (Petrie et al., 2018). The development and validation of consumer-friendly salt intake calculator are important for raising awareness about high salt foods in their diet (Zandstra, Lion and Newson, 2016). For this purpose, a thorough literature review was conducted to determine the availability of a validated UK based salt specific FFQ, that is intended to cover the specific eating patterns of people with T2DM. These validation studies conducted in different population groups across the world, varied greatly in terms of the characteristics of the questionnaire as well as study design (see table 5.1). Although, FFQ were either newly developed or adapted to match the food consumption patterns of the population under study, none of the questionnaire was designed to cater to diabetics. The length of FFQ varied from a short 23-item sodium screener to the longer questionnaire with 150 food items. The reference methods ranged from use of a single urinary sodium excretion to six urine collections solely or combined with other dietary methods. Although the results of relative validity of FFQ with multiple 24h recall dietary suggested a higher and significant correlation for total sodium estimated by these dietary methods, both the methods are memory based and have correlated errors (Charlton et al., 2008 and Tangney et al., 2019). In all, the research findings concluded that it is difficult to measure dietary salt intake even with the robust study design and even with the use of gold standard measurement in larger sample. To the best of the researcher's knowledge, there is no validated FFQ's available to capture the habitual salt intake of people with diabetes in UK population.

In present study, the researcher aims to validate a SFFQ (named dietary salt monitor) that is designed specifically for diabetes population. This validation study included group of students from London Metropolitan University enrolled for NF7015 module, who conducts urinary sodium excretion assays as a part of coursework. Due to hardships during COVID pandemic, limitations of using urine assay in participants with T2DM and the cost involved, the study is conducted with student group.

Table 5.1: Summary of the validation study of FFQs estimating dietary salt intake

Author	Study sample	Methodology	Results
Cooper et al., 2020	n= 100 Canadian population	Sodium Analysis Tool (SALT), 43* item FFQ was validated against three 24hour dietary recall. *40 food-based questions + 3 questions on discretionary salt	Pearson's correlation between methods, although significant ($p = 0.02$) was poor ($r = 0.202$). Sodium intake for SALT1 (3185 ± 1424) vs SALT2 (2735 ± 1174) were significantly different ($p = 0.005$). Sodium intake for mean of three 24h dietary recall was (2742 ± 980 mg/day) versus SALT2 (2735 ± 1174 mg/day) was not significantly different ($p = 0.960$). Conclusion: SALT has the potential to be a valid and reliable tool for assessing dietary sodium intake of Canadian adult populations.
Gallani et al., 2020	n=164 (for validity study) n=36 (for reliability study) French-Canadian population	52 item FFQ-Na and a Discretionary Salt Questionnaire validated against 24 h Uri-Na and a 3-day food record.	Correlations of the FFQ-Na with the 24h Uri-Na and the 3-day food record were 0.3 ($p < 0.001$) and 0.35 ($p < 0.001$) respectively. The results for cross- classification indicated the proportion of opposite quartile for combined questionnaire (FFQ-Na + DSQ) with 24h urinary Na was 27.1% and with a 3-day food record is 27.8%. Bland–Altman plot for the combined questionnaires suggested that there was a bias of measurement, underestimation of 2.3g when compared to the 24h urinary sodium excretion method and 1.4g when compared to the 3-day food record. Conclusion: The FFQ-Na and the DSQ demonstrated evidence of reliability, but further studies are recommended to carry on the assessment of the validity of these tools in a more diversified population.
Tangney et al., 2019	n= 102, Registered dietitian (RD) study. n= 69, Study of Household Purchasing Patterns, Eating, and Recreation (SHoPPER study).US population	A 26- item sodium screener was validated against repeated 24hr dietary recall in both RD study and SHoPPER study.	In the RD study, sodium screener predicted sodium intakes were 2604±990 mg/day and automated 24h recall- sodium intakes were 3193±907 mg/day. In the SHoPPER sample, corresponding values were 3338 ± 1310 mg/day and 2939 ± 1231 mg/day, respectively. Sodium screener -predicted and dietary recall sodium estimates were correlated in the RD study ($r = 0.381$, $p = 0.0001$) and in the SHoPPER ($r = 0.430$, $p = 0.0002$). Agreement between the sodium screener and 24h recall was poor when classifying individuals as meeting the dietary sodium guidelines of 2300 mg/day or not (RD study: kappa = 0.080, $p = 0.32$; SHoPPER: kappa = 0.207, $p = 0.08$)Conclusion: Sodium screener requires additional modification prior to its use, for estimating daily sodium intake.

<table>
<tr>
<td>Freedman et al., 2015

Pooled analysis from 5 validation studies:</td>
<td>Studies conducted across the various parts of USA.

1.OPEN study (n=484,54% Male)

2.Energetics study (n=263, 36% male)

3.AMPM study (n=524, 50% Male)

4.NBS study (n=544, all women)

5.NPAAS (n=450, all women)</td>
<td>Three FFQs were used, the Diet and Health Questionnaire in OPEN and Energetics, the Harvard FFQ in AMPM, and the Women's Health Initiative FFQ in NBS and NPAAS.

FFQ was validated against at least two 24h recalls and urine sodium excretion assay.</td>
<td>The sodium intake was underestimated by FFQ in all the studies, as presented by geometric mean (mg/d):
<table>
<tr><td>Method</td><td>Men</td><td>Women</td></tr>
<tr><td colspan="3">OPEN study</td></tr>
<tr><td>FFQ</td><td>3070</td><td>2308</td></tr>
<tr><td>Biomarker</td><td>4502</td><td>3310</td></tr>
<tr><td>24h recall</td><td>4446</td><td>3337</td></tr>
<tr><td colspan="3">Energetics study</td></tr>
<tr><td>FFQ</td><td>3377</td><td>2459</td></tr>
<tr><td>Biomarker</td><td>3692</td><td>2555</td></tr>
<tr><td>24h recall</td><td>4010</td><td>2580</td></tr>
<tr><td colspan="3">AMPM study</td></tr>
<tr><td>FFQ</td><td>2188</td><td>1851</td></tr>
<tr><td>Biomarker</td><td>4648</td><td>3494</td></tr>
<tr><td>24h recall</td><td>4176</td><td>3184</td></tr>
<tr><td colspan="3">NBS study</td></tr>
<tr><td>FFQ</td><td></td><td>2394</td></tr>
<tr><td>Biomarker</td><td></td><td>3263</td></tr>
<tr><td>24h recall</td><td></td><td>2437</td></tr>
<tr><td colspan="3">NPAAS study</td></tr>
<tr><td>FFQ</td><td></td><td>2383</td></tr>
<tr><td>Biomarker</td><td></td><td>3056</td></tr>
<tr><td>24h recall</td><td></td><td>2358</td></tr>
</table>
Average correlation coefficient for sodium intake by FFQ against urinary biomarker was 0.17 for men, 0.15 for women.</td>
</tr>
<tr>
<td>Kelly et al., 2015

Food Choice at Work Study</td>
<td>n=50

Volunteers aged 18–64y; 36% women, 12% with hypertension.

Ireland</td>
<td>150 item FFQ (version of EPIC adapted for Irish population), to determine intake pattern for past 12 months was validated against single 24h urinary sodium excretion.</td>
<td>Mean urinary sodium excretion 3174 (SD 1219) mg/d Mean sodium intake based on FFQ 2967 (SD1150) mg/d.Bland-Altman plot reported a mean difference of 9.1 (95% CI, −5.7 to 24) mmol/d; 95% mean difference, −95.7 to 113.9; AUC, 0.76 (95% CI, 0.6–0.9) Conclusion: Neither dietary nor spot urine sample methods provide adequate validity in the estimation of 24h urinary sodium at the individual level.</td>
</tr>
</table>

Trijsburg et al., 2015 DuPLO study	n = 198 participants between age 20-70yrs. Netherlands	Validation of an online, self-administered newly developed 180 item FFQ against 2 duplicate portion collection, 2urine samples and between 1-15 24h dietary recalls.	Mean sodium intake (mg/d) based on FFQ 2137 (SD 708); urinary sodium excretion 3983 (SD 1264); Duplicate portion 2505 (807) and 24-hour recall web-based 2519 (859); 24-hour recall telephone based 2568 (743).Correlated errors between DP and FFQ for sodium were lowest (0·19) and thus it was concluded that duplicate portion was probably the best available reference method for FFQ validation for nutrients that currently have no generally accepted recovery biomarker.
Bedford and Barr, 2011	n= 102 Cohort healthy volunteers (100% women) Canada	Sodium intake was analysed using 124 item FFQ for past 12 months (National Cancer Institute) and compared to sodium assessment from single 24 hr urine collection.	Mean sodium excretion was 2942 (SD 1062) mg/d and Mean sodium intake based on FFQ -2648 (SD 1089) mg/d.Significant correlation was reported between two methods was r= 0.21, p=0.032.
Charlton et al., 2008	n=180 adults with hypertension; n= 145 adults with normotension (51% women); age 20-65 years. South Africa	A 42 - item salt specific FFQ for previous 7 days was validated against three 24h urine collections and 24h dietary recalls. Completeness of urine sample was checked by PABA or urinary creatinine concentration.	Total Na content of the questionnaire was associated with Na estimations from 24h recall data (r=0.75; P=0.0001; n=328) and urinary Na (r=0.152; P=0.01; n=284). Conclusion: The questionnaire demonstrates acceptable internal consistency and criterion validity against the gold standard indicator of repeated 24h urinary Na concentrations. It demonstrated an acceptable correlation between the questionnaire and the repeated 24h recalls.
Day et al., 2001 EPIC-Norfolk cohort study	n=123Volunteers aged 45-74 y United Kingdom	130 item FFQ were administered twice, 18 months apart. Modified Questionnaire from US Nurses' Health Study. Self-administered FFQ was meant to collect information based on past 12month collection and validated against 24h urinary sodium excretions. A total of six urine collections were used, sample checked for completeness by PABA.	Mean urinary sodium excretion 3335 mg/d (SD1297) Mean sodium intake based on FFQ 2766 (SD 1074) mg/d. Correlation between two methods was 0.36.

5.2 Methodology

The validation study for the dietary salt monitor was conducted during the month of February-March 2020, that coincided with COVID pandemic. This study was approved by London Metropolitan University's Ethics committee and NHS Cambridge East Research Ethics Committee. The participants were provided with Phase 3 - PIS (Appendix C), and informed consent was obtained.

* *The dietary salt monitor is based on a short food frequency questionnaire (SFFQ) to estimate dietary salt intake and is referred as SFFQ, for better clarity and comparison with other reference methods in this chapter.*

5.2.1 Recruitment and data collection: An invitation requesting participation in this study was posted through London Metropolitan University's NF7015 module web learn site. The researcher addressed these students through an online session in the month of December 2020. A total of fifteen students attended the session, they were explained the research objectives and demonstrated the use of SFFQ. A working example for determining the number of portions consumed for a food category was discussed (see figure 5.1). The presentation and content of SFFQ was discussed with this group of students, to verify ease of comprehension of the standard portion and food items included in each food category

Figure 5.1: Working example for determination of an average portion of a food category of SFFQ

FREQUENCY OF CONSUMPTION OF PROCESSED FOODS

How many portions of the following processed foods do you consume? Please mention number of portions of each food eaten on an average per day/ week/ month.

EXAMPLES:

For bread, the amount is 'one slice', so if you consume 4 slices every day, write **4** in the column headed "Day".

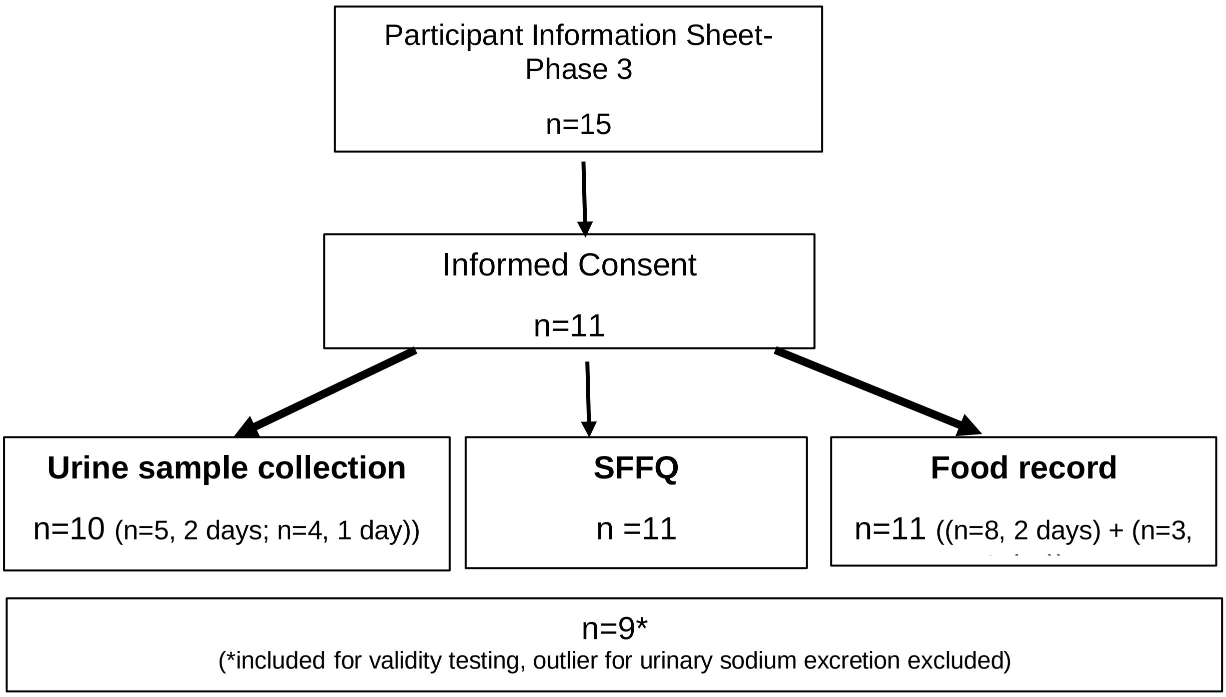
Foods	Amounts	Day	Week	Month	Never
Bread and rolls	1 slice	4			

For cheese, the amount is 'one serving', so if you consume 1 serving, thrice a week write **3** in the column headed 'Week'.

Foods	Amounts	Day	Week	Month	Never
Cheese	1 serving		3		

Another session (face to face) was conducted in February 2020, and the participants (n=15) were provided with the protocol for 24h urine collection (Appendix J). The urine collection protocol was explained, and queries answered. They were also asked to record their dietary intake for two days corresponding to the dates of urine collection. The completed research documents as 24h urine collection sheets, food record along with signed copy of informed consent was collected from the participants on the day of conducting urine sodium excretion assay in March 2020. The participants were emailed SFFQ in 1st week of April 2020 and asked to fill responses based on their average intake in past year.

Figure 5.2: Flow of participants through the validation study of SFFQ



5.2.2 Data collection tools and techniques

5.2.2a Short Food Frequency Questionnaire (SFFQ) The SFFQ (v.1.2020) had a total of twenty food categories representing processed foods contributing salt in diet and four categories for frequency of consumption are day/week/month/never. The questionnaire also included a subset of questions on frequency of eating out, use of salt in cooking and at the table, purchase of reduced salt food items and practice of reading nutrition labels. The basic demographic information such as age, gender, ethnicity and anthropometric measurements as height, weight, body fat %, waist and hip measurements details were collected as part of SFFQ. Height was measured using Doherty premier wall mounted height measure, weight and body fat percentage was measured using the Tanita Body Composition Analyzer, TBF-410GS. Hip and waist measurement were taken as standard protocol explained in chapter 2. The SFFQ was self-administered and completed questionnaire was sent to researcher by email. The researcher checked each questionnaire for completeness and requested missing data via email.

5.2.2b 24h urinary sodium excretion assay: The study's participants were requested to collect total urine excreted over the two days preferably one weekday and other weekend, since a single 24h urine collection is likely to be inadequate for validation studies of FFQ's (Sun et al., 2017). The completeness of collection was assessed by participants claim and if start and finish time are within ± 1hr of 24-hour period and urine volume not less than 500ml/day (Charlton et al., 2008; Gallani et al., 2020). The research participants measured the urine volume with container and calculated the final urine volume by subtracting the weight of the container from measured volume.
Sodium concentration in urine was measured using the Atomic Absorption Spectrometer (AAS), Analyst, PerkinElmer and its principle of working is explained here. The ground state sodium atom absorbs light energy at 589.0 nm as it enters the excited state. As the number of sodium atoms in the light path increases, the amount of light absorbed also increases. By measuring the amount of light absorbed, a quantitative determination of the amount of sodium present can be made.

A single reading for sodium concentration (ppm) for each day's sample was recorded as per the AAS results. A dilution factor of 400 was used based on the preparation of urine aliquot with distilled water (1ml in 400ml) as per the standard laboratory protocol.

This reading was multiplied by urine volume and dilution factor to calculate total sodium excretion/day as mentioned in the formula here:

Na excretion/day = Volume of urine (in litres) X Na concentration (ppm)

X dilution factor

The readings for sodium excretion were multiplied by 2.5 to calculate corresponding salt intake (g/d).

5.2.2c Food Records: All meals consumed in a day were recorded by the participants alongside their portion sizes in household measurements and brand names of the food were mentioned, where applicable. The food records were further reviewed by the researcher for any missing data and participants were further probed for the use of discretionary salt.

5.2.3 Data Analysis: The statistical analysis was carried out using IBM SPSS statistics (version 26). The socio-demographic and anthropometric characteristics were analysed using descriptive statistics. Body mass index (BMI) was calculated using weight and height details, and classified as normal weight, overweight and obese, based on WHO international and Asia-pacific classification (see chapter 2). Waist to Hip ratio (WHR) was calculated by dividing waist measurements by height measurements and interpretated as detailed in chapter 2.

The estimated daily salt intake based on SFFQ responses was computed using the research's dietary salt monitor excel sheet (see Appendix K). The frequency data for consumption of processed foods and eating out responses from SFFQ was converted to salt intake by multiplying the salt content per serving of each food category to the designated frequency factor. The working for estimated daily salt intake also considered computation for the use of discretionary salt and naturally occurring salt in a typical UK population diet. The detail of working example of dietary salt monitor (v.1.2020) is explained in Appendix K.

The data for food records was entered in Nutritics software and batch report for nutritional analysis for the study group was generated. Six out of total of nine participants provided diet record for 2 days and the rest participants recorded their diet for one day only. The sodium content of the diet was converted to salt intake by multiplying sodium values with 2.5. Mean and standard deviation was calculated for the group to review the macronutrient intake alongside their salt intake. Under-reporters for energy intake was assessed based on the dietary information in food records. Basal metabolic rates were calculated from the age and height-specific equations of Henry (Henry, 2005) and multiplied by 1.1 to calculate estimated individual minimum energy requirements for each participant (EmER) (Goldberg et al., 1991). The values for estimated energy expenditure were compared to reported energy intake to determine unfeasibly low energy intake reporters using the Goldberg cut-off of 1.1 as it identifies approximately 75% of under-reporters (MRC, 2017). The mean salt intake for low energy reporters was compared to non-low energy reporters. The data for salt intake was normally distributed in both groups, as per Shapiro-Wilk's test ($p>0.05$). Thus, Independent Samples T test was applied to determine the statistical significance for the difference in mean salt intake of two groups. Also, Levene's test for equality of variance was applied to checked for the assumption for equality of variance.

The data on urine collection was analysed to determine mean urine volume. Where participants have provided two days urine collection, average value for sodium excretion was calculated to determine 24h urinary sodium excretion. This average for urine volume is based on two full days of collection for six participants and the rest three participants collected urine for one day. The descriptive statistics such as mean and standard deviation for salt intake corresponding to urinary sodium excretion method was calculated for this study's participant group.

5.2.4 Validity testing: The data for SFFQ, food record and urinary sodium excretion was normally distributed as per the normality test Shapiro-Wilk ($p>0.05$ for all datasets). A total of nine participants were included for statistical analysis for this validation study. The outlier corresponding to 24h urinary sodium excretion values was identified using boxplot and excluded as the values seemed clinically unfeasible. Pearson correlation coefficient was conducted to determine the association between SFFQ and urinary sodium excretion; food records and SFFQ. The cross-classification into quartiles of intake and Bland–Altman plots was applied to determine the extent of agreement between the two methods. B-A plot was included as it is the preferred method for depicting the agreement between two methods, particularly in the development of FFQ's (Cade et al., 2002; Cade et al., 2004; Bland and Altman, 1999).

One sample t test was conducted, to determine if the difference between mean salt intake as estimated by SFFQ, food record and urinary sodium excretion method was statistically different. Weighted Kappa test was applied to determine the degree of disagreement between the SFFQ and urinary sodium excretion; SFFQ and food record method.

5.2.5 Reliability: The data for salt intake contribution from each of twenty food categories of SFFQ and the corresponding intake from food record, did not follow normal distribution as per results of Shapiro-Wilk's test, $p>0.05$. Thus, alternate form reliability was tested using Spearman's correlation coefficient to determine association of salt intake in the individual categories of SFFQ and that from food records Alternative-form reliability is obtained by applying two 'equivalent' forms of the measuring instrument to the same subjects (Holmefur et al., 2009) and the similar approach was used by Charlton et al. (2008) for validation of a 42-item short food frequency questionnaire to assess sodium intake.

5.3 Results

5.3.1 Study participants: The study sample included all female participants with mean age 31.1 (SD 9.4) years. The ethnicity data revealed that less than half of the participants was from white ethnic group (45%) and the rest from diverse background including 18% each from south-Asian and mixed ethnicity and 9% each from Arab and Afro-Caribbean. The anthropometric characteristics stating group statistics are displayed in table 5.2. Based on the ethnicity specific BMI cut offs for adults (see details in chapter 2), majority of the study participants (55%) classified as normal weight, followed by 18% each in overweight and obese category and one participant as underweight. Interpretation of measures of central adiposity as waist measurement, WHR and WHtR ratio at individual level indicated only one participant's measurements outside the health range.

Table 5.2: Demographic and Anthropometric characteristics of the study sample

Characteristic	**Total (n=11)**
Male/ Female, n (%)	0 / 11(100%)
Age (y)*	31.1 (9.4)
Ethnicity, n (%)	
White	5 (45%)
South-Asian	2 (18%)
Mixed ethnicity	2 (18%)
Arab	1 (9%)
Afro- Caribbean	1 (9%)
Weight (kg)*	62.7 (13.4)
Height (cm)*	164.5 (8.9)
BMI (kg/m^2) *	23.2 (4.7)
Waist circumference (cm)	64 (14)
Hip Circumference (cm)	89 (8.0)
WHR	0.7 (0.2)
WHtR	0.4 (0.1)
Body Fat %	26.0 (9.7)

Values presented as number of participants (% of sample) or * mean (SD); Abbreviations: BMI, body mass index; WHR, waist to hip ratio; WHtR, waist to height ratio.

5.3.2 Assessment of salt intake: The mean values for daily salt intake assessed by each of the three methods including biomarker is described in table 5.3. At individual level, the urine sodium excretion results indicated that 44% of the participants consumed salt above the UK government recommendation of 6g/day as compared to 33% classified by each of the dietary assessment methods.

Table 5.3: Estimated daily salt intake based on urinary assay, SFFQ and food record method

Method	**Estimated salt intake (g/ day) Mean (SD)**	**Range g/day**
Urinary sodium excretion	6.9 (2.3)	4.3-10.5
SFFQ	5.4 (1.4)	0.9-5.6
Food record	4.3 (2.1)	1.3-7.1

Data is presented for n=9, Abbreviations: SFFQ, short food frequency questionnaire

5.3.3 Dietary assessment based on food record method: Energy, macronutrient and selected micronutrient intake based on food records for the study group are presented in table 5.4 alongside NDNS report stating average nutrient intake for UK population-women between 19-64years. Intake for total calories, protein, fat, fibre and Vitamin D is higher for the study participant's group as compared to NDNS findings. However, the estimated intake for carbohydrates, vitamin A, calcium, iron, and potassium is lower for study participants as compared to the average intake of UK women reported by NDNS results.

Table 5.4: Estimated daily nutrient intake for the study group, based on food record method

Nutrient	**Mean (SD)**	**NDNS 2016/17- 2018/19**
Energy (kcal)	1658 (528)	1605 (459)
EmER (kcal)	1500 (140)	
Protein (g)	69.2 (27.5)	66.8 (20.6)
Protein (% of EI)	17 (6)	17.1 (4.9)
Fat (g)	69.8 (32.1)	62.2 (23.3)
Fat (% of EI)	37(8)	34.5 (6.7)
SFA (g)	17.5 (6)	22.5 (9.9)
MUFA (g)	18.4 (8.9)	23.2 (9.2)
PUFA (g)	10.6 (5.1)	
Omega 3 (g)	1.8 (1.9)	1.9 (1.1)
Omega 6 (g)	4.8 (2.4)	7.8 (4.0)
Carbohydrates (g)	178 (52)	192 (64)
Carbohydrates (% of EI)	44(5)	45.1 (7.8)
Sugar (g)	63 (29)	
Sugar (% of EI)	15 (6)	
Fibre (g)	19.5 (8.8)	18.1 (7.2)
Calcium (g)	407 (209)	740 (286)
Iron (mg)	7.3 (3.1)	9.4 (3.2)
Potassium (mg)	2120 (956)	2561 (788)
Vitamin A (ug)	752 (712)	876 (803)
Vitamin D (ug)	4.1 (3.5)	2.6 (1.9)
Vitamin E (mg)	7.1 (4.2)	
Vitamin C (mg)	78.9 (76.9)	

Abbreviations: EmER, estimated minimum energy requirement; EI, energy intake; SFA, saturated fatty acids; MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids, 5.3.4 Under-reporting of energy intake based on food record method:

Under-reporting at individual level as calculated with Goldberg's method, indicated one third of participants (n=4, 44%) classified as under-reporters of energy intake (EI). The estimated daily salt intake was substantially and significantly lower in under-reporters of energy intake as compared to the non- under reporters as per the results of independent samples T test (t_7= 5.025, p=0.002).

Table 5.5: Estimated salt intake in under reporters vs. non under reporters of EI

Group	**Estimated salt intake* (g/d)**	**P value**
Under reporters of EI (n, 4)	2.35 (0.9)	0.002
Non- under reporters (n, 5)	5.9 (1.1)	

**Values presented as Mean (SD); Abbreviations: EI, energy intake*

5.3.5 Short Food Frequency Questionnaire (SFFQ): All the SFFQ's food categories combined contributed more than half of the of daily salt intake (52%, 2.8 g/d) and the rest (48%, 2.6g /d) is accounted for salt naturally present in food and discretionary salt. This finding relates well with the observation that student participants recorded greater consumption of home prepared meals as per data from food records. Some of the examples of home-prepared foods recorded by the food record method include mayonnaise, kimchi, pancake, pasta, soups, rice- based dishes. The mean daily salt intake from each of the food category of SFFQ is presented in table. The percentage contribution of salt from SFFQ's categories indicated following as top categories: bread and roll (11.9%); salt- based rubs/seasonings (5.9%), cheese (5.3%), pizza (3.2%) and dine-out/takeaway main meals (4.7%). Marmite, meat substitutes and canned soups were amongst the most unpopular food for this study participant's group. Further review of frequency of intake of the popularly consumed food categories suggested that cheese and bread & roll were consumed mostly on weekly basis (1-6 time a week). All the participants reported eating out main meals and desserts though on monthly basis (1-3 times a month).

Table 5.6: Percentage contribution of salt from SFFQ's food categories

Food categories	Percentage salt contributed from each food category	Estimated daily salt intake from SFFQ's categories, n= 9		Participants with nil intake for each food category
		Mean	SD	n (%)
Bacon	2.6%	0.14	0.19	5 (45%)
Ham	0.4%	0.02	0.05	5 (45%)
Sausages	1.4%	0.07	0.08	4 (36%)
Cheese	5.3%	0.29	0.31	0%
Salted butter and buttery spreads	0.9%	0.05	0.07	4 (36%)
Marmite	0.1%	0.01	0.02	8 (73%)
Bread and rolls	11.9%	0.64	0.49	0%
Breakfast items	1.8%	0.10	0.10	3 (27%)
Baked beans in tomato sauce	2.3%	0.12	0.14	3 (27%)
Soups	0.8%	0.04	0.08	6 (55%)
Ready meals	3.0%	0.16	0.18	1 (9%)
Pizza	3.2%	0.17	0.26	2 (18%)
Bought Sandwiches	1.6%	0.08	0.09	2 (18%)
Pasta Sauces	2.3%	0.12	0.09	2 (18%)
Table sauces	0.9%	0.05	0.06	2 (18%)
Crisps	0.6%	0.03	0.05	4 (36%)
Salted Nuts	1.5%	0.08	0.14	4 (36%)
Savoury Biscuits/ Crackers	0.3%	0.02	0.03	3 (27%)
Meat Substitutes	0.4%	0.02	0.05	7 (64%)
Salt based rubs/seasonings	5.9%	0.32	0.45	2 (18%)
Eating out				
Starters	0.8%	0.04	0.0	1 (9%)
Main course	3.7%	0.20	0.2	0%
Dessert	0.2%	0.01	0.0	0%

5.3.6 Validity: The difference between mean salt intake estimated by 24h urinary sodium excretion and SFFQ; food record and SFFQ was not statistically significant as per the result of paired sample t test (p= 0.09, p= 0.13 respectively). Bland and Altman plot was used to evaluate the agreement between salt intake estimated by 24h urinary sodium excretion method and SFFQ for dietary salt monitor and the plot is depicted in figure 5.3a. The BA plot depicts bias of 1.5g/day, indicating that SFFQ underestimated salt intake of participant group as compared to urinary method. The upper agreement limit was 7.68 and the lower agreement limit was -4.72. All the measurement values were within these agreement limit.

The presence and direction of bias between the salt intake estimated by food record and SFFQ is shown in Figure 5.3b. The BA plot shows the bias of -1.1g/day agreement limits, indicating that SFFQ overestimated salt intake of participant group as compared to food records. The upper agreement limit was 4.5 and the lower agreement limit was -6.7. All the measurement values were within these agreement limit.

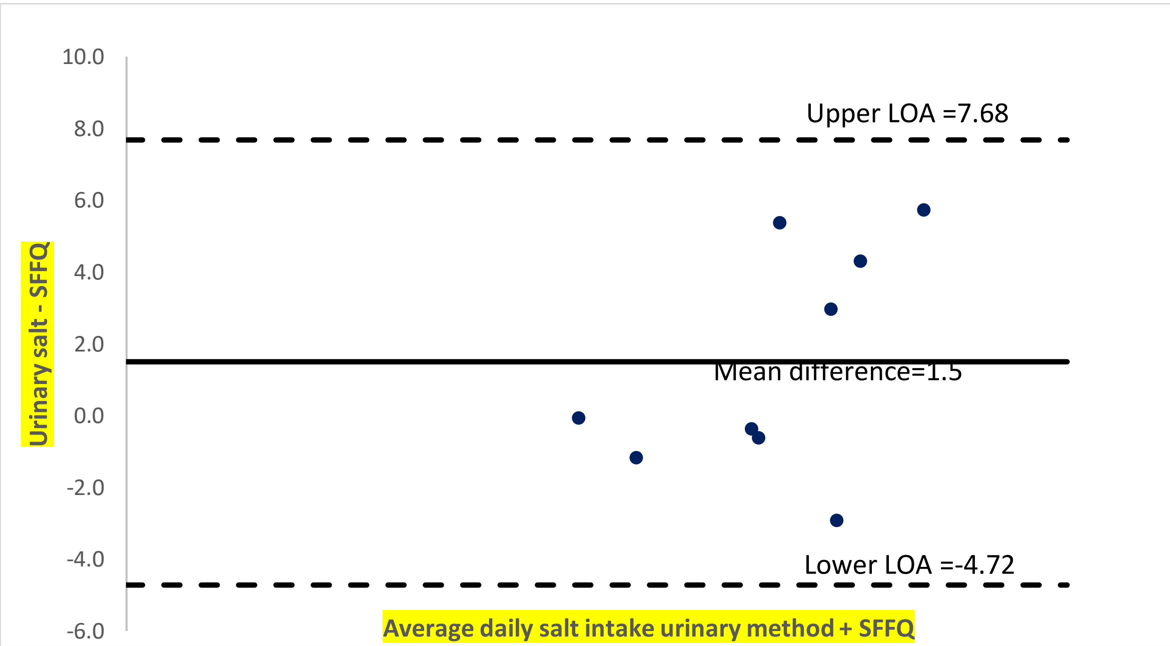


Fig 5.3a: The Bland-Altman (BA) plot showing differences in mean daily salt intake between urinary method and SFFQ against the average daily salt intake based on urinary method and SFFQ.

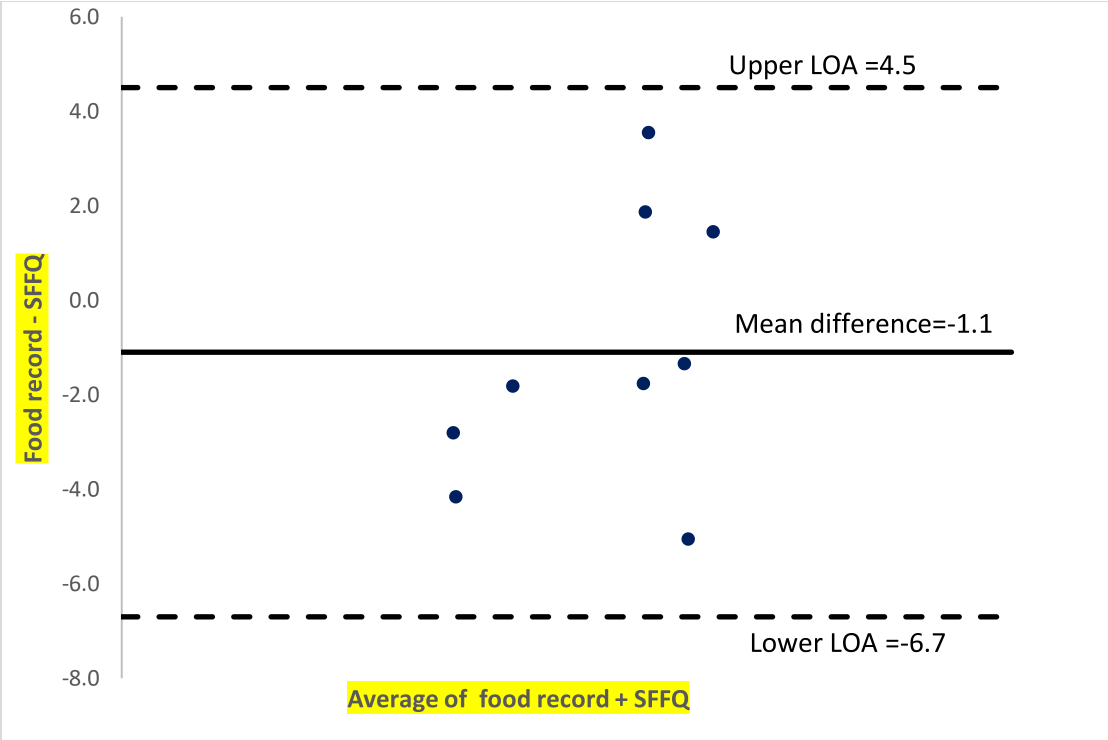


Fig 5.3b: The Bland-Altman (BA) plot showing differences in mean daily salt intake between food record and SFFQ against the average daily salt intake based on food record and SFFQ.

5.3.7 Cross-classification: Cross-classification analysis was applied to determine the agreement at individual level, considering the quartiles of the measurements. Twenty-two percent participant's salt intake from urinary method categorized in same quartile as SFFQ (see table 5.7a). Although majority (56%) of the participant's salt intake from urinary method classified into distant quartiles of SFFQ, only one participant was placed in opposite quartile (misclassified). The rate of misclassification was 33% for salt intake estimated between food record and SFFQ and is shown in table 5.7b.

Table 5.7a: Quartile correlation of salt intake from urinary sodium excretion method and SFFQ

Quartile difference	**n (%)**
Exact quartile	2 (22%)
Adjacent Quartile	1 (11%)
Distant Quartile	5 (56%)
Opposite quartile	1 (11%)

Table5.7 b: Quartile correlation of salt intake based on food record and SFFQ

Quartile difference	**n (%)**
Exact quartile	1 (11%)
Adjacent Quartile	4 (44%)
Distant Quartile	1 (11%)
Opposite quartile	3 (33%)

5.3.8 Correlation: The association between salt intake estimated by biomarker and dietary methods at individual level was checked by applying Pearson's correlation coefficient and the results showed a moderate negative correlation for mean salt intake estimated by 24h urinary sodium excretion method against SFFQ; food record and SFFQ (r= -0.45; r= -0.35 respectively, p>0.05), though this was not statistically significant. Thus, further analysis for validity coefficient for methods of triads is not performed as the correlations are negative.

5.3.9 Reliability: Alternate form reliability was considered based on the salt intake contribution by each food category based on these two dietary assessment methods- SFFQ and food record. However, it was observed that majority of the categories listed in SFFQ were not captured by food record method. Hence, correlation coefficient was computed for the following categories: bread and rolls (0.18) and a weak negative correlation reached for cheese and table sauces.

5.4 Discussion

Overview

This validation study has demonstrated the use of robust study design that included use of a biomarker (24h sodium excretion) as a reference method as well as food records collected for two days for validation of salt specific SFFQ, gathered from a total of 12 participants. The SFFQ method underestimated the daily salt intake as compared to the urinary sodium excretion method (5.4g/d and 6.9g/d respectively). The results of Bland and Altman method for agreement between SFFQ and urinary sodium excretion method suggested a bias of 1.5g/d but with wide limit of agreements (upper LOA 7.68 and lower LOA -4.72). Cross-classification between the SFFQ and urinary excretion method showed that 33% were categorised in the exact plus adjacent quartile, with a low level of misclassification (n=1, 11%). The data from food records was further analysed for energy under-reporting and it indicated that daily salt intake was substantially and significantly lower in under-reporters of energy intake Although, study has limitations due to a smaller sample size, the nutrition background of the study participants had been favourable to accurately gather data on portion size estimation for SFFQ and ensuring completeness of sample by self- claim. The further analysis of food records helped in determining the ethnic specific food that helped in revision of further description of each food category of SFFQ and extending wider applicability to the use of the dietary salt monitor.

5.4.1 Study design and participants: Measuring dietary salt intake is very challenging since it is widespread in all food items and due to greater inter and intra variability on day-to-day basis (McLean, 2017; Cook et al., 2020). Thus, this research's study design included use of a recovery biomarker (24h urinary sodium excretion) for validating daily salt intake estimated by the SFFQ component of dietary salt monitor. A two-day food record was used as an additional reference method to test relative validity of SFFQ and provided additional information on the diet quality. Such approach of triangulation techniques is recommended for validity testing (Ocke and Kaaks, 1997). Both dietary methods used in the present validation study rely on different source of measurement error. Food record method is prospective dietary assessment method and does not rely on memory; though information obtained through FFQ is based on long term memory (Ginos and Engberink, 2020).

Although, the sample size was relatively small and included only female participants, the ethnic diversity and nutrition background of the student's group was of interest for substantiating the high salt food categories finalised for SFFQ for UK population and feedback prior to its use as an educational tool. Furthermore, recruitment of only female participants with dietetic background had been previously reported in the Japanese validation study of 150 item FFQ for estimating salt intake against a single 24h urine collection (Murakami et al., 2012).

5.4.2 Estimation of dietary salt intake: The findings of this research's validation study reported SFFQ method underestimated the daily salt intake as compared to the urinary sodium excretion method (5.4g/d and 6.9g/d respectively). This tendency to underestimate is well known for FFQ's and had been reported in several validation studies with larger sample, testing validity of their FFQs against the urinary sodium excretion method as Open study, Energetics study, AMPM study, NBS and NPAAS (Freedman, 2015), DuPLO study (Trijsburg, 2015), and Food Choice at Work Study (Kelly, 2015).

The findings of Nutrition Biomarker Study for WHI 2004-2005 reported that geometric mean for sodium by urinary method (single collection) was 3263 mg/d (salt 8.15g/d) as compared to geometric mean of 2188 mg/d (salt 5.47g/d) for FFQ. This validation study's methods included single 24h urine sample collections and FFQ recording dietary intake for past three months, for a sample of 544 healthy women. The completeness of urine was checked using PABA or self-claim and total excretion was divided by 0.86 to account for loss of sodium through other routes as perspiration (Freedman, 2015). If similar principle is applied to the present research study, the mean percent difference in daily salt intake between the test method and biomarker is 8.5% as compared to 38% in a large scale WHI study. However, in present study the completeness of samples was solely checked based on self-claim by participants, thus the principle of 86% sodium excretion in urine is not suitable.

The recent study conducted for a French-Canadian population also reported underestimation of salt intake by combined research tools: Salty Food Frequency Questionnaire and Discretionary Salt Questionnaire against 24h urinary sodium excretion (6.7g/d against 9.1 g/d, n=164). This corresponds to a mean percent difference of 26.4% in estimated daily salt intake at the group level (Gallani., et al., 2020). In comparison, the mean percent difference between the dietary salt monitor and urinary excretion was 21.7%.

The salt intake assessed by food record method indicated greater underestimation as compared to SFFQ (DD 4.3g/d; Urinary Na 6.9g/ and SFFQ 5.4g/d). Under-reporting is widely common with the use of food record method (Mensink, Haftenberger and Thamm, 2001; Okubo et al., 2008) and especially the food groups perceived as socially undesirable (Strabburg et al., 2017). The recent literature has cited evidence that respondent led food records are subject to reactivity bias i.e., change of behaviour due to monitoring (Bredin et al., 2019). The Brazilian Longitudinal Study of Adult Health (ELSA-Brasil) reported similar findings where mean sodium intake estimated by food record method was lower as compared to FFQ (Pereira et al., 2016).

The dietary data was reviewed for misreporting especially for under-reporting of energy intake since sodium intake is highly correlated with total energy intake, due to its inclusion in a wide variety of foods (Whelton et al., 2012). The greater level of underestimation in salt intake as per the food record method was attributed to under-reporting of energy and therefore for salt, in a third of the present study's participant group. The Japanese Dietetic Students Study for Nutrition and Biomarkers also highlighted absolute intake of sodium was under-reported in under-reporters of energy intake (Murakami et al., 2012). Although participant's nutrition training was considered advantageous for accurate reporting of dietary data such as portion size estimate and specification of details for brand and ingredients of the meals consumed, their knowledge on nutrition and social desirability to be perceived as nutrition ambassadors, might also be the reason for under-recording of high salt foods. Such hypothesis was tested in a Japanese study where female dietitians compared with non-dietitians showed more severe under-reporting of sodium and author concluded it might be associated with their higher nutrition knowledge and health consciousness (Sugimoto et al., 2016).

Another important consideration is the difference in time frame of data collected from two measurement methods; SFFQ relied on dietary intake based on past year and food record was for two consecutive days, which could be atypical day/(s) for the respondents. A randomized dietary trial conducted a secondary analysis of 4-day food record (n= 2560) concluded that atypical days are common for food records and have a large impact on mean total intakes of most of the nutrients including sodium (Craig et al., 2000). The literature on dietary assessment methodology indicates that the estimates of food record increase as more days are recorded. In the EPIC-Norfolk cohort a 7-day food record showed closer values than FFQs to biomarkers for absolute intake of sodium (Day et al., 2001). Thus, the research evidence recommends inclusion of greater number of days for accurate estimation of salt intake based on food record method, but this was not feasible keeping in view respondent burden and unprecedented times of pandemic.

Although the high salt categories listed in SFFQ, are representative of the food contributing highest salt to the UK population (NDNS-year 7/8), the categories such as ham, sausages, ready meals, soups did not appear to be popular in diet of this participant group of nutrition students. However, it is beyond the scope of this research to ascertain if the lower intake of these food categories is predominantly due to under-eating owing to participant's higher level of awareness or dietary restraint or social desirability.

5.4.3 Validity testing: The correlation analysis computed for salt intake based on SFFQ and urinary sodium excretion method did not indicate any meaningful results. This could be due to very small sample size, feasibility as well as inherent errors associated with different assessment methods. Similar findings of negative correlation were observed for salt intake estimated by 138 item FFQ and average of two urine collections for a sample of 57 women volunteers in JPHC study (Sasaki, 2003). The results of several validation studies have highlighted the difficulty of measuring absolute salt intake using FFQ and showed weak correlation, even when multiple 24h recalls corresponding to the FFQ's data collection period and a large sample size were utilised (Charlton et al., 2008, Bedford and Barr, 2011). The EPIC Norfolk cohort study recruited 123 participants in United Kingdom for validation of salt intake estimated from 130 item FFQ against six collections of urine and reported a moderate correlation of 0.36 (Day et al., 2001).

The use of correlation analysis to validate a new measurement technique with an established one has frequently been questioned because such analysis does not measure agreement but assesses the extent of association between two variables (Bland and Altman, 1986). Therefore, Bland–Altman plots and cross-classification into quartiles of intake was used to better clarify the extent of agreement between the methods.

The results of Bland and Altman method for agreement between SFFQ and urinary sodium excretion method suggested a bias of 1.5g/d but with wide limit of agreements (upper LOA 7.68 and lower LOA -4.72). However, the wide limit of agreement is due to higher intra individual variation in salt intake as is characteristic of this nutrient and is reported in another validation study as 9.81 to-5.24 (Gallani et al., 2020). Thus, this intra-individual variability can greatly influence the ability to have strong agreement and validity of salt intake estimates from dietary methods. Also, the sodium excretion in the urine not only depends on intake but also on an internal fluctuating balance with sodium stores in the bones and the skin, and therefore may deviate from intake (Titze 2015; Rakova et al., 2017).

The results of cross-classification for salt intake estimated by SFFQ and biomarker highlighted lower level of agreement at individual level, as majority of the values were in distant quartile. Cross classification between the SFFQ and urinary excretion method showed that 33% were categorised in the exact plus adjacent quartile, with a low level of misclassification (n=1, 11%). In contrast, a misclassification rate of 29% was reported for a validation study of food frequency questionnaire estimating salt intake against the urinary biomarker (Gallani et al., 2020).

5.4.4 <u>Study strengths and limitations</u>: Although this study has several limitations, the strengths of SFFQ need to be considered keeping in view the objective and further use of this research's dietary salt monitor as an intervention tool. Firstly, it has been designed in consideration to the actual consumption patterns of individual with type 2 diabetes (detailed in chapter 4). It captures comprehensive data for estimating overall dietary salt intake from processed food categories, computation for discretionary use of salt, naturally occurring salt in food, contribution of salt from dining out, and accounts for the practice of using reduced salt food items. The SFFQ component highlights top contributors of salt in processed food category and supports nutritional messages as limiting the salt in cooking and at table; watch the salt whilst dining out and use of reduced salt foods, that are relevant to its objective of disseminating education for reducing salt intake in type 2 diabetic population.

Although errors in reporting portion size had been viewed as one of the limitations with respondent led dietary assessment methods (Thompson et al., 2015), this study's participant's education and training in nutrition field might have been useful for minimising such errors.

The study included urinary sodium excretion method as a reference method for validation of SFFQ based dietary salt monitor. However, it was not feasible to conduct this validation study in participants with T2DM population as sodium excretion is altered in many people with diabetes. A study conducted by Zhao et al. (2016) showed that there was a significant negative correlation between urinary sodium excretion and fasting blood glucose levels or HbA1c in diabetes patients. The author explained that the activation of adipose PPARd by high salt intake leads to natriuresis through increasing adiponectin mediated renal SGLT2 inhibition and this pathway is impeded in diabetes.

Since the findings of this study are based on highly selected population of female nutrition students, who had higher education level and greater knowledge of diet, the results cannot be extrapolated for the population with type 2 diabetes. But a careful review of data of food records, provided information for further refinement of SFFQ such as description of food categories to include examples of ethnic diverse foods (see details in chapter 6).

Another limitation of the study is that SFFQ was not tested for reproducibility since the principal use of this SFFQ based 'dietary salt monitor' is an educational tool. The literature has suggested completing the dietary assessment may draw respondent's attention to their diets (Cade et al., 2002) and thus, the checklist of high salt food categories used in dietary salt monitor to create awareness and reduce salt intake might pose a major restraint to the design of reproducibility study.

The completeness of urine sample was checked by participant's self-claim due to limitation to the use of PABA recovery and urinary creatinine excretion method. Two previous, multi-country population-based studies as Intermap and Intersalt, Cooperative Research Group (1988) also reported use of similar approach of checking completeness of 24h urine collection through comprehensive instructions and criteria for minimum accepted urine volume.

The study faced certain limitations in methodology due to COVID 19 pandemic. Although the laboratory analysis for urine samples was performed by each student participant for their respective sample under the supervision of a trained staff, inaccuracies in pipetting needs to be counted in as a measurement error. Similarly, face-to-face meetings would have been preferred over e-mail to resolve the queries related to the dietary data. Although, the best possible plan was developed to complete the research work, it is considered that these alterations might have impacted the measurement of salt intake in some respect.

5.5 Conclusion

In all, it is concluded that dietary salt monitor based on SFFQ showed some degree of validity at group level, despite small sample size. Further validation study needs to be conducted in a larger sample of participants with type 2 diabetes.

Chapter 6: A Pilot study to evaluate the use of a novel dietary salt monitor as a nutrition educational tool in T2DM.

Overview

Research studies have established evidence for the effectiveness of structured diabetes education in achieving optimal health targets, but the uptake of structured education programme is often met with varied challenges such as logistics, inability to attend face to face as well as lack of value associated with diabetes education. There is paucity of intervention studies targeting salt reduction behaviours in type 2 diabetes This marked the first intervention study in UK aimed at reducing dietary salt intake in type 2 diabetes and describes the design, implementation, and evaluation of this online educational tool. The intervention included a short education video highlighting the checklist for the food categories of 'dietary salt monitor', delivered online to 25 participants recruited through various social media platforms including Diabetes UK. The dietary salt intake was estimated at the baseline and at the end of 6 weeks using SFFQ component of dietary salt monitor. There was statistically significant and substantial reduction in median salt intake for the group, with baseline of 7.9 g/d shifting to 5.2 g/d post the intervention (p=0.001). The research findings also highlighted statistically significant reduction in the salt contribution from eight food categories as sausages, cheese, bread & rolls, baked beans, salted nuts, stock, gravy, and salt- based rubs & seasoning.

6.1 <u>Introduction</u>

6.1.1 <u>Nutrition education in Type 2 Diabetes</u>

Behavioural change communication refers to the use of communication strategies to promote the sustained adoption of a desired health behaviour or behaviours that may lead to positive health outcomes. Common means of this approach include interpersonal counselling, print and virtual educational method, and mass media campaigns (Kennedy et al., 2018).

Type 2 diabetes is a long-term medical condition that an individual predominantly self-manages. The management of type 2 diabetes encompasses a whole range of tasks that individual must perform to improve disease outcomes. Self-management has been defined as ‘the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a ‘long term disorder’ (Department of Health, 2005). For a long time, diabetes self-management education (DSME) has been an important component of the national medical care guideline and plays a major role in the medical attendance and treatment of people with T2DM (ADA, 2015; Deakin et al., 2012). National and international specialist societies recommend that type 2 diabetes patients take part in DSME programme (International Diabetes Federation, 2017; Powers, 2017). Structured and quality-controlled patient training courses are internationally approved procedures with a proven positive effect on health parameters as blood glucose control blood pressure and body weight. The clinical and cost effectiveness of structured education to improve diabetes management has been well-established (Norris et al., 2001; Jacobs-van Der Bruggen et al., 2009; Deakin et al., 2012).

Several studies have highlighted the importance of nutrition education interventions in T2DM for improving the health outcomes as HbA1c (Hornsten et al., 2008; Zareban et al., 2014; Moradi et al., 2019) and lipid levels (Loveman, Frampton and Clegg, 2008; Rodriguez et al., 2009) and blood pressure (Trento et al., 2020; Muchiri, Gericke and Rheeder, 2021). Thus, well designed health education advocacy and awareness creation programme for positive lifestyle changes should be promoted in this population (Askari, Rabiei and Rastmanesh, 2013; Muchiri, Gericke and Rheeder, 2016). Such programme are often carefully planned and interwoven into theories of behaviour change. The NICE guidelines have summarized key behaviour change theory that could be useful for promotion and adoption of healthy eating behaviours (NICE, 2007) and are summarized in table 6.1.

Table 6.1: Theories of behaviour change

Theory	Authors	Highlights/ Definition
Resilience and coping	Lazarus and Folkman, 1984; Antonovsky, 1987	Antonovsky argued that there are 'health-giving' or 'health-generating' factors in many situations, and these factors help people to respond to stress and difficulties. Lazarus argued that people develop habitual ways of coping with life. Behaviour change and readiness to change behaviour takes place in this context.
Habitus	Bourdieu, Pierre and Passeron, 1977	Bourdieu argued that many of the things that people do and believe are so familiar and habitual that they go largely unnoticed, making change difficult.
Social capital	Putnam, 2001; Morgan and Swann, 2004	Social capital is commonly defined as those features of a society, such as networks, social trust and cohesion. These factors might influence health behaviours and people's ability to change.
Society	Giddens, 1979	Society was the product of interaction between individual human behaviour and the social structure. Human actions or agency produce societal patterns.
The Theory of Planned Behaviour (TPB)	Ajzen,1991; Bandura, Freeman and Lightsey,1999	Intention is the main determinant of action and is predicted by attitude, subjective norms and perceived behavioural control (PBC). PBC is a person's perception of whether they can control their actions and is closely related to Bandura's construct of self-efficacy. PBC and self-efficacy are likely to bolster intentions and sustain action.

6.1.2 Diabetes education programme in United Kingdom: In UK, the standards for diabetes education have been set by the Diabetes UK Patient Education Working Group in collaboration with the Department of Health (Diabetes UK Patient Education Working Group, 2005). Structured patient education is recommended by NICE for everyone with T2DM (and/or their carers) at and around the time of diagnosis (Poduval et al., 2022). Diabetes UK and NICE recommend that education programme should have a structured written curriculum, be evidence-based, theory-driven, and have specific aims and objectives (NICE, 2015). There are several structured education models with variations in mode of delivery, course duration and follow-up as Diabetes

Education for Ongoing and Newly Diagnosed Diabetes (DESMOND) (Davies et al., 2008), X-PERT (Deakin et al., 2006) and the Diabetes Manual (Sturt et al., 2008). DESMOND intervention was one of the first programme to meet the quality criteria for education programme that are listed by the Department of Health and Diabetes UK Patient Working Group, 2005. This programme has been recommended by NICE as a validated education programme for people with type 2 diabetes in the UK since 2008. It is currently available in 103 health organisations across the United Kingdom, Republic of Ireland, Gibraltar, and Australia, with 735 trained educators. DESMOND has a theoretical and philosophical base; the programme supports people in identifying their own health risks and responding to them by setting their own individualized behavioural goals. The programme consists of a six-hour face-to-face education session delivered by two trained educators over one day or two half-days to a group of 8–12 people with newly-diagnosed or ongoing type 2 diabetes.

Although a previous study evaluating the effectiveness of DESMOND programme reported no significant difference in HbA1c but significant difference in health belief scores was achieved at 12 months (Davies et al., 2008) and sustained at three years (Khunti et al., 2012). A more recent study reviewed the outcomes of participants who attended a DESMOND course delivered by Leicestershire and Rutland (LLR) clinical commissioning groups. The study results demonstrated statistically significant HbA1c reductions are achievable at 6 months and 12 months in people with newly diagnosed or ongoing type 2 diabetes. Further results for qualitative evaluation indicated that the DESMOND programme was well received by participants who felt empowered and upskilled to manage their diabetes more effectively (Chatterjee et al., 2018). MyDESMOND has been designed to support self-management through digital means in the modern world. It is a responsive website that can be used on phone, tablets, and computers as a stand-alone product, as well as a follow-on from group programme.

X-PERT structured education programme consists of six weekly sessions lasting 2.5 hours that are delivered by healthcare professionals who are trained as diabetes educators. The X-PERT programmes include X-PERT Diabetes, X-PERT Insulin and X-POD (Prevention of Diabetes). These programmes are designed to increase participant's knowledge, skills, and confidence to make informed decisions and self-manage their condition (Deakin, 2012). The findings of a randomized controlled trial reported statistically significant improvements in the X-PERT patients compared with the control patients for body weight, BMI, waist circumference, total cholesterol, self-empowerment, diabetes knowledge, physical activity levels, foot care, fruit and vegetable intake, enjoyment of food and treatment satisfaction (Deakin et al., 2012).

6.1.3 Barriers to the uptake of structured diabetes education

Although the scale of implementation of structured education for type 2 Diabetes is huge, with 80 commissioning groups running the DESMOND programme and a similar number running the X-PERT programme across UK, the uptake of these programme has been rather low (Sturt et al., 2008; Deakin et al., 2012). The findings of the recent National Diabetes Audit highlighted that nearly 90% of patients with T2DM were offered structured education but only 16% of those were recorded to have attendance at the education program (National Diabetes Audit, 2021). A systematic review of the reasons for non-attendance to diabetes education programme, revealed two broad categories of non-attenders. The first category comprised of the patients who were unable to attend due to social or logistical reasons, whilst the second category comprised those who chose not to attend or perceived no benefit in doing so (Horigan et al., 2017). It is imperative that the healthcare community, responsible for delivering quality care mobilizes efforts to address the barriers and explores resources for DSME to meet the needs of adults living with and managing type 2 diabetes (Powers and Marrero, 2016). Also, it is highlighted that structured education through face-to-face interventions are not always accessible. Digital behaviour change interventions have emerged as accessible, effective alternatives to face-to-face interventions (Pinder et al., 2018).

There is substantial evidence on the effectiveness of diabetes structured education programme on improving glycaemic control, as these programs are focused on metabolic control and handling of anti-diabetic agents (Hassanein et al., 2021). Structured hypertension education program for people with type 2 diabetes and hypertension (SHED study) is one of the first and seemingly only UK study that demonstrated the role of structured education program led to significantly higher percentage of participants achieving the BP target, early after intervention, together with a significant reduction in the number of antihypertensive pills.

The intervention included weekly group education sessions covering areas as dietary advice to reduce salt, weight reduction, medication adjustment and home-based blood pressure monitoring. The education programme confirmed the significance of lifestyle approach including dietary salt reduction in management of hypertension in patients with T2DM.

6.1.4 Nutrition education interventions for reducing dietary salt intake in T2DM

There is dearth of research studies evaluating the role of nutrition education for reducing salt intake in type 2 diabetes. To the best of researcher's knowledge, there has been no nutrition education intervention studies undertaken in United Kingdom, aimed solely at lowering dietary salt intake in individuals with type 2 diabetes. The recent studies investigating the role of nutrition education focused on salt reduction in T2DM conducted in Japan, are summarised here.

The findings of a single-arm trial conducted in Japan by Ushigome et al., 2019 indicated that instructions on dietary salt restriction by a registered dietitian to the patients with T2DM was beneficial in reducing dietary salt intake and home blood pressure. In this study, daily salt intake was significantly reduced by 0.8 g at 2 months and 0.7 g at 6 months. Moreover, morning systolic blood pressure was significantly reduced by 2.7 mmHg at 2 months and 5.8 mmHg at 6 months after the instruction.

Another nutrition education intervention study with a randomized controlled trial design, included 200 patients with T2DM from the diabetes clinics in Japan. This trial tested a new intervention to assess whether guidance on dietary salt restriction provided by physicians during outpatient visits is effective in reducing salt intake in these patients. The control group was only given routine treatment. There was significant change in estimated salt intake in both control and intervention group (-0.6g/d and -0.9g/d respectively) and no significant differences between the groups (Oyabu et al., 2021).

Thus, the findings of both studies confirmed the positive outcomes of nutrition education for achieving salt reduction in type 2 diabetes. This signifies the importance of culturally tailored nutrition education interventions for at -risk population. Therefore, such interventions need to be carefully planned to match the theme of national salt reduction strategy.

UK had been one of the first countries across the globe, to set an example of successful salt reduction programme as reported by a statistically significant shift in population's salt intake from 9.5g/d in 2000/2001 to 8.6g/d in 2008 (Wyness, Butriss and Stanner, 2011). However, there has not been further progress in population's salt intake based on urinary sodium excretion results for the last decade (Ashford et al., 2020), owing to lack of food industry's further progress in achievement of salt targets for many food categories (Public Health England, 2018b) and non-appearance of consumer awareness campaigns on varied aspects of salt reduction since FSA's last campaign in 2003 (Zandstra, Lion and Newson, 2016). Although research studies including experimental and real-life settings have suggested the role of education on interpretation of FOPL's in improving the selection and purchases of healthier products (Hersey et al., 2013; Talati et al., 2017; Ikonen et al., 2020; Temple 2020); its usefulness as an intervention strategy for salt reduction is limited due to lack of consistent scheme and voluntary approach.

Thus, in view of the existing challenges faced by national salt reduction strategy, and health risk associated with high salt intake in T2DM (McGurnaghan et al., 2019) and overwhelming burden of CVD management on healthcare, a nutrition education intervention targeting salt reduction in this vulnerable group is essential. Especially in the absence of a blood biomarker or measurement device that can accurately measure salt intake, the use of consumer-friendly tools for estimating salt intake could aid consumer awareness (Zandstra, Lion and Newson, 2016). Thus, the researcher aims to review the effectiveness of a novel 'dietary salt monitor' as a comprehensive nutrition educational tool to impart knowledge, improve dietary choices, and monitor salt intake of individuals with T2DM.

6.2 <u>Research aim and objectives</u>

Aim: To evaluate the use of 'dietary salt monitor' in reducing dietary salt intake in T2DM.

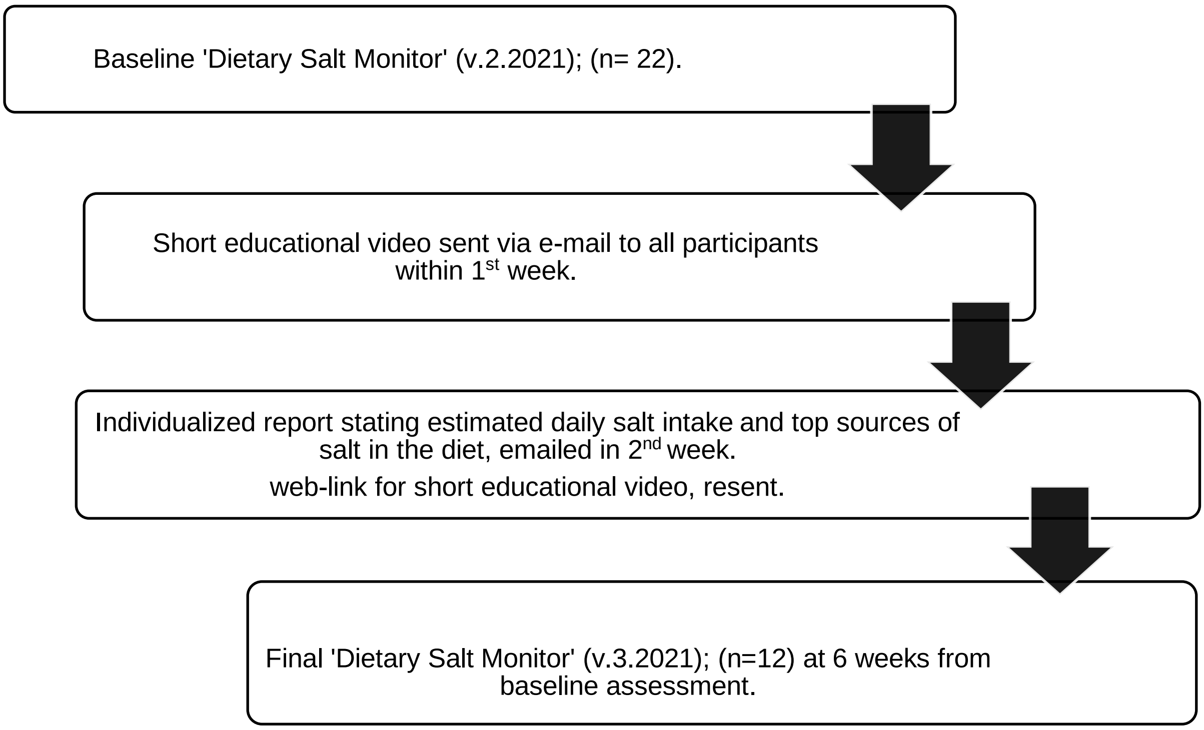
Objectives:

- To estimate the dietary salt intake of the type 2 diabetes participants.
- To determine the contribution of salt from the food categories.
- To determine the net change in overall salt intake in participants after the intervention.

6.3 Methodology

6.3.1 Study design and process: The design of this study was a quasi-experimental study, and the participants completed the dietary salt intake at the baseline and 6 weeks after the intervention. The study process describing the timelines and flow of participants is illustrated in figure 6.1.

Figure 6.1: Study process for ‘Dietary salt monitor’ intervention study



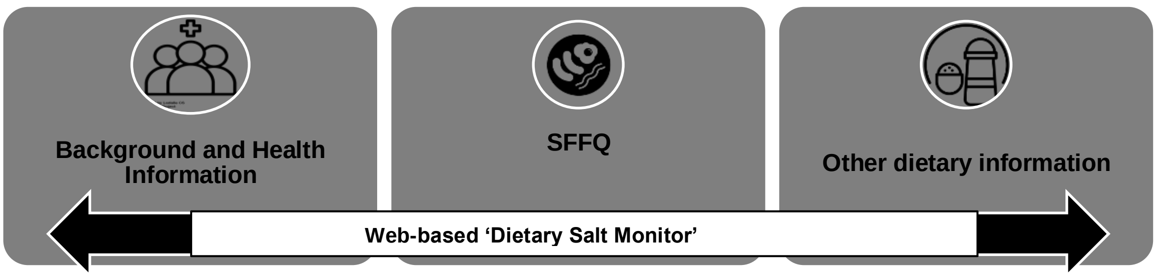
6.3.2 Recruitment of participants: The research participants were recruited using an anonymous online survey via the online platform Google forms. The webform for baseline dietary salt monitor was converted to a web link (Bit.ly/T2DSFFQresearch) and posted along with an invitation message to the digital media platforms as Facebook and What’s app groups. The research invitation message was also posted on Diabetes UK website (Appendix O). The participants were recruited online from March 2021 to April 2021. Other avenues as Diabetes Research and Wellness Foundation (DRWF) and consultant endocrinologist running private diabetes clinic at Nuffield Health, Chester was explored but the application request was not successful. All adults with type 2 diabetes were invited for participation except for those already on salt restricted diet due to any medical condition.

6.3.3 Study interventions: The study interventions included a web-based dietary salt monitor, an educational video supporting its messages and individualized report on baseline estimated salt intake. The 'dietary salt monitor' (v1.2020) used in the validation study was further modified to be used as a comprehensive tool for both data collection and nutrition education for this intervention study. Both the design and content were enhanced to cater to the virtual participants and study objectives.

6.3.4 Further refinement of 'Dietary Salt Monitor'

'Dietary salt monitor' was embedded in the google-form, for its use as a web-based tool for baseline and final assessment. The key components included in it are illustrated in the figure 6.2

Figure 6.2: Key components of web-based 'Dietary Salt Monitor'



The sections on background and health information were incorporated to gather data on study participant's characteristics. The demographic information included age, gender, ethnicity along with self-reported weight and height. The section on health information had questions on length of diabetes, co-existence of high blood pressure, use of medications for managing both conditions and prior attendance to diabetes education course.

The questions on food habits, use of salt in cooking and table, use of herbs and spices in low or no salt recipes, interpretation of FOP and BOP label, and practice of reading menu whilst dining out were restructured under the section - other dietary information. The additional question regarding awareness on FoodSwitch app was included in this section. It is a smartphone app that can scan the barcodes of packaged food and presents its nutritional information using MTL colour coded scheme for nutrition labels. FoodSwitch UK was developed by leading independent nutrition research groups as

Action on Salt, Sugar and Health, The George Institute for Global Health and Medical Research Council Elsie Widdowson Laboratory. A research paper published in the journal 'Clinical Medicine' mentioned it as a useful resource for patients as well as healthcare professionals, seeking dietary salt reduction (Suckling and Swift, 2015).

6.3.5 Further refinement of SFFQ

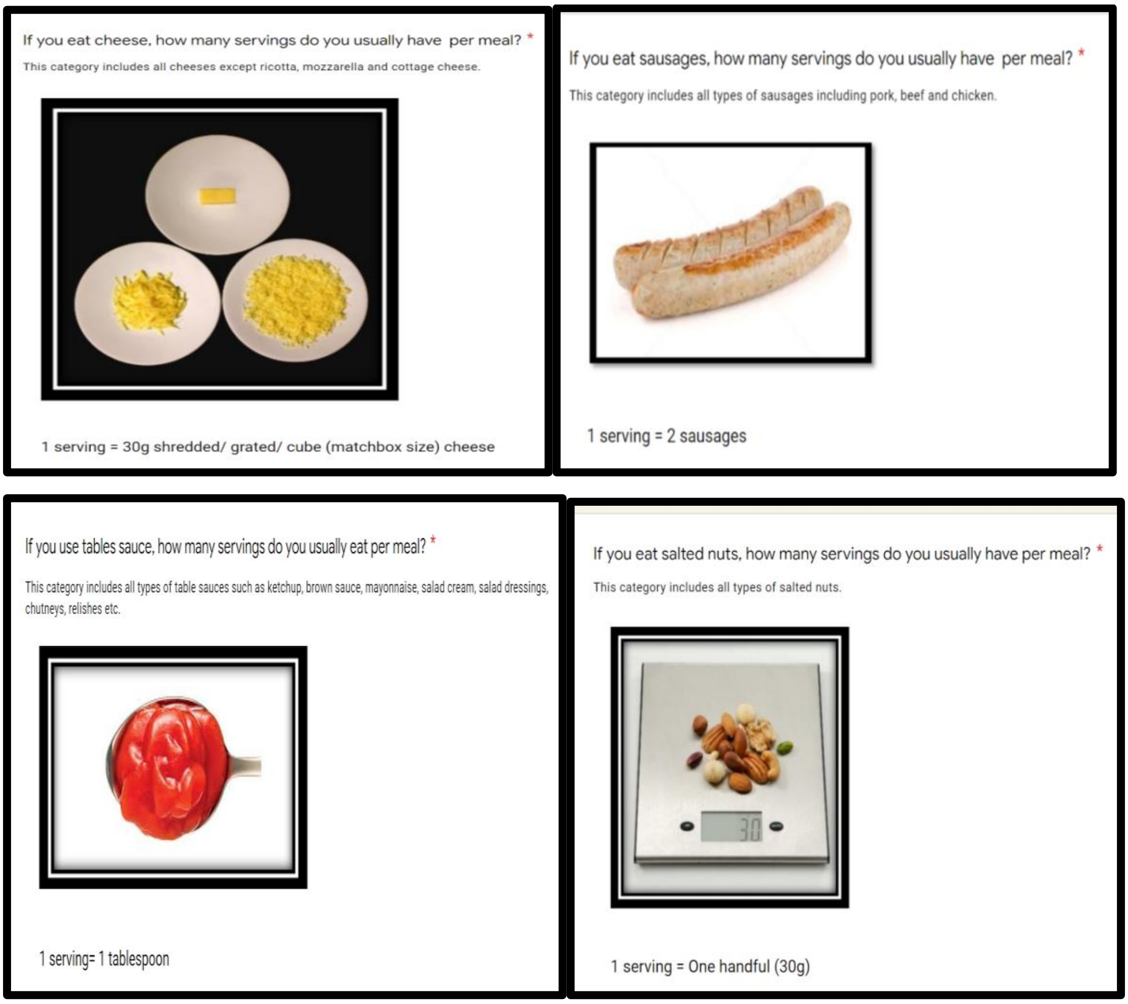
6.3.5a Food categories description: Based on the feedback of ethnic diverse participants of the validation study, description was included for each of the food categories along with the examples of ethnically diverse food items as naan bread and pitta in bread & rolls category; Indian cooking sauce, Chinese stir-fry sauce, Thai curry sauce in cooking sauce category; chutneys in table sauce category and Bombay mix in crisps category.

6.3.5b Additional food categories: Three new food categories included are other processed meats, gravy, and stock. These food items got missed in the first version of 'dietary salt monitor' (v.1.2020) used for the validation study. Other processed meats categories included items as meat loaf, tinned fish in brine, pate, corned beef slices, smoked fish etc. The median value for serving size of the varieties of processed meat except bacon,ham and sausages was computed as 49g (IQR 40-100). The median salt content of other processed meats category was 1.8g/100g (IQR 1.3-2.0). Smoked salmon in this category had highest salt density (3g/100g) whereas tinned tuna in brine had lowest salt density (0.7g/100g). Smoking prolongs shelf life, enhances flavour, and give it characteristic colour. Although this process contributes to the relative increase in the concentration of nutrients, including crude protein and reduced the fat content, the use of brine prior to fish smoking increased the sodium content (Kiczorowska et al., 2019). Stock and gravy were missed as these categories were picked up as miscellaneous by Nutritics software. Although stock and gravy did not contribute substantially to the overall daily salt intake of participants with T2DM (for details see Chapter), both categories were considered relevant for the purpose of nutrition education on dietary salt. Both these ingredients are used as an addition/ accompaniment for regular meals and potentially increase overall salt content of the dish. As per NDNS year 7 and year 8 survey, stocks ranked as 15th top contributor of sodium in the diet of UK population.

The size of stock cube was not consistent across brands, so we referred to Nutritics software and it indicated 1 stock cube as 10g. For Gravy, we used 50ml as a standard serving based on demographic average stated in Nutritics and as referenced from the FSA, 2002The GB15 database from Nutritics was referred to calculate median salt value for various varieties of stock and gravy, and it was 2.1g per standard serving of 250ml of stock (as consumed) and 0.4g salt per 50ml of gravy. Building upon theme “More Flavour, less salt’’ for 2021 Salt awareness week’ by Action on salt, we aim to track the salt contributed by this category and encourage use of no added salt and gravies.

6.3.6 <u>Photographs and serving size</u>: A photograph depicting approximate ‘serving size’ of the representative food in each of the food category was chosen, as an aid for participants to quantify their usual serving per meal. An example of photographs for some food categories are shown here in figure 6.3

Food photographs depicting serving size of food categories



6.3.7 Frequency of consumption: The earlier version of dietary salt monitor (v.1.2020) used three categories as daily/ weekly/ monthly, and the numerical values indicating frequency option had to be entered by the respondents (see details in Appendix I). Keeping in view, the virtual interface and varied literacy level of participants for this nutrition education intervention, the options for frequency of consumption were revised. The options for frequency of consumption were adapted from the EPIC- FFQ and are as follows: never/ 1-3 month/ once a week/ 2-4times a week/ 5-6 times a week/ once a day/ 2-3 times a day. It was assumed that tick mark selections for one of the seven categories will ensure user-friendliness and precise estimation of dietary salt intake (Appendix L).

The web-based dietary salt monitor was further adapted for its use in final assessment of the participants (v.3.2021, see Appendix M). The sections on background information and health information were deleted and the rest sections were re-phrased to estimate changes in intake of food categories over the past one month.

6.3.8 Development of educational video on practical tips for reducing salt intake

An educational video was developed as a supplementary resource, highlighting the food categories listed in dietary salt monitor and other nutritional messages related to dietary salt intake. The PowerPoint presentation for this short educational video was audio recorded (approximately 8 minutes of length), converted to a shareable web link (Bit.ly/reducingsaltintake) and emailed to all the participants completing the baseline assessment and registering interest for further information.

Rationale: The topics for this presentation were informed by the research conducted on KAP related to dietary salt intake in participants with T2DM (Babber and Bhakta 2020). The health and nutrition messages delivered through this video were well researched and addressed the key barriers to adoption of dietary salt intake guidelines. The summary of key messages supported by the scientific evidence, is presented in table 6.2. A copy of all the slides for this educational video is available in Appendix P.

Summary of evidence for the development of key messages of educational video

Slide no. & Title	Key message	Reference
Slide 2 Type 2 diabetes and dietary salt intake	Prevalence of hypertension is high in T2DM. Dietary salt reduction is vital for managing high blood pressure in T2DM	Suckling et al., 2010 Suckling et al., 2016 Grossman and Grossman, 2017 Petrie, Tomasz and Touyz, 2018
Slide 3 How much salt is too much?	Recommended daily salt intake in T2DM is <6g/day.	Evert et al., 2014 Based on Diabetes UK, Evidence based dietary guidelines for T2DM Dyson et al., 2018.
Slide 4 Sources of salt in diet	In UK, majority of salt in diet comes from processed foods.	As per the recent NDNS survey published by Public Health England, 2018a Mhurchu et al., 2011
Slide 5 Checklist: Top sources of salt	23 food categories listed in dietary salt monitor as top sources of salt	Babber and Bhakta, 2020 Based on the results of NDNS survey 2014/15 & 2015/16 and the categories selected for salt targets published by Public Health England, 2018a
Slide 6 Steps for reducing dietary salt intake	4R's for lowering salt intake Reduce portion Reduce frequency of intake Reduced salt food products Read Nutrition Label	McLean et al., 2012 Zhang et al., 2017 Mork, Lahteenmaki and Grunert, 2019
Slide 7 Reduced salt food products	Interpretation of 'reduced salt' claim	As stated in document guidance for nutrition claims by FSA, 2016
Slide 8 Nutrition Label interpretation	Interpreting salt content on FOP and BOP labels	Guidance document on understanding nutrition labels in UK developed by FSA, 2016
Slide 9 Healthy swaps	Salt swaps as a strategy to reduce dietary salt intake. Examples of salt swaps were illustrated.	Riches et al., 2019
Slide 10 FoodSwitch App	How to use SaltSwitch app for ensuring healthier shopping basket. Link for downloading FoodSwitch App	Eyles et al., 2017 Supported by actiononsalt.org.uk
Slide 11 Tips to reduce salt in cooking	Use of herbs and spice to enhance flavour of low or no salt food, Signposting low or no salt recipes	Ghawi, Rowland and Methven, 2014; Anderson et al., 2015 Available on actiononsalt.org.uk
Slide 12 Eatwell guide	Re-enforcing holistic approach for reducing salt intake: Healthy eating and active lifestyle	As recommended by PHE, 2016 Levy and Tedstone, 2017

The emphasis of this educational video was to highlight the checklist of all the food categories of ‘dietary salt monitor’ as illustrated in figure. Most of these food categories were identified as top contributors of salt in the diet of participants with T2DM (Babber and Bhakta, 2020). Some of these food categories are not ‘high in salt’ as per the nutrition label thresholds and appears ‘amber’ on MTL - FOP label, though is a top contributor to salt intake such as bread and rolls. Other categories as portion of baked beans and canned soups are on higher end of ‘medium salt content’ threshold. The frequent consumption of such food items can add up to the overall salt intake and thus needs to be consumed in a balanced approach. This checklist could be used as an important reminder for categories with medium salt density, that could not be identified by MTL - FOP schemes and often not recognised as important contributor to dietary salt intake (Sarmugam and Worsley, 2014; Gray et al., 2014)

Figure 6.4: Slide 5 of educational video highlighting the food categories as high salt density (red) or medium salt density (amber)

The macro-nutrient profiling including energy, fat, saturates, sugar, carbohydrates, and protein for the food categories of 'dietary salt monitor' was reviewed, alongside the salt content. The recommendations for salt swaps were developed keeping in consideration that the message of an overall healthy eating choice is reinforced to the participants (refer table 6.3 and slide 9 in Appendix P).

Table 6.3: Analysis of key nutrient profile of food categories of 'dietary salt monitor'

Median nutrients values reported for each food category; *nutrient threshold per standard portion is considered for the interpretation of label 'red'-high; 'amber'-medium and 'green'- low, in nutrient content

Food Categories	Nutritional Composition per 100g #						
	Energy (Kcal)	Fat (g)	Saturates (g)	Sugar (g)	Salt (g)	Carbohydrates (g)	Protein (g)
Bacon	228	18.5	6.8	0.0	2.8	0	16.5
Ham	132	5	1.7	0.8	2.6	0.8	21
Sausages	283	23	7.9	0.9	1.8	4	13.7
Other processed meats	184	10.9	2.2	0.4	1.8	1	18.3
Cheese	381	31.5	20.5	0.1	1.7	0.1	24.1
Salted butter and buttery spreads	228	18.5	6.8	0.4	1.6	0.8	18.3
Marmite	180	0.4	0	1.6	10.8	3.3	41
Bread and rolls	240	2.7	0.6	2.8	1.0	42.8	9.2
Breakfast items	228	4.1	0.8	3.6	1.0	40.3	6.8
Baked beans in tomato sauce	78	0.4	0.0	4.7	0.7	13.4	5.1
Soups	43	1.4	0.2	1.4	0.7	6	1.4
Ready meals *	144	2.0	2.0	7.4	0.6	15.15	5.7
Pizza*	257	8.6	0.0	3.0	1.0	31.5	12.2
Bought Sandwiches	234	10.2	1.3	2.1	0.9	23.1	10.7
Pasta Sauces	47	1.4	0.2	4.8	0.8	6.5	1.5
Table sauces	141	9.2	0.0	9.5	1.9	13.9	1.3
Crisps	497	29.6	10.1	1.2	1.7	51.6	6.3
Salted Nuts	605	53.2	8.8	4.6	1.1	11.6	19.2
Savoury Biscuits/ Crackers	434	2.6	4.6	9.1	1.1	60.6	14.4
Meat substitutes	171	8.5	0.9	1.2	1.2	6.6	16.1
Stock	205	16	0.0	0.0	42.0	0	14.4
Gravy	423	16.1	10.7	5.0	13.0	65	4.4
Salt based rubs/seasonings .	256	4.8	0.7	10.0	18.0	38.5	7.7

6.3.9 Individualized report on estimated daily salt intake: All the participants were emailed a report on of their estimated daily salt intake, stating their baseline estimated daily salt intake and top sources of salt in diet. This report reinforced the message of reducing dietary salt by comparing their usual intake with the limit of ‘6g/day’ (see Appendix P).

6.3.10 Pilot testing**:** The study’s intervention tools were pilot tested in February-March 2021 with a group of 19 participants including lay-person and nutrition students. The feedback on the clarity of language, design, functioning, and practical use was sought, and amendments were incorporated prior to its use with study participants.

6.3.11 Data collection: The participants completing baseline ‘dietary salt monitor’ were assigned a research number based on their order of completion. The data was carefully reviewed for duplicate entries and the last entry made by the participant was considered and retained. The responses for each section of baseline and final ‘dietary salt monitor’ were reviewed by the researcher and participants were contacted via email to check for any missing information or other queries. For cases, where email was not responded by the participant following assumptions were made. If serving size information was missing but the frequency of consumption was marked, the serving size was assumed as one standard portion. Where serving per meal of any food category was marked as ‘nil’ but the response to ‘use of reduced salt variety’ was marked ‘yes’; it was auto-corrected as ‘no’. The summary sheet for the participants completing the baseline and final ‘dietary salt monitor’ was generated as per the functions of google form and downloaded as excel sheet and used further, for data analysis.

6.3.12 Data analysis: For anthropometric data, self-reported height and weight measures were used to calculate BMI and categorise the participants as per the International and Asian specific BMI cut offs as detailed in Chapter 2. The blood pressure readings reported by the participants were compared to the treatment target of <140/ 90 as defined by NICE, 2019.

The dietary salt intake (baseline and at 6 weeks) was estimated using ‘Excel worksheet’ for dietary salt monitor (v2.2021) and the detail of computation with working example is available in Appendix P.

6.3.13 Statistical analysis: The data analysis was carried out using IBM SPSS Statistics (version 27). The study participant's demographics, health information and data on dietary practices related to salt were analysed using the descriptive statistics. The distribution of all continuous data was checked for normal distribution. The gender-based difference in the estimated daily salt intake for the overall study sample was analysed using independent sample t test.

The characteristics of the participants in study completion group was compared to drop out group. For the continuous variables as age, BMI, length of diabetes and estimated salt intake, distribution of data in each group was checked for normality. Independent sample T test was applied to determine if the mean difference in age and BMI between two groups was statistically significant at $p<0.05$. sample. Levene's tests were used to assess the variance of participant age and BMI. Mann Whitney U test was used to determine if the mean difference in length of diabetes and estimated salt intake in two groups was statistically significant at $p<0.05$. For the categorical variables as gender, ethnicity, prevalence of hypertension, attendance at diabetes education course and other dietary practices, Fisher's exact test was used to see whether the proportions of one variable are different depending on the value of the other variable, at $p<0.05$.

The difference in the estimated total daily dietary salt intake of the group (baseline to 6 weeks) was tested for statistical significance using Wilcoxon signed rank test at $p<0.05$. For small samples ($n<23$), Exact test using the Legacy Dialogs method for Wilcoxon is used and the exact sign (2-tailed) p value is reported to conclude if there is statistically significant difference for the results observed. Further, effect size was calculated to determine the magnitude of difference in salt intake post the intervention. The formula used for calculating effect size is as follows, dividing the absolute (positive) standardised test statistic z by the square root of the number of pairs. The interpretation of effect size was based on Cohen's classification of effect sizes which is 0.1- small effect, 0.3-moderate effect and 0.5 and above, large effect (Cohen, 1988). The difference in median salt intake from the processed food category at the group level was tested for statistical significance using two sample paired sign test. This test was applied since one of the assumptions for Wilcoxon test as symmetry of distribution was violated. The group difference in salt intake from the eating out category and discretionary plus naturally occurring salt, was tested for statistical significance using

Wilcoxon signed rank test. For testing the difference in the median salt content from each of the twenty-three food categories (baseline to 6 weeks) Wilcoxon signed rank test at p<0.05 was applied.

The difference in the number of participants adhering to daily salt limit of 6g at the baseline as compared to 6 weeks was tested using McNemar's test at p<0.05.

6.4 Results

6.4.1 Study participant's characteristics: A total of twenty-two participants completed the baseline 'dietary salt monitor' and a summary of the study participant's demographic characteristics and health information is depicted in table 6.4a & 6.4b indicating majority of the participants were male and of white ethnic origin. The mean (SD) age of the participant's group was 51.2 (10.2) years, and the mean BMI value was 31.6 kg/m2. The classification of each study participant as per WHO or Asia Pacific BMI cut offs indicated that majority 73% of the participants were obese, followed by 23% as overweight and rest 4% as normal weight. Obesity was much more widespread in men as compared to women in this study participant group (83% and 60% respectively). Also, the use of ethnicity specific BMI cut offs in the present study corrected misclassification of 9%, (n=2) of the Asian participants from normal weight to overweight and another 9% from overweight to obese.

The average duration of T2DM for the group was 5.3 years and all the participants reported managing their diabetes with medications. Forty-five percent of the study participants reported hypertension as a co-morbidity and prevalence of hypertension was higher (50%) in men as compared to women group (40%). All the hypertensive participants stated taking medications for managing their blood pressure. Only 50% of the participants reported their blood pressure readings; mean SBP and DBP for the group is shown in table. More than a quarter of the participants (27%, n=3) had systolic blood pressure above the NICE treatment target of <140 mm/Hg and 18% (n=2) had diastolic readings above the target of <90mm/Hg.

Table 6.4a: Demographic characteristics of study participants at baseline

Variable	Sub-category	All (n=22) n (%)
Gender	Male	12 (54.5%)
	Female	10 (45.5%)
Ethnicity	White	13 (59%)
	Asian	9 (41%)

Table 6.4b: Baseline age, anthropometric and health status of study participants

Variable	All (n=22) Mean (SD)
Age (yrs.)	51.2 (10.2)
Weight (kg)	88.8 (19.8)
Height (m)	1.67 (0.09)
BMI (kg/m^2)	31.6 (6.0)
Length of Diabetes (yrs.) [a]	5.3 (4.2)
SBP (mm/Hg) [b]	133 (11.7)
DBP (mm/Hg) [b]	82 (8.1)

Abbreviations: BMI, Body mass index; SBP, Systolic blood pressure; DBP, Diastolic blood pressure [a] n= 21 due to missing data, [b] n=11 due to missing data

6.4.2 Baseline estimated dietary salt intake: The baseline mean (SD) daily salt intake for the participant group was 8.4 (2.9) g/d as presented in table 6.5. The gender-specific data for mean estimated daily salt intake indicated that intake was higher in men than women participant (NS). The mean salt intake from the broad categories is depicted in table and indicates majority of the dietary salt is contributed from the processed foods (66.7%), followed by naturally occurring salt (19%), discretionary use of salt (11.5%) and eating out (3.8%).

Table 6.5: Baseline estimated daily salt intake of study participants

Categories	Estimated salt intake (g/d) Mean (SD)		
	Men (n=12)	Women (n=10)	Total (n=22)
Processed foods*	5.7 (2.7)	5.4 (2.8)	5.6 (2.7)
Eating out*	0.28 (0.1)	0.37 (0.31)	0.32 (0.2)
Discretionary use of salt^	0.87 (0.8)	1.1 (0.38)	0.97 (0.6)
Naturally occurring salt^	1.7	1.4	1.6 (0.15)
Total daily salt intake	8.6 (3.0)	8.2 (3.0)	8.4 (3.0)

*No significant differences were observed between men & women group (p>0.05); ^ salt intake contribution from these categories is computed based on assumption of average UK population intake reported by NDNS survey (detailed in chapter 4)

6.4.3 Non-adherence to recommended level of salt intake in T2DM: Majority (86%, n=18) of the study participants had baseline salt intake above the recommended limit of 6g/day. The gender specific data indicated that non-adherence to the recommended salt intake was high in both groups (83.3% and 80% in men and women respectively). Notably, all the participants with co-morbid hypertension had their baseline salt intake above the recommended level.

6.4.4 Top sources of salt at baseline dietary salt assessment: Amongst the twenty-three high salt food categories under the processed foods, processed meat (bacon, ham, sausages, tinned fish etc.) contributed 20% of the total daily salt intake, followed by breakfast items (9%); soups and stock accounted for 8% each; bread & rolls (7%); 5% of salt contributed each from baked beans, ready meals, pizza, salt-based rubs/ seasonings and 4% of the salt contributed each by cheese, sandwich, crisps, salted nuts.

6.4.5 Baseline dietary practices of the study participants: The baseline dietary practices for the study group are described in table. Majority of the participants identified themselves as meat-eater (73%), followed by flexitarian (18%) and the rest (9%) as vegetarian. The use of salt during cooking seems a common practice in this group as compared to adding salt at table (68% and 32% respectively). Only 18% of the participants reported not adding salt both in cooking and at table. Majority (82%) of the participants reported the use of herbs and spices to improve the flavour of low or no salt food. Nearly a third of the participants (32%) stated not using 'reduced salt' variety for any of the 23 high salt food categories. The food categories that were most popularly consumed as 'reduced salt variety' were baked beans (57%), soups (50%), butter & spreads (42%), ready meals (30%), pasta sauces (24%) and table sauces (22%). Forty-one percent of the participants reported not reading salt content on nutrition label while shopping for food. Majority (77%) of the participants stated not reading menu to identify low salt options.

Table 6.6: Baseline dietary practices of the study participants

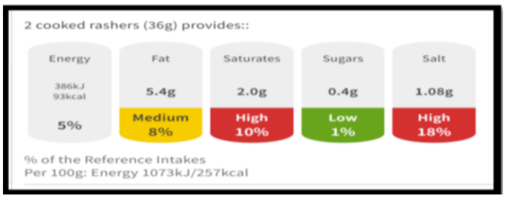
Dietary Practices	**Responses**	**All (n=22) n (%)**
Food Habits	Meat-eater	16 (73%)
	Flexitarian	2 (9%)
	Vegetarian	4 (18%)
Use of salt in cooking	Yes	15 (68%)
	No	7 (32%)
Use of salt at table	Yes	7 (32%)
	No	15 (68%)
Use of herbs and spices in low or no salt food	Yes	18 (82%)
	No	4 (18%)
Uptake of 'reduced salt' food	Yes	15 (68%)
	No	7 (32%)
Reading salt content on the nutrition label	Yes	13 (59%)
	No	9 (41%)
Reading menu to identify low salt options	Yes	5 (23%)
	No	17 (77%)

6.4.6 Baseline knowledge of salt content on nutrition label indicated that a greater number of participants are confident in interpreting FOP traffic light label as compared to BOP nutrition label (see table 6.7).

Table 6.7: Baseline knowledge on interpretation of salt content on nutrition label

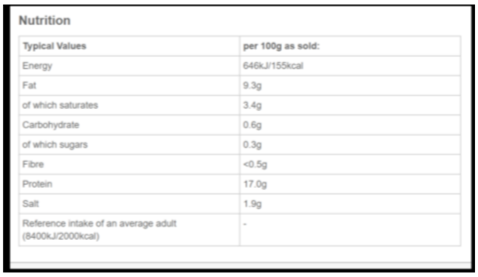
Nutrition label reading	**Responses**	**All = 22 n (%)**

If this FOP label indicates high salt content?



	Yes	20 (91%)
	No	1 (4.5%)
	Do not Know	1 (4.5%)

If this BOP label indicates high salt content?



Nutrition

Typical Values	per 100g as sold:
Energy	646kJ/155kcal
Fat	9.3g
of which saturates	3.4g
Carbohydrate	0.6g
of which sugars	0.3g
Fibre	<0.5g
Protein	17.0g
Salt	1.9g
Reference intake of an average adult (8400kJ/2000kcal)	-

	Yes	13 (59%)
	No	6 (27%)
	Do not Know	3 (14%)

Abbreviations: FOP, front of pack; BOP, back of pack

6.4.7 Awareness on FoodSwitch app: The study investigated the participant's awareness and practice of using FoodSwitch app for healthier alternatives and the findings revealed that none of the participants used this app. However, more than half of the study participants (59%) stated that they 'don't know about FoodSwitch'.

6.4.8 Effectiveness of the study intervention: The study completion rate was 55% as only twelve participants completed both baseline and final dietary salt monitor. The characteristics of the participants who completed the study is compared to dropouts (see table 6.8) and there was no significant different in any of the variables between these two groups. The study completion group included predominantly male participants (67%); majority of Asian ethnicity (58%); mean age 49.9 (SD 8.4) years; mostly obese as represented by mean BMI of 31.5 (SD 5.9) kg/m^{2}. and of Asian origin (58%). The data for co-morbidities indicated higher prevalence of hypertension in the study completion group as compared to the drop-out group (58% and 30% respectively, p=NS). And the practice of reading salt content on the label was more popular in the study completion group as compared to the dropout group (75% and 40% respectively, p=NS).

Table 6.8: Baseline characteristics of the participants who completed the intervention study and dropouts

Variable	Sub-category	Study completion group (n=12)	Dropout group (n=10)
Gender, n (%)	**Male**	8 (67%)	4 (40%)
	Female	4 (33%)	6 (60%)
Ethnicity, n (%)	**White**	5 (42%)	8 (80%)
	Asian	7 (58%)	2 (20%)
Age (years), Mean (SD)		49.9 (8.5)	52.7(12.2)
BMI (kg/m^2), Mean (SD)		31.5 (5.9)	31.7 (6.5)
Length of T2DM, Median (IQR)*		3(3)	5.5 (8.3)
Hypertension, n (%)	**Yes**	7 (58%)	3 (30%)
	No	5 (42%)	7 (70%)
Attendance at diabetes education course, n (%)	**Yes**	4 (33.3%)	4 (40%)
	No	8 (66.7%)	6 (60%)
Estimated daily salt intake Median (IQR)		7.9 (2.9)	8.5 (5.2)
Adherence to daily salt limit of $\leq$6g/day, n (%)	**Yes**	2 (16.7%)	2 (20%)
	No	10 (83.3%)	8 (80%)
Adding salt during cooking, n (%)	**Yes**	9 (75%)	6 (60%)
	No	3 (25%)	4 (40%)
Adding salt at table, n (%)	**Yes**	3 (25%)	4 (40%)
	No	9 (75%)	6 (40%)
Read salt content on label while shopping, n (%)	**Yes**	9 (75%)	4 (40%)
	No	3 (25%)	6 (60%)

Abbreviations: BMI, body mass index; IQR, interquartile range; *n=11 due to missing data, no significant differences were observed (p>0.05)

6.4.9 Monitoring dietary salt intake in participants with T2DM: The research findings indicate statistically significant reduction in median salt intake for the group, with baseline of 7.9 g/d shifting to 5.2 g/d post the intervention (p=0.001). Further data analysis highlighted downward trend for the number of participants consuming salt above the recommended 6g/d limit post-intervention as compared to baseline (42% and 83% respectively, p= 0.03). Notably, majority of the dietary salt reduction achieved from the processed food categories (see table) as indicated by reduction of 2.8g/d corresponding to 61% decline in salt intake within a relatively short duration of 7.7 (SD 2.8) weeks. None of the participants had their salt intake above 6g/d solely accounted from processed foods at post-intervention as compared to a third of participants at the baseline. There is a slight decrease in the estimated salt intake from eating out occasion, but this was not statistically significant.

Table 6.9: Changes in estimated dietary salt intake at baseline and post-intervention (6 weeks)

Categories	**Estimated daily salt intake, n=12 Median (IQR)**		**Difference from baseline, g/d (%)**	**p value**	**Effect size**
	Baseline	**6 weeks**			
Processed foods (g)	4.6 (2.8)	1.8 (3.1)	-2.8 (-61%)	0.001	0.6
Eating out (g)	0.25 (0.2)	0.23 (0.2)	-0.02 (-8%)	NS	0.17
Discretionary use of salt + naturally occurring salt in food, (g)	2.6 (1.3)	2.9 (1.3)	+0.3 (+10%)	NS	0.20
Total daily salt intake (g)	7.9 (2.9)	5.2 (3.1)	2.7 (-34%)	0.001	0.6

The salt content from each of the 23 processed food categories showed downward trend except bacon and marmite and the median difference in salt content of these categories from baseline to 6 weeks is depicted in table 6.9. There is statistically significant decrease in salt contribution from the following eight categories as sausages, cheese, bread & rolls, baked beans, salted nuts, stock, gravy, and salt-based rubs & seasoning.

Table 6.10: Change in dietary salt contribution from 23 food categories, post the intervention

Food Categories	Baseline salt intake (g/d) ^	Final salt intake (g/d) ^	difference (g/d)	p value
Bacon	0.06 (0.35)	0.06 (0.94)	0.000	0.72
Ham	0.02 (0.54)	0.00 (0.19)	0.018	0.12
Sausages	0.08 (0.87)	0.02 (0.14)	0.06	**0.02**
Other processed meats	0.03 (0.11)	0.05 (0.12)	-0.023	1.00
Cheese	0.07 (0.36)	0.05 (0.04)	0.018	**0.03**
Salted butter & buttery spreads	0.05 (0.14)	0.02 (0.05)	0.030	0.11
Marmite	0.0 (0.0)	0.0 (0.0)	0.000	0.32
Bread & rolls	0.39 (0.64)	0.11 (0.34)	0.281	**0.03**
Breakfast items	0.07 (0.66)	0.02 (0.19)	0.048	0.35
Baked beans in tomato sauce	0.15 (0.72)	0.09 (0.19)	0.063	**0.04**
Soups	0.08 (0.82)	0.04 (0.16)	0.040	0.06
Ready meals	0.11 (0.15)	0.0 (0.15)	0.110	0.34
Pizza*	0.21 (0.14)	0.0 (0.18)	0.210	0.07
Bought Sandwiches	0.03 (0.19)	0.0 (0.19)	0.027	0.44
Pasta sauces	0.06 (0.11)	0.02 (0.13)	0.045	0.35
Table sauces*	0.06 (0.20)	0.05 (0.12)	0.005	0.51
Crisps*	0.26 (0.32)	0.06 (0.21)	0.193	0.06
Salted nuts*	0.12 (0.28)	0.02 (0.04)	0.094	**0.01**
Crackers*	0.05 (0.11)	0.02 (0.05)	0.030	0.16
Meat substitutes	0.04 (0.20)	0.00 (0.04)	0.036	0.07
Stock	0.06 (0.29)	0.00 (0.11)	0.055	**0.03**
Gravy	0.06 (0.28)	0.03 (0.06)	0.034	**0.02**
Salt based rubs	0.14 (0.93)	0.0 (0.0)	0.140	**0.02**

^ Median and interquartile ranges are presented except for food categories with* are presented as Mean with standard deviation.

6.4.10 Improvement in other dietary practices from baseline to post intervention: The number of participants reading menu to choose lower salt options increased from 33% at baseline to 50% post the intervention. The uptake of food items with reduced salt claim increased from 20% at the baseline to 35% at post assessment. More than a third of participants reported switching to reduced salt variety food in each of the following food categories rub/seasonings, crackers, pasta sauces, meat substitutes and salted nuts. There was a slight upward shift in the use of herbs and spices in cooking to enhance the flavour of low or no salt recipes, as the number of participants adopting the practise increased from 75% at baseline to 83%. The knowledge on interpretation of salt level on nutrition labels showed improvement for both FOP and BOP labels (92% to 100% and 58 to 67% respectively). Although, none of the participants were aware of FoodSwitch application at baseline, 58% of the participants indicated their willingness to use the app in future, post the intervention.

6.4.11 Study participant's feedback on the study intervention: Half of the participants completing the study (n=6) shared their feedback on use of dietary salt monitor and supporting educational video. Following were the comments of the participants:

"Informative and reminds me to keep a track of my overall salt intake in my diet"

"It was very straight forward. In fact, good part is at least personally, I don't usually see the salt content on the food package (see usually only sugars). So, it does make one to start looking at salt content too."

"Very useful"

"I have found this very useful and have consciously tried to reduce salt intake to improve my wellbeing."

''Informative''

"Have been helpful"

6.5 Discussion

6.5.1 Overview

This is UK's first nutrition education intervention study using a novel dietary salt monitor for reducing dietary salt intake in type 2 diabetes participants. The baseline data on the estimated salt intake of all the study participants indicated poor adherence to salt intake recommendations in T2DM. The study findings showed that more than a third (34%) of salt was removed from the diet of type 2 diabetes participants at the end of intervention period. Majority of the salt reduction resulted from the processed food category. There was significant reduction in salt contribution from eight food categories including sausages, cheese, bread & rolls, baked beans, salted nuts, stock, gravy, and salt-based seasonings. The study group also benefited from improvements in other dietary practices related to salt intake as increased uptake of reduced salt food, reading menu, appropriate interpretation of salt content on nutrition label and increased awareness on FoodSwitch app for choosing healthier alternatives. The feedback of the participants on the use of dietary salt monitor and educational video was positive.

6.5.2 Study interventions: Inclusion of photographs representing a 'standard serving' for representative item from each food category, aided portion size calculation for estimation of habitual intake for this online intervention study. The use of photographs for food consumption assessment has long been described in various studies (Nelson, Atkinson and Darbyshire, 1996; Robinson et al., 1997; Huybregts etal., 2007). A systematic review of validation and comparison studies on portion size estimation elements (PSEEs) conducted by Amoutzopoulos et al. (2020) concluded that food image based PSEEs were more accurate than food models and household utensils.
An audio -recorded short educational presentation reinforcing nutritional messages of dietary salt monitor, could be downloaded, and used as ready reference for use at any given time by the respondents. This could have been instrumental in adopting various measures to reduce dietary salt intake. Also, the key strategies addressing dietary salt reduction provided flexible approaches '4R's (**R**educing portion/ **R**educing frequent intake, **R**educed salt food, **R**ead nutrition label) instead of solely focusing on list of foods to avoid.

6.5.3 Study sample characteristics: The demographic characteristics of the study participants highlighted male preponderance for T2DM. Such trend for gender differences in T2DM is a known risk factor and underlying mechanisms are explored in many research studies (Aregbesola et al., 2017 and Nordstrom et al., 2016). The proportion of men and women in the present study matches to that of cohort of National Diabetes Audit (Holman et al., 2021a). The mean age and BMI of the participants of the present study is consistent with that of participants from DiRECT trial that were representative of wider diabetic population with shorter duration of diabetes (Taylor et al., 2018). The prevalence of obesity and overweight was very high in this study group (96%) as compared to the prevalence rate (85%) reported in National Diabetes Audit report 2017-2018. This could be attributed to substantial number of participants from Asian ethnicity, enrolled in this study.

Higher number of Asian participants is not consistent with national or area specific ethnicity rate as the recruitment was from social media avenues and might have attracted more Asians due to high level media attention and awareness on COVID risk and mortality in Asians with type 2 diabetes and hypertension. Higher number of Asians as compared to the participants from white ethnicity completed the study, probably due to similar reasons. Prevalence rates for hypertension in present study was lower than prevalence rate (45% and 57%) reported in DiRECT trial (Taylor et al., 2018) and could be attributed to reliance on self-reported data, in absence of access to health records. The adherence rates to systolic blood pressure targets for the present study participants are in consistent with the report of National Diabetes Audit (Holman et al., 2021b).

6.5.4 Baseline salt intake and dietary practices: A majority of the participants had their salt intake above the recommended daily limit of 6g. This contrasts with the findings of our preliminary study with diabetes participants from Diabetes foot clinic (see chapter 3), where non-adherence to salt recommendation was 27%. The greater proportion of people with non-adherence to salt guidance might be due to difference in the age group of participants in both study (mean age 51.2 years compared to 61.7years for preliminary research study). Also, the research tools for estimating salt intake differs in two study, dietary salt monitor for the present study as compared to use of single 24h recall method used in preliminary research.

The practice of using salt at table was less frequent as compared to use of salt in cooking amongst the participant group. This practice is consistent with general practice indicating declined use of saltshakers in UK households following public health campaigns by FSA and Department of Health (Sutherland et al., 2013). The knowledge of appropriate interpretation of salt content FOP label was higher as compared to interpreting BOP labels. This finding is well supported by the evidence suggesting consumer's better understanding and interpretation of FOP Traffic light labels (Herpen, Hieke and Trijp, 2014) as compared to BOP labels.

6.5.5 Effectiveness of dietary salt monitor: The result of the present study highlights the usefulness of dietary salt monitor intervention in reducing salt intake in T2DM. This short-term intervention was designed for a single nutrient dietary modification and focused primarily on the processed foods high in salt. The research evidence supports the approach of offering education on salt content in food as it may have more bearing on health outcomes (Trevena et al., 2015). Also, such an approach is of more value in western countries as majority of the dietary salt comes from processed foods. In contrast to the results of present study reporting an estimated 2.9g/d of reduction in salt intake at 6 weeks from baseline, the results of salt education intervention study conducted in Australia by Petersen et al. (2013) reported no changes in mean urinary sodium excretion at 3 months. This intervention relied on a single session of nutrition label education to choose products <120 mg sodium/100 g food. Non-achievement of positive outcomes for salt reduction might be attributed to intervention's sole focus on nutrition label education for choosing low sodium foods. Also, the author acknowledged the limited availability of low sodium foods, in Australian food supply. Another relevant consideration is the evidence that sodium is not the top nutrient of interest on labels for this at-risk population (Grunert, Wills and Fernandez – Celemin, 2010; Tierney et al., 2017). Also, the time associated with identifying foods has been reported as one of the barriers for non-adherence to low salt diet (Ireland, Cliffton and Keogh, 2010). Also, the use of dietary salt monitor for estimating salt intake was beneficial to capture the changes in dietary intake for the entire intervention period as compared to a single 24h urine collection used for determining salt intake during three months of the intervention in Australian salt education study.

Another intervention study conducted by Ushigome et al. (2019) concluded the nutrition education delivered by registered dietitian was successful in significantly reducing salt intake (by 0.8 g at 2 months and 0.7 g at 6 months) and lowering SBP by 2.7 mmHg at 2 months and 5.8 mmHg at 6 months for Japanese participants with type 2 diabetes (n=37). This intervention included a 30-minute session for recording baseline diet and a modified diet plan with dietary salt restrictions, was handed over to each participant. The daily salt intake was measured using spot urine sample. The author highlighted that 59% of the study participants taking antihypertensive medications showed lower reduction in salt intake as compared to the rest and this might have impacted the overall daily salt intake reduction for the group. In present study, salt intake was estimated using dietary salt monitor and the results were not affected even when all the participants were on antihypertensive medications.

A large-scale intervention study with randomized control design was recently conducted in Japan and the education included physician delivered sessions on salt restriction for type 2 diabetic patients (n=200). The study reported a significant reduction in salt intake of 0.9 g (from 10.1 to 9.2 g, p = 0.001) in the intervention group and 0.6 g (from 10.1 to 9.5 g, p = 0.029) in the control after 8 weeks, although there was no significant differences between them (p = 0.47). The author stated that the salt intake results were provided to both the group and that could be the reason for decline in salt intake for the control even though no education was given (Oyabu et al., 2021). A similar approach of providing individualized report for each participant's estimated daily salt intake, top sources of salt and suggestions for salt reduction was also included as part of the intervention for the present study.

Both Japanese studies reported less favourable results in terms of salt reduction (7.9% and 8.9% respectively) even though baseline salt intake (10.1g/day) was higher as compared to the participant's intake in the present study. The comparison of the present intervention study to the Japanese studies emphasised many strengths of the dietary salt monitor intervention, that accounted for its successful implementation in type 2 diabetes. It highlighted the practicability of using dietary salt monitor for periodic monitoring of salt consumption as compared to expensive and cumbersome methods as urinary sodium excretion assays that have inherent limitations for use in patients with type 2 diabetes (Baqar et al., 2020; Zhao et al., 2016).

The present study's nutrition education messages focused on creating awareness on salt contribution from a concise list of 23 food categories, were helpful in reducing excessive salt from processed foods. The intervention resulted in a significant reduction in salt intake from eight of these food categories sausages, cheese, bread & rolls, baked beans, salted nuts, stock, gravy, and salt-based seasonings. This is an important finding in context of the challenges faced by food industry for further salt reduction in some food categories especially processed meats with respect to safety and sensory considerations (Inguglia et al., 2017; Kim et al., 2021). Dietary salt monitor showed a great potential for use as a practical and suitable strategy for salt reduction with larger population, especially in the present scenario where the salt reduction targets for several food categories are not met (Public Health England, 2018b) and FOP label are not consistent across the business and not even mandatory (Packer et al., 2021).

Even though majority of the reduction in salt intake was accounted from processed food category, the research design did not capture information on alternatives chosen by participants. But in theory, cutting down the portion or frequency of intake of these food categories as processed meats, butter, cheese, ready meals, pizza would translate into reduction of calories, total fat, saturated fat as well. The educational video intervention used for the present study also reinforced 'Eat well guide' beyond the message of lowering salt intake as a keystone for managing hypertension as well as type 2 diabetes. However, it would be interesting to capture changes in uptake of other food groups as fruits and vegetables; determine the impact of salt reduction on overall diet quality and future studies in this aspect are needed.

6.5.6 Study limitations: Although there had been many strengths of the present study there are several limitations of this pilot study. The study participants were self-referred and so may have been more motivated to engage than the average person with type 2 diabetes. Importantly, the attrition rate of this online intervention was high (45%), and though the primary outcome measure of dietary salt reduction was achieved, is for the small number of highly motivated participants and thus, cannot be generalized to the larger diabetic population. High attrition of 49% was reported in other observational studies of chronic diseases as suggested by systematic review and metanalysis of 17 app-based intervention studies (Meyerowitz-Katz et al., 2020). Another study investigating adherence to a web-based intervention to support diabetes self-management indicated that web-based trials should plan for a 50% dropout rate in the first month of the intervention (Wangberg, Bergmo and Johnsen

2008). Though certain intervention studies in T2DM reported lower dropout rates as 20%, it was inferred that studies with randomized controlled design had lower attrition as compared to observational studies (Holmen et al., 2014; Meyerowitz-Katz et al., 2020). It is also assumed that the high attrition rates seen with 'dietary salt monitor' intervention, might be related to the administration of the study during unprecedented times of Covid-19 pandemic to some extent. It is speculated that participants had commitments that required more attention than continuing participation for this intervention. Similarly, lack of perceived importance of dietary salt reduction in T2DM might be the reason for higher number of dropouts. Some of these reasons can be dealt with the improvement in the study design such as recruitment of participants through primary care and delivering the intervention in partnership with the healthcare staff. Healthcare settings can create awareness on importance of lifestyle intervention such as dietary salt restriction for preventing and managing hypertension in Type 2 diabetes population.

This study was originally planned to be conducted one to one with the type 2 diabetic participants, to be enrolled from Diabetes clinic, Basildon Hospital but the study design was adapted, for its online implementation during pandemic. Due to limited study resources, a basic free version of Google form was used to conduct the research online. The scientific literature argues that online study lacks immediate opportunity to ask questions, are perceived as less obligatory and participants experience less sense of relatedness (Lie et al., 2017). For future use, these limitations can be dealt to a large extent by enhancing the function and design of web application providing user-interface.

A pre-post study design was adopted since a randomized control trial with adequate number of participants for a good statistical power was not feasible during the COVID pandemic. Sinch the research study was implemented online during pandemic, outcome measures were limited to improvement in salt related dietary practices and health parameters as blood pressure readings, glycated Hba1c, lipid profile; repeat anthropometric measurements were not recorded to avoid participant burden and in view of lack of involvement of the healthcare team in study design. Similarly, questions on demographics were limited to the basic information as age, gender, and ethnicity.

The dietary salt intake was assessed using FFQ component of dietary salt monitor instead of urinary sodium excretion method since it is expensive and has limitation for its use with diabetic population (Baqar et al., 2020; Ushigome et al., 2019; Zhao et al., 2016). Although the use of three-day food record along with the use of dietary salt monitor could have increased respondent burden, it might stand useful to determine impact of salt restriction on improving overall quality of diet for future research studies.

6.6 Conclusion: Although this was a small pilot study with limited scope, the results of dietary salt reduction in type 2 diabetes participants were encouraging and highlights their acceptance of advice on dietary salt restriction. In future, a large-scale randomized control trial with a long-term follow up of participants is needed, to determine if this approach for salt reduction could be sustained and can have impact on managing as well as prevention of high blood pressure and thus, a reduced CVD risk. The positive feedback of the study participants about the ‘dietary salt monitor’ implies its potential as a self-monitoring web-based tool (mobile app) for monitoring their salt intake in partnership with their healthcare team.

Chapter 7: Summary and Recommendations

The present research study has successfully addressed an important yet understudied topic ‘dietary salt reduction in T2DM’. The overall methodology employed a comprehensive plan for identifying key issues related to non-adherence to dietary salt recommendation, development of a novel dietary salt monitor- a tool to address the identified barriers and further validation study. This research also accomplished the objective of reducing salt intake in diabetes population, by using the dietary salt monitor as an educational intervention tool. Through different phase of this research study, the researcher has been able to gather data on dietary practices related to salt intake across the broad age groups as older adults with longer duration of onset of T2DM in phase 1 and a younger participant group with relatively new diagnosis of diabetes from more ethnic diverse population in phase 4. This study has been useful to explore a large gap in translation of nutrition guidelines related to salt intake, that is central to nutritional management of T2DM and significant for prevention as well as treatment of CVD in this vulnerable group. Nationally, this tool can be used as an educational resource for Diabetes workshop/ structured diabetes education programme for creating awareness on ways to reduce dietary salt intake in T2DM. The methodology for the development of this tool could be adapted in future research studies, for its application at international level. The study has limitation in terms of smaller sample size, that is not representative of overall population of type 2 diabetes, careful considerations have been reviewed for its applicability and is discussed specific to the respective study phases.

7.1 Overview

7.1.1 Phase 1: Identification of barriers in adherence to dietary salt intake in T2DM

Chapter 3 entitled ‘Knowledge, attitudes and dietary practices related to dietary salt intake in T2DM’, highlighted the poor achievement of health targets as blood pressure as well glycaemic control of those with dual burden of diabetes as well as hypertension. Although this participant group had been living with these health conditions for a fairly longer time (more than a decade) and have had ample opportunities for interface with varying HCP, focus on salt reduction had not been strengthened as much as other of nutrients. Most participants reported interest to inspect sugar as compared to salt content on FOP food labels (78% and 24% respectively) despite good knowledge to interpret salt content on FOP labels. Such prioritisation seems to come from greater emphasis on dietary guidance ‘to reduce sugar and sugary drinks/foods’ as 92% of the participants indicating receipt of such advice as compared to only 58% receiving advice on limiting salt. Also, the awareness on daily salt limit of $\leq$6g, was completely missing. This observation is notable in the context, that limiting salt intake is key part of ‘healthy eating’ advice for diabetes patients with or without hypertension. The mean KAP score for this study participant’s group was 22.6 (SD 6.1) corresponding to 56.5% score, explaining the key gap areas to be addressed for improving self-efficacy. Food as bread, cheese, pickle, biscuits, and ketchup were not recognised as ‘salty’, however take-away meals were recognised as ‘high in salt’ by nearly all respondents (96%). This correlates well with the fact that practice of takeaway or dine-out was not popular. Although home-cooking was preferred option for this study group, lack of awareness on salt content of ingredients and disinterest in reading label, had potentially masked the nutritional benefits of home cooked meals. The lack of knowledge on various aspects of dietary salt consumption might be implicated in poor self-perception for salt intake as only 8% (n=4) recognised their salt intake as ‘far too much’ as compared to 28% consuming >6g/d as estimated by 24h dietary recall method. To the best of researcher’s knowledge, this is the first UK study exploring various aspects of dietary salt intake in T2DM. Although the treatment guidelines for diabetes have clearly demonstrated positive shift from glycaemic control to CVD risk management, there is scarcity of research investigating the beliefs and practices related to dietary salt intake, despite its clear and substantial role in reducing CVD risk. The main limitation of this study is the relatively small and homogeneous sample recruited from diabetes foot clinic and is not representative of overall type 2 diabetes community and thus, limited the scope to conduct sub-category or multivariate analysis. However, the study provided useful information on baseline knowledge and other aspects of dietary salt intake, in this group of vulnerable participants, where healthy eating inclusive of lowered salt intake plays key role in good glycaemic control and thus, wound healing of diabetic foot ulcer/(s).

7.1.2 Phase 2: Development of dietary salt monitor for use in T2DM

Various methods as 24h urinary sodium excretion and use of Sodium- Magnetic Resonance Imaging (MRI) have been well researched for estimating excessive salt intake and tissue sodium deposition in T2DM (Villani et al., 2012; Kannenkeril et al., 2019). However, these methods are not practical for routine monitoring and do not provide any information on food sources of salt in diet. Thus, the Chapter 4 entitled 'Development of a novel dietary salt monitor' presented the detailed process and methodology for development of a practical tool, for identification and estimation of salt contribution from different food categories. This novel dietary salt monitor is essentially a salt specific short FFQ, that covers a list of food categories identified either as high in salt threshold of >1.5g/100g or top contributor of overall salt intake in diet of T2DM participants (n= 50). The staple food as bread, though not high in salt threshold contributed highest to the overall salt intake of this diabetic participant's group and consistent with the results of NDNS survey in general population. The food categories for dietary salt monitor, were reviewed against the top sources of salt identified by NDNS survey (Public Health England, 2018a) and the categories where PHE's 2017 salt targets were not met. This salt monitor was comprehensive as the computation for estimating daily salt intake, also accounted for salt intake from processed foods, discretionary use, salt naturally present in foods. It also has provision to capture information on portion size alongside frequency of food categories, thus improving accuracy of estimate at individual level. A careful consideration was made to include various sub-categories and computation of respective salt content using COFIDS 2015 database, and up-to-date brand specific nutrition label information for categories as ready meals, meat substitutes and salt-based seasoning. The main advantage of this novel dietary salt monitor is it is based on the dietary patterns of T2DM participants residing in UK. The limitation of this study's methodology is the calculation for the salt content against food category did not include sales based weighted averages for sub-categories, and might show under-estimation of salt intake, as reported by Mhurchu et al. (2011) for categories as bread and processed meats. However, this preliminary version of dietary salt monitor could be a useful educational tool for recognising top sources of salt in diet of T2DM, especially in context of lack of mandatory and consistent FOP nutrition labelling as well as serving size guidance in UK.

7.1.3 Phase 3: Validation of dietary salt monitor

Chapter 5 entitled 'Validation of the novel dietary salt monitor, based on a SFFQ against 24h urinary sodium excretions and a food record' discusses the various methods used for validating this novel tool. The study design included use of gold standard 24h urinary excretion method, as reference method alongside food record for testing validity of SFFQ based dietary salt monitor. Further strength of the study design is that both dietary methods (FFQ and food record) don't have common measurement errors as FFQ relies on long term memory but the later records current dietary intake. The results of Bland and Altman method for agreement between SFFQ and urinary sodium excretion method suggested a bias of 1.5g/d but with wide limit of agreements (upper LOA 7.68 and lower LOA -4.72). These results are consistent with findings of other validation studies reporting even greater bias and wider limits of agreement in general as well as diabetic population (Villani et al., 2012; Gallani et al., 2020). The results of cross-classification for agreement of SFFQ with urinary biomarker at individual level, indicated low level of miss-classification (11%) as compared to 28% reported in validation study with Canadian population (Gallani et al., 2020). One major limitation of this study is small sample of highly selected population of female nutrition students, who had higher education level and greater knowledge of diet, the results cannot be extrapolated for the population with type 2 diabetes. But the feedback of this educated and ethnic diverse study participant's group and review of their food records, refined the content of SFFQ such as description of food categories to include examples of ethnic diverse foods. Further, larger samples of T2DM participants are needed to substantiate the validity of this tool for estimation of habitual salt intake.

7.1.4 Phase 4: Use of dietary salt monitor as a dietary education intervention

Chapter 6 entitled 'A pilot study to evaluate the use of a novel dietary salt monitor as a nutrition educational tool in T2DM' highlighted the effectiveness of this tool by reducing a substantial and significant amount of salt within a short intervention period of 6 weeks (baseline of 7.9 g/d shifting to 5.2 g/d post the intervention (p=0.001) and effect size =0.6). As expected, the downward shift in salt intake primarily was from the processed food items, this includes sausages, cheese, bread & rolls, baked beans, salted nuts, stock, gravy, and salt-based seasonings. The major strength of this study was emphasis on the list of 23 high salt foods included in dietary salt monitor and clear advice on reducing its portion and/ its frequency of consumption and suggestions for healthier alternatives delivered through a supporting video. Other key aspect of this intervention was individualised e-mails reporting participant's estimated salt intake and food sources of salt in their diet. The results of an Australian study using nutrition label education for identification of low salt foods in T2DM participants indicated at 3 months, there was no reduction in the urinary sodium excretion (Petersen et al., 2013). However, the two of recent intervention studies in Japanese population was successful in reducing salt intake in T2DM participants, where the education aimed at increasing awareness on high salt food items and suggesting healthier alternatives (Ushigome et al., 2019; Oyabu et al., 2021). One of the limitations of the study is that participants were a small group of volunteers and thus not representative of a larger diabetic population. Further, the results need to be confirmed with a larger sample and if the salt reduction can be sustained in long-term.

7.2 Practical applications

The research for T2DM management has shown a paradigm shift from glycaemic control per se to a comprehensive approach for CVD risk management (Ismail-Beigi et al., 2017). Hypertension is a key risk factor in development of CVD in diabetes, especially in context of its higher prevalence rates in diabetes (Sun et al., 2019). The role of dietary salt reduction in controlling high blood pressure is well established through scientific evidence (Filippini et al., 2021) but collaborative efforts are needed to appreciate the importance, and dissemination of this topic in type 2 diabetic population, at large. Thus, for this purpose the findings of the present study and tools could be potentially used in an integrated manner involving the diabetic patients as well as multidisciplinary team involved in their care.

KAP- dietary salt survey: The survey questionnaire developed for the present study, can be used in future research studies with larger sample of T2DM participants, to review the association of various demographic and health factors as age, gender, ethnicity, education, length of diabetes, co-morbidities etc with the KAP score. The results of such research work shall be helpful for further adaptation of nutrition education interventions using dietary salt monitor for various sub-groups of type 2 diabetic population.

Screening tool: The list of 23 food items included in dietary salt monitor, could be potentially used as a quick screener by health professional/(s) involved in diabetes care, to determine the patient priority and need for referral for dietary salt education session.

Nutrition educational intervention: All the patients with T2DM irrespective of hypertension diagnosis shall benefit from the education session provided through the web-based dietary salt monitor and supporting educational video. The design and functionality of dietary salt monitor can be further enhanced for its use as a web-based or mobile app for its wider use and accessibility. It is envisaged that it can be used across NHS by professionals in outpatient diabetic clinics by dietitians/ nutritionist for monitoring their patient's salt intake and even for the purpose of educating patients as well as allied health professionals involved in the care of diabetic patients.

Awareness and accessibility: A collective approach including pharmacists, GP, diabetic nurse, dietitian/nutritionist, care staff across NHS and private sector and charities as Diabetes UK, Action on salt is needed to signpost additional messages for reducing dietary salt intake in T2DM. And the promotion of web-based application for dietary salt monitor through such platforms could be highly beneficial for reaching diabetic population at large.

Since T2DM is a chronic condition, life-long care and management requires self-efficacy, education on various aspects of dietary management including salt intake, needs to be continuous and refresher session can be interlinked at various interfaces with healthcare team including health check-ups such as annual blood pressure check-ups. Reinforcement of the use of dietary salt monitor and reviewing the results for patients can be interlinked with these appointments. A national level collaborative approach including various stake holders is needed to introduce a 'structured education programme to reduce CVD risk in T2DM' and dietary salt monitor contribute and be an important component of such an initiative. 'Canadian Hypertension Education programme (CHEP)' which has been extremely successful in increasing hypertension awareness, control, and treatment, is one such example of an international model for the development and implementation of healthcare recommendations (Drouin, Campbell and Kaczorowski, 2006; Feldman, Campbell and Wyard, 2007).

7.3 General recommendations

Although there seems to be clear insight for 'population's salt reduction' as demonstrated through a government- commissioned independent review into the food system 'New Food Strategy', where 'salt tax' has been proposed as a top recommendation to encourage manufacturers to reformulate their products to use less salt (Dimbleby, 2020; 2021). There are few more important aspects in the current food policy and healthcare system that call for 'urgent action' by UK government, to aid awareness and compliance to dietary salt recommendations in general as well as diabetic population.

Front of Pack Nutrition Label (FOPNL): There is urgent need for consistent FOPNL scheme to be made mandatory. The British Nutrition Foundation also published a report of a virtual round table with wide range of stakeholders about effectiveness of FOPNL, and the discussions supported mandatory FOPNL. It was highlighted that such decision would create consistency for consumers to make informed choices and a level playing field for industry across the marketplace (Gibson Moore and Spiro, 2021).

Serving size guidance for industry: The lack of UK serving size guidance for industry has been highlighted as one of the key challenges for appropriate interpretation of nutrition labels (Lewis, Ahern and Jebb, 2012; Gibson Moore and Spiro, 2021). In view of lack of such database, the nutrient content is expressed as per 100g on the label, and this is challenging for consumers especially for the food items that are consumed in amounts less than 100g.

Structured education: Dietary salt reduction need to be realized as important aspect of diabetes nutrition education irrespective of the diagnosis of hypertension. The algorithm for prevention of hypertension should be developed and advocated for T2DM, and dietary salt reduction shall be a key component of it. At present, NICE has published pathways for hypertension diagnosis and treatment, that included lifestyle advice for those with BP levels of >140/90 (NICE, 2019). Also, structured diabetes education should be a continuous process and not just be offered at time of diagnosis, and key information on salt reduction shall be covered as an exclusive session, in context of complexity of sources of salt in diet.

Database for nutritional intake of diabetic population: Secondary analysis of NDNS survey for key lifestyle conditions such as type 2 diabetes shall be published to inform policy makers and health care-community, so that existing gaps are covered, and strategies be directed for improving their dietary practices including salt intake.

7.4 Future research directions

The present research study has contributed to the development of an online dietary salt monitor, that proved effective as an educational tool. This novel dietary salt monitor shall be further designed as a comprehensive web and mobile based application, that shall include user/ patient and healthcare profession interface and functionality to record and plot the trend for dietary salt intake.

Also, a large-scale study involving patients recruited from multiple outpatient diabetic clinic or GP surgeries across the nation, including fair representation of ethnic minority to assess their dietary intake, KAP related to dietary salt intake and validation using urine samples from a sub-sample. Such information shall be useful to amend the dietary salt monitor, for its wider use across NHS and private health care sector.

7.5 Research impact

The process and conduct of the research itself have been instrumental in raising awareness of the message and relevance of 'salt intake in T2DM', especially in context of very limited research work in this key area. This was evident from the interactions and discussion of PIS sheet handed over to the participants of Phase-1 of this study. Majority of the participants with diabetic foot disease have had T2DM for over a decade but it was clear from the findings of the survey, that salt intake was of least priority and not prominently discussed by HCP as compared to other aspects of dietary modification.

The findings of the present study provided useful information on key gap areas in KAP levels related to dietary salt intake in T2DM, and especially in absence of any such previous study conducted in UK. The dietary information on the sources of salt in diet of diabetic participants, helped in the development of a novel dietary salt monitor, that has positively improved dietary practices and lowered the salt intake of the participants. This could potentially have some impact on the food choices of family members and shall help in cutting down the CVD risk in future generation, as diabetes has its genetic pre-disposition. Although, the study was short-term, the likely reduction in salt intake, if sustained shall improve the health parameters as blood pressure in long-term. This dietary tool has been able to reach to the wider diabetic community through 'Diabetes UK' website, as the research protocol was published for participants recruitment.

Thus, in conclusion the present research has been relevant in development of an educational tool for reducing salt intake and suggested its acceptability and effectiveness with T2DM participant.

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APPENDIX A

Approval letter from NHS REC

NHS
Health Research Authority

East of England - Cambridge East Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

16 May 2016

Dr Dee Bhakta
London Metropolitan University
Faculty of Life Sciences & Computing ,Room T11-01 Tower Building
166-220 Holloway Rd, Holloway, London
N7 8DB

Dear Dr Bhakta

Study title:	**Reducing salt intake in Type 2 diabetics; barriers in adherence to recommendations and development of a salt intake calculator for use in dietary education.**
REC reference:	**16/EE/0088**
IRAS project ID:	**190946**

Thank you for your letter of 4 May 2016 responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Assistant Miss Joanne Unsworth, NRESCommittee.EastofEngland-CambridgeEast@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

APPENDIX B

PARTICIPANT INFORMATION SHEET – Phase 1

Full title of Project: Diet Survey on Diabetes, High Blood Pressure and Salt Intake.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?

There is evidence to suggest that decreasing salt intake in patients with diabetes and high blood pressure can decrease the risk of developing long-term complications. The purpose of this survey is to assess which foods are the main sources of salt in the diet and to identify common barriers so that we can try to find ways to help reduce intake.

Why have I been invited to participate?

You have been approached because you have type 2 diabetes and hypertension. You also meet the age range and attend the outpatient clinic at Basildon Hospital.

Do I have to take part?

It is up to you to decide whether or not to take part.If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to participate, you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

Following agreeing to take part in the study, we shall ask you to answer a set of questions about your understanding on dietary salt intake, recommended level of salt intake, its food sources and record your usual dietary pattern. We shall collect information on your height, weight, blood pressure, medical history, and blood sugar and lipid levels as maintained in your records. The whole process should not take more than thirty minutes and will be conducted on the same day as your visit to the diabetic clinic at Basildon Hospital.

What are the possible disadvantages and risks of taking part?

There shall be no major risks involved with participation in this study as it involves providing answers to a set of questions related to your dietary practices and measuring your height and weight. It is expected that this burden would be small. To minimize inconvenience, we shall arrange to collect all information on the day of your regular visit to Diabetic Clinic at Basildon Hospital.

What are the possible benefits of taking part?

There is no immediate or direct benefit of participating in this study. The information we collect from you, shall be used for development of a salt calculator for identification and monitoring salt intake in diabetic population. In phase 4 of the study, we shall evaluate the use of a new dietary salt calculator, which helps identify sources of salt in the diet. If you are interested to participate in Phase 4 of study that includes nutrition education session using salt calculator, you can register your interest with the researcher and ask for Phase 4 participant information sheet and provide your consent for participation in Phase 4 and we shall contact you in near future.

Will my data be kept confidential?

We shall require your consent to access your medical records but this will be kept to a minimum and on a strictly 'need-to-know' basis. All information collected about you will be kept strictly confidential (subject to legal limitations). Access to the data will only be by research team working on this study. Computer files will be password protected and all data, codes and identifying information will be kept in locked filing cabinets. The findings generated in the course of the research will be kept securely for a period of ten years after the completion of a research project.

What should I do if I want to take part?

If you would like to take part in this study, you can do so by contacting the researchers at the email address given at the end of this information sheet.

What will happen to the results of the research study?

The results of this research will be published in a scientific journal. Your identity will not be recognizable from this. If you would like a copy of the published research you can contact the researchers at the email address given below following completion of the study.

Who is organizing the research?

This study is being conducted as part of PhD research work at Faculty of Life Sciences at London Metropolitan University, in collaboration with medical staff at Basildon Hospital.

Who has reviewed this study?

This research has been reviewed by the NHS Cambridge East Research Ethics Committee.

Further Information: If you require more information about this study you can send email with your questions to the member of the research team: Ranjana Babber, rab0805@my.londonmet.ac.uk

We would like to thank you, in advance, for your participation.

Dr Dee Bhakta RD
Senior Lecturer in Human Nutrition
London Metropolitan University
166-220 Holloway Road
London N7 8DB
020 7133 4197

APPENDIX C

PARTICIPANT INFORMATION SHEET – Phase 3

Full title of Project: Validation of dietary salt calculator with urinary sodium excretion.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?

Twenty-four-hour urinary sodium excretion is widely recognized as the best method for the estimation of dietary salt intake. The purpose of this study is to validate a newly developed salt calculator with urinary sodium excretion. A validated salt calculator will be a useful nutrition education tool because it will be able to assess and monitor intake, and identifying the main sources of salt in the diet. It will primarily be used in patients with type 2 diabetes and high blood pressure.

Why have I been invited to participate?

You are asked to participate in this study as you are studying at London Metropolitan University.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

What will happen to me if I take part?

You will be asked to complete a dietary salt intake calculator that will include set of questions on your dietary intake, which should take a few minutes. You will also need to collect urine over a 24 hour period on two separate occasions and bring the sample to the Science Centre, London Metropolitan University. You will be provided with all the equipment you require to collect your urine.

What are the possible disadvantages and risks of taking part?

There is no risk involved in participating in this study.

What are the possible benefits of taking part?

There is no direct or immediate benefit of this study to you. The information we obtain from this study will be used to validate the dietary salt calculator, which will be used for nutrition education for identification and monitoring salt intake in diabetic population.

Will my data be kept confidential?

All information collected about you will be kept strictly confidential (subject to legal limitations). Access to the data will only be by researchers working on this study. Computer files will be password protected and all data, codes and identifying information will be kept in locked filing cabinets. The findings generated in the course of the research will be kept securely for a period of ten years after the completion of a research project.

What should I do if I want to take part?

If you would like to take part in this study, you can do so by contacting the researchers at the address, phone number or email address given at the end of this information sheet.

What will happen to the results of the research study?

The results of this research will be published in a scientific journal. Your identity will not be recognizable from this. If you would like a copy of the published research, you can contact the researchers at the address, phone number or email address given below following completion of the study.

Who is organizing the research?

This study is being conducted as part of PhD research work at Faculty of Life Sciences, London Metropolitan University.

Who has reviewed this study?

This research has been approved by the NHS Cambridge East Research Ethics Committee

Further Information: If you require more information about this study you can send email with your questions to the member of the research team -Ranjana Babber, rab0805@my.londonmet.ac.uk.

We would like to thank you, in advance, for your participation.

Dr Dee Bhakta RD
Senior Lecturer in Human Nutrition
London Metropolitan University
166-220 Holloway Road
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020 7133 4197

APPENDIX D

LONDON metropolitan university

PARTICIPANT INFORMATION SHEET – Phase 4

Full title of Project: Evaluating the use of the dietary salt calculator in type 2 diabetes and high blood pressure.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?

The purpose of this research project is to evaluate the use of a new dietary salt calculator, which helps identify sources of salt in the diet. We would like to evaluate its usefulness in educating individuals with type 2 diabetes and high blood pressure.

Why have I been invited to participate?

You have been approached because you have type 2 diabetes and hypertension. You also meet the age range and attend the Outpatient Clinic at this hospital.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do not wish to take part in this study or withdraw from this study the usual care you receive will not be affected. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

You will be requested to attend a twenty-minute education session that includes how to use dietary salt calculator, measuring your daily salt intake and identification of sources of salt in diet. We would like to contact you again in about three months through phone/skype or through e-mail, as per your convenience. During this session you will be asked to complete a set of questions included in dietary salt calculator.

What are the possible disadvantages and risks of taking part?

There shall be no disadvantages and risks of taking part in this study as it is a nutrition education study aimed to provide information on reducing dietary salt intake.

What are the possible benefits of taking part?

Reducing salt intake is beneficial in the management of hypertension and reducing complications related to type 2 diabetes. You shall benefit from participating in nutrition education sessions and gain valuable information on identification of food sources of salt and ways to reduce dietary salt intake.

Will my data be kept confidential?

All information collected about you will be kept strictly confidential (subject to legal limitations). Access to the data will only be by researchers working on this study. Computer files will be password protected and all data, codes and identifying information will be kept in locked filing cabinets. The findings generated in the course of the research will be kept securely for a period of ten years after the completion of a research project.

What should I do if I want to take part?

If you would like to take part in this study, you can do so by contacting the researchers at the email address given at the end of this information sheet.

What will happen to the results of the research study?

The results of this research will be published in a scientific journal. Your identity will not be recognizable from this. If you would like a copy of the published research you can contact the researchers at the address, phone number or email address given below, following completion of the study.

Who is organizing the research?

This study is being conducted as part of PhD research work at Faculty of Life Sciences at London Metropolitan University, in collaboration with medical staff at Basildon Hospital.

Who has reviewed this study?

This research has been reviewed by the NHS Cambridge East Research Ethics Committee.

If you require more information about this study you can send email with your questions to the member of the research team- Ranjana Babber, rab0805@my.londonmet.ac.uk.

We would like to thank you, in advance, for your participation.

Dr Dee Bhakta RD
Senior Lecturer in Human Nutrition
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* This PIS is obsolete as the protocol for phase 4 was amended due to the global pandemic

APPENDIX E

LONDON metropolitan university

CONSENT FORM – Phase 1

Title of Project: Diet Survey on Diabetes, High Blood Pressure and Salt Intake

Name of individual (capitals) ______________________________

Please initial each statement to show your agreement

☐ I confirm I have read the participant information sheet on the above study and have been given a copy to keep. I have had the opportunity to ask questions about the study and I am satisfied with the information that I have been given.

☐ I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

☐ I give permission for my medical records to be looked at using my personal details and NHS number, and for information from them to be used in strict confidence by members of the research team.

☐ I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.

☐ I agree to take part in the study and know how to contact the research team if I need to.

6. I am interested to take part in another phase of this research study (Phase 4), which involves nutrition education sessions to identify sources of salt in diet.

YES ☐

NO ☐

Volunteer's signature ____________________ Date _____________

I confirm that I have fully explained the nature of this study to the above named volunteer

Researcher's signature _________________ Date_____________

APPENDIX F

CONSENT FORM –Phase 3

Title of Project: Validation of dietary salt calculator using urinary sodium excretion.

Name of individual (capitals) ______________________________

Please initial each statement to show your agreement

I confirm I have read the participant information sheet on the above study and have been given a copy to keep. I have had the opportunity to ask questions about the study and I am satisfied with the information that I have been given. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

agree to give urine samples for research in the above study. I understand that all data and samples will be made anonymous prior to being circulated to other research team members. ☐

I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers. ☐

I agree to take part in the study and know how to contact the research team if I need to. ☐

Volunteer's signature ____________________ Date _____________

I confirm that I have fully explained the nature of this study to the above-named volunteer.

Researcher's signature _________________ Date_____________

APPENDIX G

LONDON metropolitan university

CONSENT FORM – Phase 4

Title of Project: Evaluating the use of the dietary salt calculator in type 2 diabetes and high blood pressure.

Name of individual (capitals) ______________________________

Please initial each statement to show your agreement

☐ I confirm I have read the participant information sheet on the above study and have been given a copy to keep. I have had the opportunity to ask questions about the study and I am satisfied with the information that I have been given.

☐ I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

☐ I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.

☐ I agree to take part in the study and know how to contact the research team if I need to.

☐ I agree to be contacted for follow up nutrition education session of this study through:

Skype

Phone

E-mail

Volunteer's signature ____________________ Date _____________

I confirm that I have fully explained the nature of this study to the above-named volunteer.

Researcher's signature _________________ Date_____________

* This consent form is obsolete as the protocol for phase 4 was amended due to the global pandemic.

APPENDIX H

Research Questionnaire

Dietary salt intake in hypertensive type 2 diabetic patients

Dear Participant,

Thank you for providing consent to participate in this research study- Dietary salt intake of hypertensive type 2 diabetic patients. You are requested to answer questions related to your usual dietary intake.

This questionnaire consists of seven parts (Part 1-Part 7) – You are requested to write responses to questions asked in Part 1,2,4,5 and 6 of the questionnaire.

Part 1: Medical History

Part 2: Dietary practices related to salt intake

Part 4: Knowledge of salt intake & its role in health

Part 5: Attitude towards salt intake

Part 6: Personal Information

Part 3: 24 hr dietary recall (information shall be recorded by researcher in face- to face interview.)

Part 7: Health Information (information shall be filled by researcher based on data from hospital records.)

I appreciate your time and value the information provided by you. I will need your name and date of birth for cross-reference purposes only.

Forename: ____________________

Surname: ____________________

Date of birth (DD-MM-YYYY) □□-□□-□□□□

Gender □ Male □ Female

For interviewer:

Date of interview: □□-□□-□□□□

Location: ____________________________

Part 1: Medical History

1. How long have you been diagnosed with type 2 diabetes?

□ Less than a year
□ 1-5 years
□ 5-10 years
□ >10 years
□ other, please *specify* ……………………………………………………

2. How long have you been diagnosed with hypertension?

□ Less than a year
□ 1-5 years
□ 5-10 years
□ >10 years
□ other, please *specify* ……………………………………………………

3. Are you taking medication/(s) for any of below mentioned health conditions?

□ Diabetes
□ Hypertension

4. Do you have medical condition other than type 2 diabetes and hypertension?

- ◻ Yes
- ◻ No
- ◻ other, please *specify* ………………………………………………

5. Do you have family history of any of the below mentioned medical condition?

- ◻ Diabetes
- ◻ Hypertension
- ◻ other, please *specify* ………………………………………………

Part 2: Dietary practices related to salt intake

1. Specify how often you consume below mentioned meal preparations:

	Daily	2-3 times a week	Once a week	Once a fortnight	Rarely	Never
i. Home prepared meals	◻	◻	◻	◻	◻	◻
ii**.** Ready meals	◻	◻	◻	◻	◻	◻
iii**.** Restaurant/Takeaway	◻	◻	◻	◻	◻	◻

2. How often do you add salt during cooking?

- ◻ Always
- ◻ Sometimes
- ◻ Rare
- ◻ Never

3. How often do you use salt at table?

- ◻ Always
- ◻ Sometimes

◻ Rare

◻ Never

4. What type of salt you use in cooking?

◻ Table salt
◻ Lo salt
◻ Rock & Sea salt

◻ other, please specify…………………………………………..................................

5. How would you rate your intake of salt?

◻ Far too much
◻ Average
◻ Low

◻ Don't know

6. Does nutrition label influence your food purchase?

◻ Yes
◻ No

7. Specify, the nutrient on label that influence your food purchase?

◻ Energy
◻ Fat
◻ Saturates
◻ Sugar

◻ Salt

◻ other, please specify

8. Rank the following in order of preference to control your dietary salt intake?

◻ Avoid eating out
◻ Buy low salt alternatives

◻ Reduced intake of processed foods

◻ Compare salt content on nutrition labels

◻ Do not add salt at the table

□ Do not add salt when cooking

□ Use herbs& spices instead of salt when cooking

9. Specify the reasons that pose difficulties in controlling your salt intake.

……………………………………………………………………………………………………

…………………………………………………………………………………………………….

Part 3: 24 hr Dietary Recall

(*Note: The data for this section shall be collected by researcher in face to face interview with participant.)*

Date ………………
Day ………………

Meal & timings	Menu	Ingredients	Amount in household measures (e.g.teaspoon(s) or table spoon(s) /cup/bowl etc.)

Part 4: Knowledge of salt intake and its role in health

1. Have you ever received advice from health care professional for both diabetes and hypertension?

- □ Yes
- □ No

2. If yes, tick mark against the option/(s) which was part of the advice given by your healthcare professional.

- □ Lose weight
- □ Stop smoking
- □ Diet Modification
- □ Exercise
- □ other, specify……………………………………………………………………………

3. If you have received advice on dietary modification, specify the professional/(s) involved in it?

- □ GP
- □ Dietitian
- □ Nurse
- □ other, specify……………………………………………………………………………

4. Tick against the options that was part of your advice on dietary modification?

- □ Limit intake of sugar & sugary drink/foods
- □ Limit intake of fried and fatty foods
- □ Eat 5 a day -Fruits & Vegetables
- □ Intake of oily fish
- □ Limit alcohol consumption
- □ Limit salt intake
- □ other, specify……………………………………………………………………………

5. Do you think reducing salt intake is related to improved health?

- □ Yes
- □ No

6. Tick against the options for health conditions, which in your opinion are associated with excessive salt intake.

- □ Stroke
- □ Osteoporosis
- □ High blood pressure
- □ Kidney stones
- □ Stomach cancer
- □ none of the above
- □ other, specify………………………………………………………………………………

7. Are you aware of UK government recommendation to lower salt intake for the population?

- □ Yes
- □ No

8. If yes, what is the recommendation for daily salt intake for general population?

- □ <6 g/day
- □ <5g/day
- □ <3g/day
- □ other, specify………………………………………………………… ……….

9. What contributes highest to daily salt intake amongst UK population?

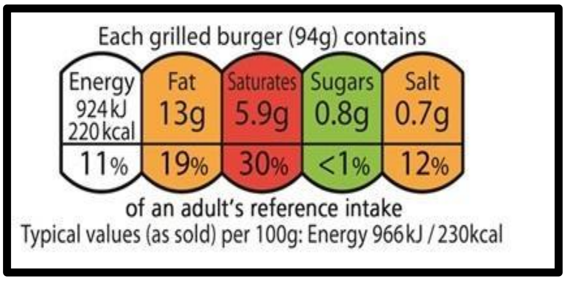
Salt in cooking

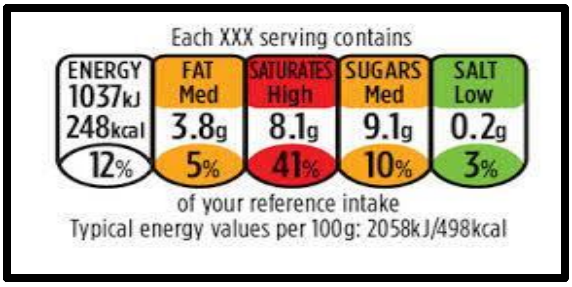
- □ Processed foods
- □ Salt at table

10. Refer to the nutrition label below and tick against the typical values/(s) that is related to salt content.

Typical values	**Per 100g prepared soup**
Energy	206kJ/49kcal
Protein	1.2g
Carbohydrate	3.9g
of which sugars	0.6g
Fat	3.3g
of which saturates	0.3g
Fibre	0.1g
Sodium	0.26g
Salt equivalent	0.65g

11. Read the below mentioned nutrition labels and tick against the low salt food option?





11. Mark (YES/NO) against the food item that are often high in salt.

Food Item *(Description of food item /category)*	**High in salt**		
	YES	**NO**	**Don't Know**
Bread *(Various brands & varieties of bread including bagel, bun, flat bread, pitta etc.)*			
Tomato Ketchup *(all brands of tomato ketchup)*			
Bacon *(Various varieties & types of bacon –streaky, back, middle)*			
Pasta- ready meal *(all varieties of cooked ready meal pasta)*			
Pizza *(all types of takeaway or supermarket pizza)*			
Soy sauce *(various brands of dark & light soy sauce)*			
Smoked fish *(any smoked white fish or smoked oily fish)*			
Pickles *(various preparation of pickles in vinegar or oil)*			
Stock cubes *(different brand of stock cubes)*			
Cheese *(various brands & varieties of cheddar cheese)*			
Salami & Sausages *(salami / sausages made of any meat pork, beef, veal, chicken etc.)*			
Crisps *(various brands of salted crisps)*			
Biscuits (different brands of biscuits)			
Cakes (different variety of cakes)			
Takeaway meals			

Part 5: Attitude towards salt intake

1. Mark the below statements as Agree /Strongly Agree/Disagree

Statement	**Agree**	**Strongly Agree**	**Disagree**
a)I feel reducing salt intake is important for better control of my health condition			
b)I would like to take action to cut down the amount of salt I consume on regular basis			
c) I would make effort to read the salt content on nutrition label prior to food purchase.			
d) While eating out or take away orders, I can request to either reduce or avoid adding salt to the dishes.			
e) Food cooked using less salt, with flavourings as lemon, ginger, garlic etc. tastes good.			
f) I am interested to gain more information on simple ways of reducing salt.			

Part 6: Personal information

1. Tick against the suitable option, to indicate your ethnicity.

- □ White
- □ Asian or Asian British
- □ Black / African / Caribbean / Black British
- □ Mixed ethnic group
- □ other ethnic group, specify.....................................

2. Tick against the suitable option indicating your occupation.

- □ Unemployed
- □ Employed, specify your profession……………………..
- □ Self-employed

3. Tick against suitable option indicating your yearly income status

- □ Less than £5,200
- □ £5,200 to £10,399
- □ £10,400 to £25,999
- □ £26,000 to £36,399
- □ £36,400 to £51,999
- □ £52,000 or more

4. Tick against the option for highest level of education attained.

- □ School level

- ◻ University education
- ◻ Post-graduation
- ◻ other, specify……………………………………

Part 7: Health information

Data to be filled by researcher

Patient Hospital No: ………………………………………...

Research Participant No: ……………………………………

<u>Biochemical Parameters:</u>

Hba1c ……………..

Total Cholesterol …………

LDL ……… HDL …………..

B.P …………...

<u>Anthropometric measurements:</u>

Height: …. m

Weight: .... Kg

Waist Measurement ………cm

APPENDIX I

Dietary Salt Monitor (v.1.2020)

DIETARY SALT CALCULATOR*

This calculator is a short food frequency questionnaire to determine an individual's average salt intake per day. Do you know that UK's population, on an average consumes 8g salt /day which exceeds the daily recommended target of 6g/day? Let's find out how much your daily salt intake is?

You are requested to provide some background information about you, and what you eat.

Please fill the following background information:

PARTICIPANT NAME: ______________________________

GENDER: ☐ **MALE** ☒ **FEMALE**

DATE OF BIRTH: ☐☐ / ☐☐ / ☐☐☐☐

HEIGHT (cm): ____________ **WEIGHT(Kg):** ____________

RESEARCH PARTCIPANT NO.: ______________________________
(To be filled by researcher)

DATE: ____________

FREQUENCY OF CONSUMPTION OF PROCESSED FOODS

How many portions of the following processed foods do you consume? Please mention number of portions of each food eaten on an average per day/ week/ month.

EXAMPLES:

For bread, the amount is 'one slice', so if you consume 4 slices every day, write **4** in the column headed "Day".

Foods	Amounts	Day	Week	Month	Never
Bread and rolls	1 slice	2			

For cheese, the amount is 'one serving', so if you consume 1 serving, thrice a week write **3** in the column headed 'Week'.

Foods	Amounts	Day	Week	Month	Never
Cheese	1 serving		1		

Please estimate your average food consumption and specify your answer in the column headed DAY/ WEEK/ MONTH/ NEVER.

FOODS	AMOUNT	DAY	WEEK	MONTH	NEVER
Bacon	1 Serving				
Ham	1 Serving				
Sausages	1 Serving				
Cheese Exclude soft cheese and cottage cheese.	1 Serving				
Salted butter and buttery spreads	1 Portion				
Marmite	1 Portion				
Bread and rolls Exclude homemade bread as roti/ flat bread made from scratch with no added salt/baking soda/sodium-bi-carbonate.	1 Slice or 1 Roll				
Breakfast items Includes Waffles, Pancakes, English Muffins, Crumpets, Soda farls, Scones, Potato farls, Wheaten bread.	1 Portion				
Baked beans in tomato sauce	1 Serving				
Soups Exclude soup made from scratch without added salt or salt based seasoning/(s).	1 serving				
Ready meals Includes all Chinese, Thai, Indian, Italian, Traditional meals and meal products as breaded fish and chicken, pies, pasties, burgers etc.	1 Serving				
Pizza	1 Portion				

FOODS	AMOUNT	DAY	WEEK	MONTH	NEVER
Bought Sandwiches With high salt fillings as ham, bacon, olives, hard cheese, dressings, seasonings, canned hotdogs etc.	1 Portion				
Pasta Sauces	1 Serving				
Table sauces Includes Ketchup, Brown sauce, Mayonnaise, Salad cream, Salad dressings etc.	1 Serving				
Crisps	1 Bag				
Salted Nuts	1 Portion				
Savoury Biscuits/ Crackers	1Serving				
Meat Substitutes Includes burgers, sausages, mince made from Quorn, soy or other ingredients.	1 Portion				
Salt based rubs/seasonings.	1 Portion				

Please tick the following statements if it applies to you:

I mostly read nutrition label. ☐

I mostly purchase reduced or lightly salted food products. ☐

I often add salt during cooking. ☐

I often add salt at table. ☐

FREQUENCY OF CONSUMPTION OF EATING OUT

How often do you eat out and consume food from the following food categories. Please tick the suitable option.

FOOD CATEGORY	WEEK			MONTH		NEVER
	5-6 times	3-4 times	1-2 times	2-3 times	1 or less	
Starter & Sides Examples: chicken wings, onion rings, calamari rings, grilled halloumi, breaded mushrooms, chicken tikka etc. and sides of vegetables, rice, beans, coleslaw, potato salad, dumplings, nachos. Excludes fresh vegetable/fruit salad without seasoning/dressings.						
Main course Examples: pasta mains, rice bowls, waffles, French toast, pancakes, porridge, quiches, sushi, mac and cheese, pizza, sandwich, chicken katsu curry, roast turkey carvery etc.						
Desserts Examples: chocolate brownie, ice-cream, panna cotta, cookie dough, mango sorbet etc.						

Please tick the following statements if it applies to you:

I mostly read the menu and look for nutrition information to select low salt options. ☐

I often limit food portion/(s) when eating out. ☐

**** Dietary Salt Calculator was renamed as Dietary salt Monitor (v.1.2020)***

APPENDIX J

24h Urine Collection Protocol

You are requested to collect all your urine over a 24h period on two separate occasions preferably one weekend and one weekday.

Equipment

Following equipment will be provided:

- 5L screw cap container to collect urine.
- Optional: 2L capacity screw cap container for urine (for collection away from home)
- Jug
- Funnel (for transferring the sample from Jug/ 2L container into 5L container).

Instructions

1. **Start day:** get up and go to the toilet, flush it away and note the start time. This will be the 24-hour urine 'START' time. (DO NOT COLLECT THIS URINE).
2. Collect ALL urine passed after this time for the next 24 hours.
3. To do this pass urine into a separate clean container such as a plastic jug and then pour it into the container provided.
4. **Next day:** get up and go to the toilet and collect the urine sample into the equipment provided. Note the time. This will be the 'END' time of the urine collection and should be EXACTLY 24-hours after the start time. (COLLECT THIS URINE).
5. Screw the top on the bottle tightly. Please take extra care not to contaminate the outside of the container with urine.

NOTE: Females should not collect urine sample during periods.

Labelling your sample

Label the container with your name, student id, date and time of starting and finishing the collection. Please use permanent marker for labelling on the container.

Storing your sample at your residence

The sample must be kept in as cool place as possible, and not sit near any heaters / radiators. The sample must be returned on the same day as completion of the collection/ within 48hrs of collection.

Packaging, dispatch, and storage of the sample in laboratory

The dispatch, storage and disposal of the urine sample shall be in accordance to London Metropolitan University's Safety Code of Practice guidelines – Faculty of Life Science & Computing.

Checklist

- All urine collected over 24 hours ☐
- Container had been tightly sealed ☐
- Urine Collection form is completed ☐
- Container has been clearly labelled ☐

  (Student name, student ID, time & date of start and finishing the collection)
- Time and date of collection are recorded on urine collection form ☐

24 Hour Urine collection sheet

Student Name:

Student ID:

DOB: ……/……/………..

Gender: Male / Female

Start Date of 24 hour collection: ……/……/………..

SECTION 1

DATE/ TIME FOR 24 HOUR COLLECTION PERIOD

<table>
<tr><th rowspan="2">Order of events</th><th rowspan="2">Date
DD/MM/YY</th><th rowspan="2">Time
HH:MM</th><th colspan="2">Please tick AM/ PM</th></tr>
<tr><th>AM</th><th>PM</th></tr>
<tr><td>START: Flush this urine away and record the start time.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>END: Collect this urine and record end time</td><td></td><td></td><td></td><td></td></tr>
</table>

Note: For collections at 12 o'clock mid-day, tick PM; at 12 o'clock mid-night, tick AM.

SECTION 2

MISSED URINE

It is very important that you collect all the urine you produce in the 24 hour period. However, if you have MISSED any urine collections, even just through spillage or overflowing, please make a note in the table below:

MISSED URINE

<table>
<tr><th rowspan="2">S. No.</th><th rowspan="2">Date
DD/MM/YY</th><th rowspan="2">Time
HH:MM</th><th colspan="2">Please tick</th><th rowspan="2">Comments
(e.g. overflow/spillage)</th></tr>
<tr><th>AM</th><th>PM</th></tr>
<tr><td>1.</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>2.</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>3.</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>4.</td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

THANKS FOR PARTCIPATING IN THIS STUDY!

APPENDIX K

Working example for calculating salt intake with Dietary Salt Monitor (v.1.2020)

FOODS	Amount (g) per serving	Salt content per 100g	Salt content per serving	Day	Week	Month	Never	Estimated salt intake g/day
Bacon	60	2.9	1.7	0	2	0	0	0.50
Ham	20	2.6	0.5					0.00
Sausages	32	1.5	0.5			5		0.08
Cheese	30	1.7	0.5			2		0.03
Salted butter and buttery spreads	10	1.6	0.2					0.00
Marmite	5	9.5	0.5					0.00
Bread and rolls	39	1.00	0.4		7			0.39
Breakfast items	64	1	0.6		1			0.09
Baked beans in tomato sauce	205	0.7	1.4		2			0.41
Soups	220	0.7	1.5		1			0.22
Ready meals	350	0.6	2.1		1			0.30
Pizza	300	1	3.0			1		0.10
Bought Sandwiches	180	0.9	1.6					0.00
Pasta Sauces	30	0.7	0.2		1			0.03
Table sauces	8	1.8	0.1		3			0.06
Crisps	35	1.7	0.6		2			0.17
Salted Nuts	19	1.1	0.2	1				0.21
Savoury Biscuits/ Crackers	9	1.1	0.1	1				0.10
Meat Substitutes	85	1.2	1.0		1			0.15
Salt based rubs/seasonings.	25	18	4.5		2			1.29
Eating out								
Starters			0.51			1		0.02
Main course			2.5			1		0.08
Dessert			0.51			1		0.02
					Estimated daily salt intake (g/d)			**4.2**

Columns that are grey are input fields and those with amber are output fields with automated formulas for computation.

Estimated daily salt intake computation takes into consideration salt contributed from all twenty food categories, eating out occasion and also account for discretionary salt intake.

Appendix L

Short Food Frequency Questionnaire

Dear Participant,

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and discuss it with others if you wish. Ask if anything is unclear or you wish more information.

What is the purpose of the study?

The purpose of this research project is to use a short food frequency questionnaire to estimate your dietary salt intake and check if our food frequency questionnaire can be useful in reducing your salt intake.

Why have I been invited to participate?

We are including participants with Type 2 Diabetes and those who are not salt-restricted diet for any medical reasons.

Do I have to take part?

It is up to you to decide whether to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

We would like you to fill up a short food frequency questionnaire that records your intake of processed foods, eating out and other dietary practices. We will then provide an educational video, suggesting practical ways to reduce salt in your diet. We will ask you to fill out the food frequency questionnaire again after four weeks.

What are the possible disadvantages and risks of taking part?

There shall be no disadvantages and risks of taking part in this study as it is a nutrition education study aimed to provide information on reducing dietary salt intake.

Will my data be kept confidential?

The questionnaire will be completed anonymously. Access to the data will only be by researchers working on this study. By completing the questionnaire, you will be automatically consenting on being able to use your data for this research study.

What will happen to the results of the research study?

We will send you copy of results from the data analysis of your dietary intake. The results of this research will be published in a scientific journal. If you would like a copy of the published research, you can contact the researchers via an email.

Who is organizing the research?

This study is being conducted as part of PhD research work at Faculty of Life Sciences, London Metropolitan University.

Who has reviewed this study?

This research has been approved by the London Metropolitan Research Ethics Committee.

How will you be able to get in touch with the researcher?

If you require more information about this study, you can send email with your questions to the research team.
We would like to thank you in advance, for your participation.

Research student: Ranjana Babber Email: rab0805@my.londonmet.ac.uk

Research supervisor: Dr Dee Bhakta Email: d.bhakta@londonmet.ac.uk

Background Information

1. Gender *

Mark only one oval.

- Male
- Female
- Prefer not to say

2. Age (years) * *

3. Height *

4. Weight *

5. Ethnicity *

Mark only one oval.

- White
- Asian or Asian British
- Black, African, Caribbean, or Black
- British Mixed or Multiple Ethnic
- Background Other: ____________________

Health Information

6. How long you have been diagnosed with Type 2 diabetes? *

____

7. Are you taking any medications for your diabetes? *

Mark only one oval.

- Yes
- No

8. Do you have high blood pressure?

Mark only one oval.

- Yes
- No

9. Are you taking any medications for high blood pressure? *

Mark only one oval.

- Yes
- No
- Not applicable

10. Do you know your last blood pressure readings? If yes, please provide the readings here, otherwise state 'don't know'. *

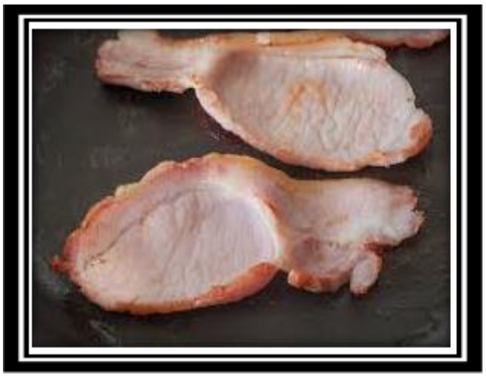
11. Have you ever been to a diabetes education course?

Mark only one oval.

- Yes
- No

Processed Foods: Average serving eaten per meal

12. If you eat bacon, how many servings do you usually have per meal? *
This category includes all types of bacon rashers; streaky, back, middle, medallion/fat trimmed.



1 serving = 2 bacon rashers

13. If you eat ham, how many servings do you usually have per meal? *

This category includes all types of ham including luncheon meat, premium ham, denny slices, prosciutto and parma.

1 serving = 1slice of ham

14.If you eat sausages, how many servings do you usually have per meal? *This category includes all types of sausages including pork, beef, and chicken.

1 serving = 2 sausages

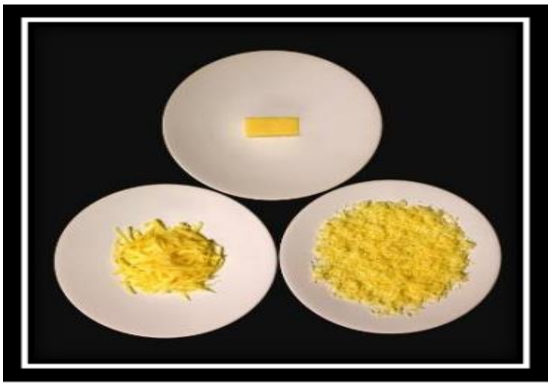
15. If you eat other processed meats, how many servings do you usually have per meal? *

This category includes other cured and processed meats as meat loaf, corned beef slices, pate, smoked fish, and tinned fish like tuna in brine.

1 serving of other processed meat or fish = 1 slice of meat loaf/corned beef/half a tin of tuna in brine.

16. If you eat cheese, how many servings do you usually have per meal? *

This category includes all cheeses except mozzarella, ricotta, and cottage cheese.



1 serving = 30g shredded/ grated/ cube (matchbox size) cheese

17. If you eat salted butter and buttery spreads, how many servings do you usually have per meal? *

This category includes all types of salted butter and spreads (dairy & non-dairy).

1 serving = 2 teaspoon/ Individual portion pack

18. If you eat marmite, how many servings do you usually have per meal? *
This category includes all types of yeast- based extracts: marmite/ vegemite/ promite etc.

1 serving = One individual sachet or 1 level teaspoon

19. If you eat bread and rolls, how many servings do you usually have per meal? *
This category includes all types of bread -white, brown, wholemeal, granary and bread products such as rolls, flat breads, tortilla, pitta, and naan bread.

1 serving = 1 medium slice of bread or 1 roll

20. If you eat breakfast items, how many servings do you usually have per meal? *
Examples includes crumpets, waffles, pancakes, English muffins, scones.

1 serving = 1 crumpet or 1 waffle or 1 scone

21. If you eat baked beans, how many servings do you usually have per meal? *
This category includes all varieties of canned beans in tomato sauce.

1serving = Half a standard can

If you have soups, how many servings do you usually take per meal? *

This category includes all types of tinned and dehydrated powdered soups.

1serving = Half a can

22. If you eat ready meals, how many servings do you usually have per meal? *
This category includes both chilled and frozen varieties of ready meals Chinese/Thai/Indian/Italian/Traditional meals including breaded fish, fish fingers, breaded chicken, chicken nuggets, pies, pasties, burgers, and sausage rolls.

1 serving = Pre-packed meal for one

23. If you eat pizza, how many servings do you usually have per meal? *
This category includes all varieties of supermarket pizza.

1 serving = 1 standard pizza

24. If you eat shop-bought sandwiches, how many servings do you usually have per meal? * This category includes all varieties of shop-bought sandwiches including wrap.

1 serving = 1 pre-packed sandwich

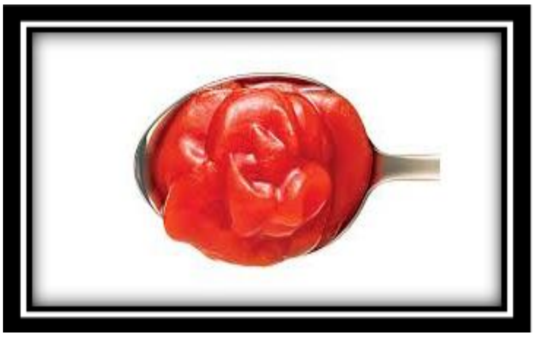
25. If you use pasta and cooking sauces, how many servings do you usually take per meal? *

This category includes all types of sauces as Bolognese, Carbonara, Indian cooking sauce, Thai curry sauce, Chinese stir-fry sauce etc.

1 serving = 7–8 tablespoon or a quarter of a standard jar

26. If you use tables sauce, how many servings do you usually eat per meal? *

This category includes all types of table sauces such as ketchup, brown sauce, mayonnaise, salad cream, salad dressings, chutneys, relishes etc.



1 serving= 1 tablespoon

27. If you eat crisps, how many servings do you usually have per meal? *

Examples includes all potato crisps, corn puffs, vegetable crisps and bombay mix.

1 serving= 1 regular bag
of crisp (grab bag)

28. If you eat salted nuts, how many servings do you usually have per meal? *

This category includes all types of salted nuts.

1 serving = One handful (30g)

29. If you eat savoury biscuits/crackers, how many servings do you usually have per meal?

*This category includes all types of savoury biscuits/crackers and crispbread.

1 serving = 1 cracker/ crispbread

30. If you eat meat alternatives, how many servings do you usually have per meal? *

This category includes meat free burgers, sausages, mince, and other ready meals made from Quorn/soy/pea protein etc.

1 serving = One individually packed ready meal or one serving as sold

31. If you use stock, how many servings do you usually include in one meal? *

This category includes stock cubes and made-up stock.

1 serving = Half a stock cube or half a cup of made- up stock

32. If you use gravy, how many servings do you usually have per meal? *

This category includes all types of gravy made up from granules or ready pots or gravy pouches.

1 serving = 3 tablespoons

33. If you use salt-based rubs or seasonings, how many servings do you usually include for one meal? *

Includes all types of salt-based rubs/seasoning or marinades.

1 serving = 1 heaped tablespoon

Frequency of intake of processed foods

34. Please estimate how often you eat each of these food items and choose the option that best matches your average use for the LAST YEAR. *

Mark only one oval per row.

	2-3/day	Once/day	5-6/week	2-4/week	Once/week	1-3/month	Never
Bacon	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Ham	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Sausages	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Processed meats	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Cheese	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Salted butter & spreads	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Marmite	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Bread & rolls	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Breakfast items	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Baked beans	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Soups	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Ready meals	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Pizza	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Bought sandwiches	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Pasta & cooking sauces	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Table sauces	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Crisps	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Salted nuts	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Savoury biscuits/crackers	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Meat substitutes	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Stock	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Gravy	⬭	⬭	⬭	⬭	⬭	⬭	⬭
Salt based rubs	⬭	⬭	⬭	⬭	⬭	⬭	⬭

35. Please let us know if you use reduced or lightly salted variety of following foods. *

	Yes	No
Bacon	◯	◯
Ham	◯	◯
Sausages	◯	◯
Other processed meats	◯	◯
Cheese	◯	◯
Salted butter and spreads	◯	◯
Marmite	◯	◯
Bread & rolls	◯	◯
Breakfast items	◯	◯
Baked beans	◯	◯
Soups	◯	◯
Pizza	◯	◯
Bought sandwiches	◯	◯
Pasta & cooking sauces	◯	◯
Table sauces	◯	◯
Crisps	◯	◯
Salted nuts	◯	◯
Savoury biscuits/ crackers	◯	◯
Meat alternatives	◯	◯
Stock	◯	◯
Gravy	◯	◯
Salt based rubs & seasonings	◯	◯

Frequency of eating out

How often do you eat out or have a takeaway? Select the suitable option based on your average use LAST YEAR.

37. Eating out *

Mark only one oval per row.

	5-6/week	2-4/week	Once/week	1-3/month	Never
Starter and sides	⬭	⬭	⬭	⬭	⬭
Main course	⬭	⬭	⬭	⬭	⬭
Dessert	⬭	⬭	⬭	⬭	⬭

Other dietary information

Finally, we will like to ask you few questions about food shopping and your dietary habits.

38. Which of the following options describes you best? *

Mark only one oval.

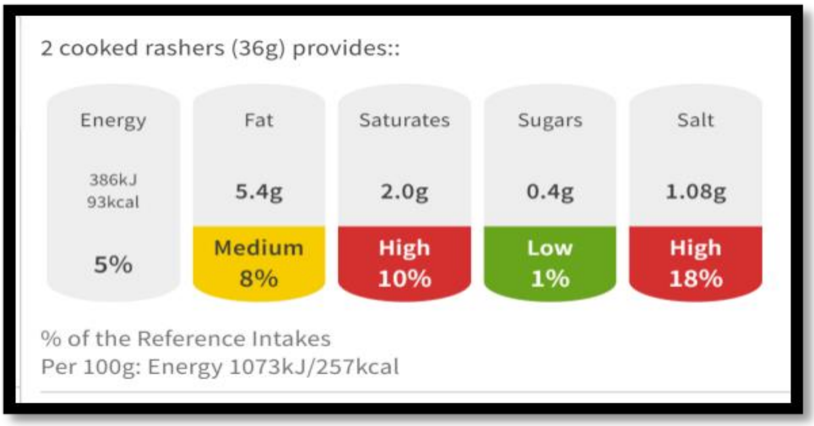
- Vegetarian
- Meat-eater
- Vegan
- Flexitarian

39. I often read salt content on the nutrition label, while shopping for food. *

Mark only one oval.

- Yes
- No

40. Please review the salt content on the below mentioned nutrition label and specify if the food product is high in salt? *



Mark only one oval.

- Yes
- No
- Don't know

41.Please review the salt content on the below mentioned nutrition label and specify if the food product is high in salt? *

Nutrition

Typical Values	per 100g as sold:
Energy	646kJ/155kcal
Fat	9.3g
of which saturates	3.4g
Carbohydrate	0.6g
of which sugars	0.3g
Fibre	<0.5g
Protein	17.0g
Salt	1.9g
Reference intake of an average adult (8400kJ/2000kcal)	-

Mark only one oval.

- Yes
- No
- Don't know

42. I often use FoodSwitch app to compare the nutrient content and purchase the healthier options. *

Mark only one oval.

- Yes
- No
- Don't know about FoodSwitch

43. I often add salt during cooking. *

Mark only one oval.

- Yes
- No

44. I often add salt at table. *

Mark only one oval.

- Yes
- No

45.I often use herbs and spices to improve flavor of foods cooked with less or no salt. *

Mark only one oval.

- Yes
- No

45. I mostly read the menu and look for nutrition information to select low salt options.

Mark only one oval.

- Yes
- No

46.*Thank you for filling out this survey! We would like to send some feedback on your salt intake and send you a short video presentation offering practical advice to reduce salt intake. Would it be possible for us to contact you again? Mark only one oval.*

- Yes
- No

Please provide us with your email address. *

APPENDIX M

Dietary Salt Monitor (v.3.2021)

Evaluating the use of dietary salt monitor in type 2 diabetes

Dear Participant,

Thank you for filling out 'short food frequency questionnaire'. You must have received a copy of your results and viewed the video presentation on 'reducing salt in your diet'. Now, we request you to kindly share your feedback and give us information on your food intake in the LAST FOUR WEEKS. Your answers will help us to evaluate the usefulness of our dietary salt monitor in creating awareness on salt intake in Type 2 Diabetes.

Email *

If you require more information about this evaluation survey, you can send email with your questions to the research team.

Research student: Ranjana Babber

Email: rab0805@my.londonmet.ac.uk

Research supervisor: Dr Dee Bhakta

Email: d.bhakta@londonmet.ac.uk

We would like to thank you again in advance, for your participation.

Section 1: Processed Foods: Average servings eaten in <u>last 4 weeks.</u>

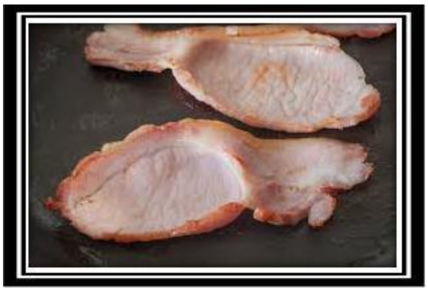
Instructions for filling this section

You are provided with a photograph of a typical serving per food item. Based on this photograph, please estimate the number of servings, you had in a single meal based on your intake in the LAST 4 WEEKS.

Example: 1 serving of bacon is equal to two rashers. If you mostly eat three rashers, state 1.5 servings. If you don't eat this food item, please enter '0'.

1. If you eat bacon, how many servings do you usually have per meal? *

This category includes all types of bacon rashers; streaky, back, middle, medallion/fat trimmed.



1 serving = 2 bacon rashers

2. If you eat ham, how many servings do you usually have per meal? *

This category includes all types of ham including luncheon meat, premium ham, denny slices, prosciutto and parma.

1 serving = 1slice of ham

3. If you eat sausages, how many servings do you usually have per meal? *

This category includes all types of sausages including pork, beef and chicken.

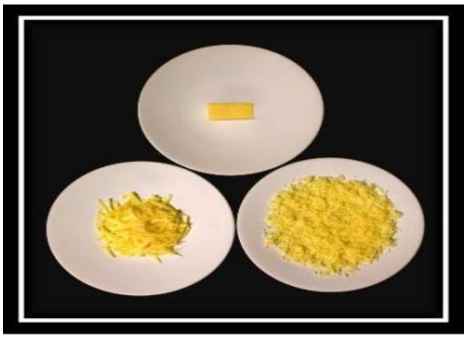
1 serving = 2 sausage

4. If you eat other processed meats, how many servings do you usually have per meal? *

This category includes other cured and processed meats as meat loaf, corned beef slices, pate, smoked fish and tinned fish like tuna in brine.

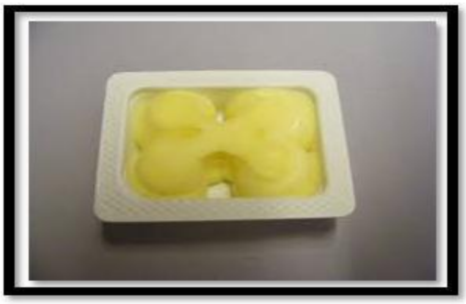
1 serving of other processed meat or fish = 1 slice of meat loaf/ corned beef/ half a tin of tuna in brine.

5.If you eat cheese, how many servings do you usually have per meal? *This category includes all cheeses except mozzarella, ricotta, and cottage cheese.



1 serving = 30g shredded/ grated/ cube (matchbox size) cheese

6. If you eat salted butter and buttery spreads, how many servings do you usually have per meal? * This category includes all types of salted butter and spreads (dairy & non-dairy).



1 serving = 2 teaspoon/ Individual portion pack

7. If you eat marmite, how many servings do you usually have per meal? * This category includes all types of yeast- based extracts: marmite/ vegemite/ promite etc.

1 serving = One individual sachet or 1 level teaspoon

8.If you eat bread and rolls, how many servings do you usually have per meal? *

This category includes all types of bread -white, brown wholemeal, granary and bread products such as rolls, flat breads, tortilla, pitta and naan bread.

1 serving = 1 medium slice of bread or 1 roll

9. If you eat breakfast items, how many servings do you usually have per meal? *
Examples includes crumpets, waffles, pancakes, English muffins, scones.

1 serving = 1 crumpet or 1 wafe or 1 scone

10. If you eat baked beans, how many servings do you usually have per meal? *This category includes all varieties of canned beans in tomato sauce.

1serving = Half a standard can

11. If you have soups, how many servings do you usually take per meal? *This category includes all types of tinned and dehydrated powdered soups.

1 serving = Half a can

12. If you eat ready meals, how many servings do you usually have per meal? *This category includes both chilled and frozen varieties of ready meals Chinese/Thai/Indian/Italian/Traditional meals including breaded fish, fish fingers, breaded chicken, chicken nuggets, pies, pasties, burgers and sausage rolls.

1 serving = Prepacked meal for one

13. If you eat pizza, how many servings do you usually have per meal? *

This category includes all varieties of supermarket pizza.

1 serving = 1 standard pizza

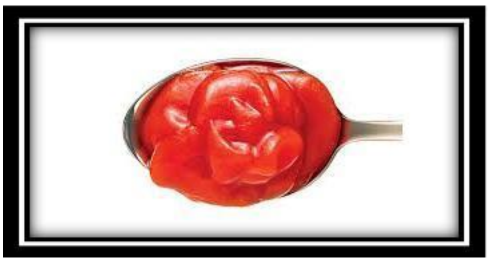
14. If you eat shop-bought sandwiches, how many servings do you usually have per meal? *This category includes all varieties of shop-bought sandwiches including wraps.

1 serving = 1 pre-packed sandwich

15. If you use pasta and cooking sauces, how many servings do you usually take per meal? * This category includes all types of sauces as Bolognese, Carbonara, Indian cooking sauce, Thai curry sauce, Chinese stir-fry sauce etc.

1 serving = 7 - 8 tablespoon or a quarter of a standard jar

16. If you use tables sauce, how many servings do you usually eat per meal? * This category includes all types of table sauces such as ketchup, brown sauce, mayonnaise, salad cream, salad dressings, chutneys, relishes etc.



1 serving= 1 tablespoon

17. If you eat crisps, how many servings do you usually have per meal? * Examples includes all potato crisps, corn puffs, vegetable crisps and Bombay mix.

1 serving= 1 regular bag of crisp (grab bag)

18. If you eat salted nuts, how many servings do you usually have per meal? * This category includes all types of salted nuts.

1 serving = One handful (30g)

19. If you eat savoury biscuits/crackers, how many servings do you usually have per meal? * This category includes all types of savoury biscuits/crackers and crispbread.

1 serving = 1 cracker/ crispbread

20. If you eat meat alternatives, how many servings do you usually have per meal? * This category includes meat free burgers, sausages, mince, and other ready meals made from

Quorn/soy/pea protein etc.

1 serving = One individually packed ready meal or one serving as sold

21. If you use stock, how many servings do you usually include in one meal? * This category includes stock cubes and made-up stock.

1 serving = Half a stock cube or half a cup of made- up stock

22. If you use gravy, how many servings do you usually have per meal? * This category includes all types of gravy made up from granules or ready pots or gravy pouches.

1 serving = 3 tablespoon

23. If you use salt-based rubs or seasonings, how many servings do you usually include for one meal? * Includes all types of salt-based rubs/seasoning or marinades.

1 serving = 1 heaped tablespoon

Section 2: Frequency of intake of processed

Please estimate how often you eat each of these food items and choose the option that best

your average use for the LAST 4 WEEKS. *

Food categories	2-3 times/ day	Once/ day	5-6 times/ week	2-4 times/ week	Once a week	1-3 times/ month	Never
Bacon							
Ham							
Sausages							
Processed meats							
Cheese							
Marmite							
Bread & rolls							
Breakfast items							
Baked Beans							
Soup							
Ready meals							
Pizza							
Bought sandwiches							
Pasta & cooking sauces							
Table Sauces							
Crisps							
Salted nuts							
Savoury biscuits/ crackers							
Meat substitutes							
Stock							
Gravy							
Salt based rubs and seasonings							

Section 3: Reduced or lightly salted food items

Please let us know, if you use reduced or lightly salted variety of following foods in LAST 4 WEEKS? *

Food categories	Yes	No	Not applicable
Bacon			
Ham			
Sausages			
Processed meats			
Cheese			
Marmite			
Bread & rolls			
Breakfast items			
Baked Beans			
Soup			
Ready meals			
Pizza			
Bought sandwiches			
Pasta & cooking sauces			
Table Sauces			
Crisps			
Salted nuts			
Savoury biscuits/ crackers			
Meat substitutes			
Stock			
Gravy			
Salt based rubs and seasonings			

Section 4: Frequency of eating out

Please give your response based on average number of eating out/takeaway occasions in LAST 4 WEEKS?

	5-6 /week	2-4 /week	Once /week	1-3 /month	Never
Starter and sides					
Main course					
Dessert					

Section 5: Other dietary information

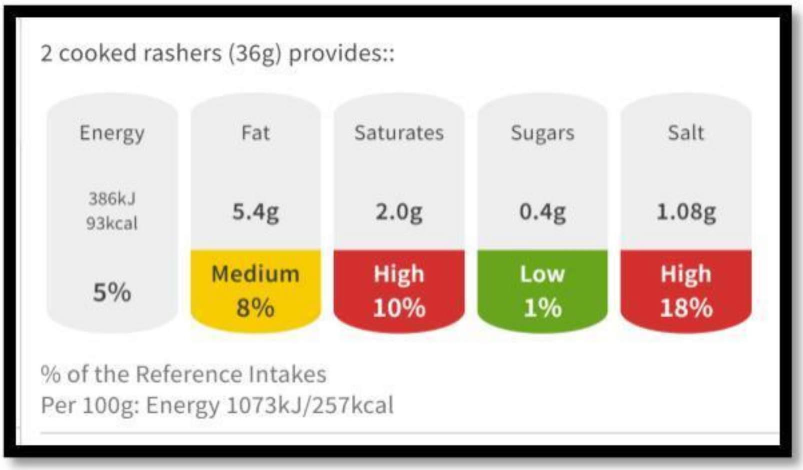
Finally, we would like to ask you few questions about food shopping and your dietary habits.

1.I read salt content on the nutrition label while shopping for food during last 4 weeks. *

Yes

No

2a. Please review the salt content on the below mentioned nutrition label and specify if the food product is high in salt?



Yes

No

Don't know

2b. Please review the salt content on the below mentioned nutrition label and specify if the food product is high in salt?

Nutrition

Typical Values	per 100g as sold:
Energy	646kJ/155kcal
Fat	9.3g
of which saturates	3.4g
Carbohydrate	0.6g
of which sugars	0.3g
Fibre	<0.5g
Protein	17.0g
Salt	1.9g
Reference intake of an average adult (8400kJ/2000kcal)	-

- Yes
- No
- Don't know

3. What is your opinion about FoodSwitch app? *

- This app is useful to choose healthier food options and am using it.
- This app can be useful for choosing/shopping healthier food options and i plan to use it in future
- Other

4. Please give response to below statements based on your dietary practices in LAST 4 WEEKS. *

	Yes	No
I often add salt during cooking		
I often add salt at table		
I often use herbs and spices to improve flavour of foods cooked with less or no salt.		
I mostly read the menu and look for nutrition information to select low salt options, whilst eating out.		

5. Please share your feedback about the information hared through our research's dietary salt monitor and video presentation.

Thank you for completing this survey and your feedback!

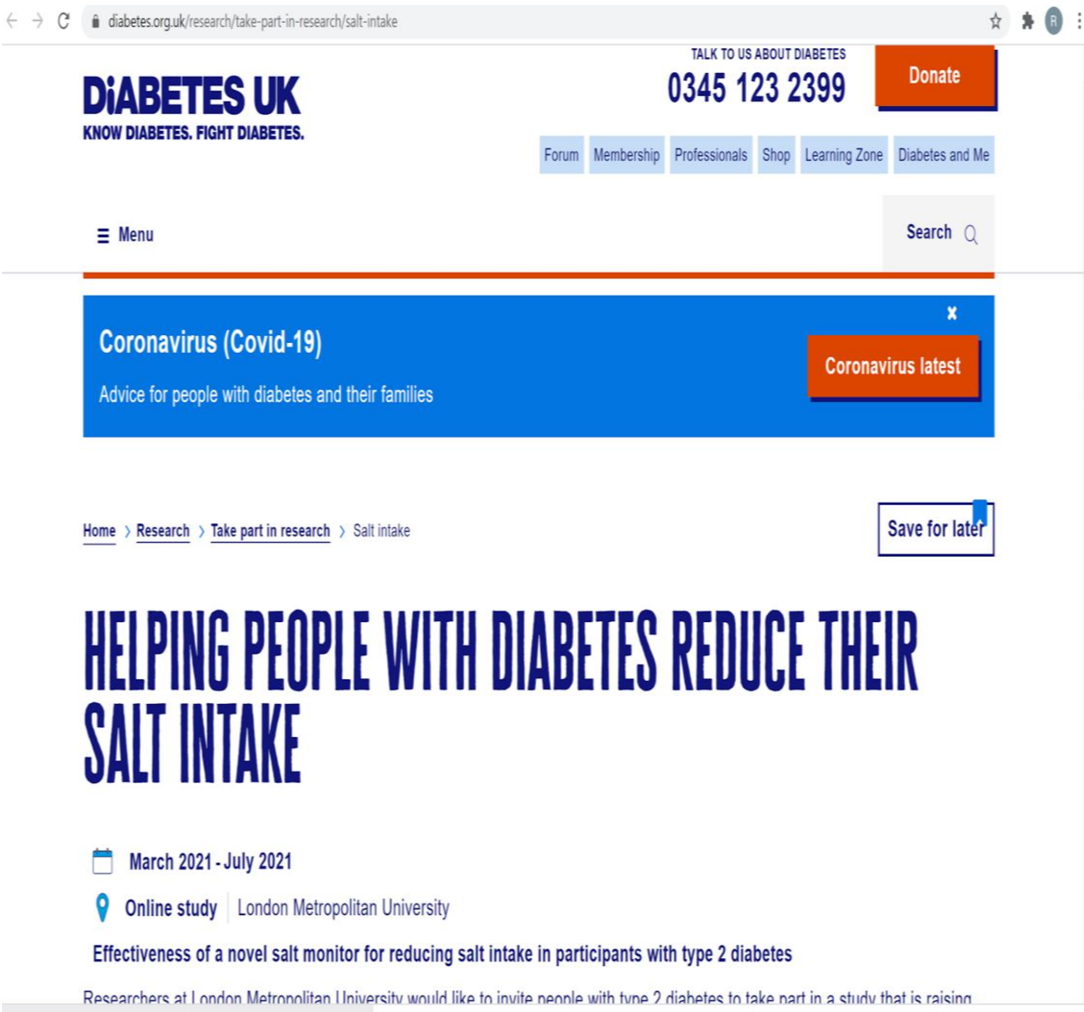
APPENDIX N

Comparison of salt content computed for categories by Nutritics against the salt values for categories published by PHE

Food Category	Salt content based on PHE survey (g/ 100g)	Salt content as computed by Nutritics database (g/ 100g)	PHE's 2017 salt targets (g/100g)	PHE's 2024 salt targets (g/ 100g)
Bacon	3.14	2.8	2.88	2.59
Ham	2.07	2.6	1.63	1.63
Sausages	1.42	1.8	1.13	1.08
Other processed meats	0.87/ 0.95		0.8- 0.9	0.8 -0.9
Cheese	1.78	1.7	1.75	0.66
Salted butter and buttery spreads	1.47	1.6	1.48/ 1.06	1.33/ 0.95
Marmite	NA			
Bread and rolls				
Breakfast items				
Baked beans in tomato sauce		0.7	0.56	0.56
Soups	0.56	0.7	0.53	0.5
Ready meals	0.66	0.6	0.63	0.6
Pizza	1.05	1.0	1.0	1.0
Bought Sandwiches		0.9	0.9	0.85
Pasta Sauces	0.81	0.8	0.9	0.85
Table sauces		1.9	0.75	0.68
Crisps	1.36	1.7	1.7	1.63
Salted Nuts		1.1	1.31	1.25
Savoury Biscuits/ Crackers	1.53	1.1	1.3	1.3
Meat Substitutes	1.12	1.2	0.63	0.63
Stock	0.7		0.75	0.71
Gravy	0.88		0.95	0.85
Salt based rubs/seasonings.		17.3		

APPENDIX O

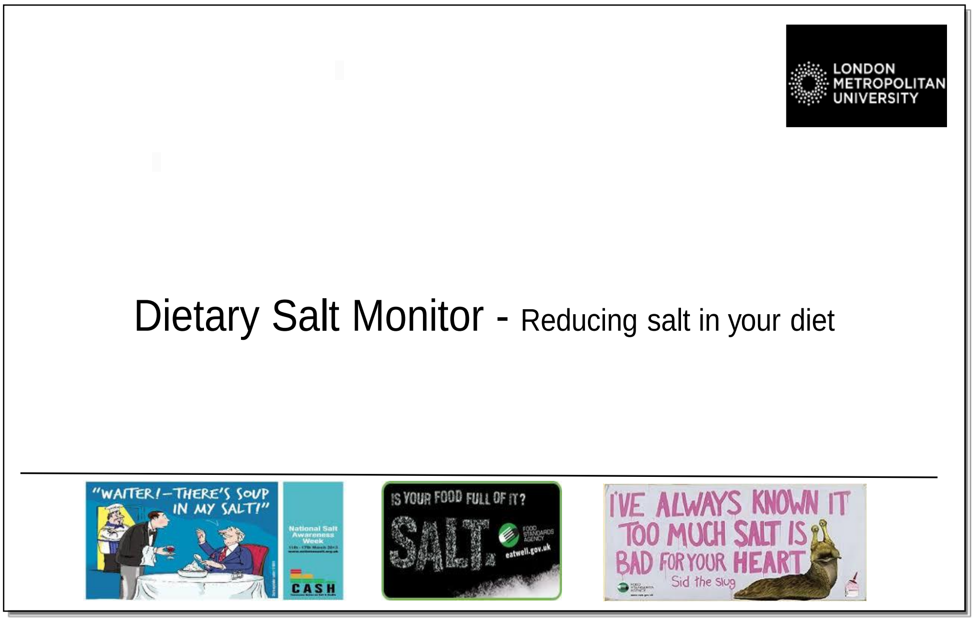
Advertisement on Diabetes UK's website for recruitment of participants with Type 2 diabetes, for dietary salt monitor intervention study



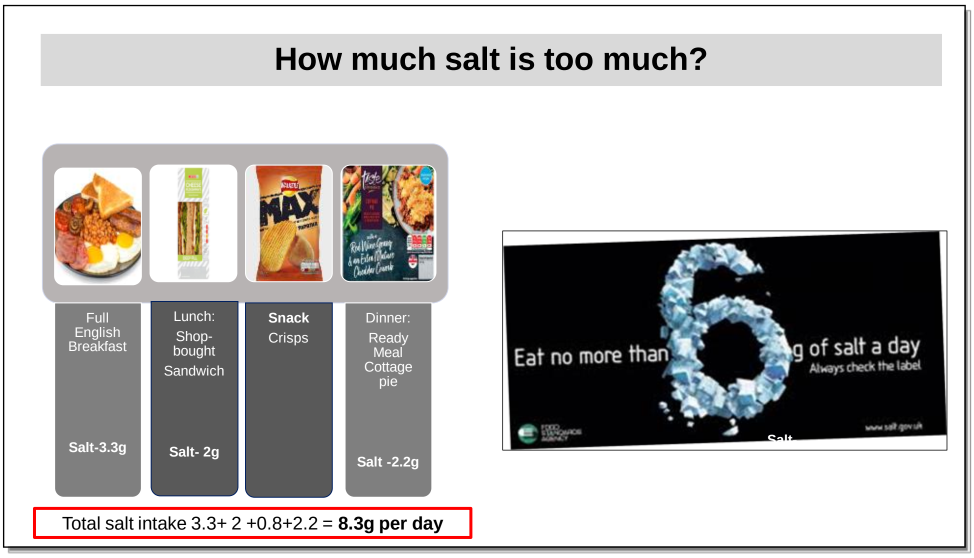
APPENDIX P

Educational video – Dietary Salt Monitor, Reducing salt in your diet

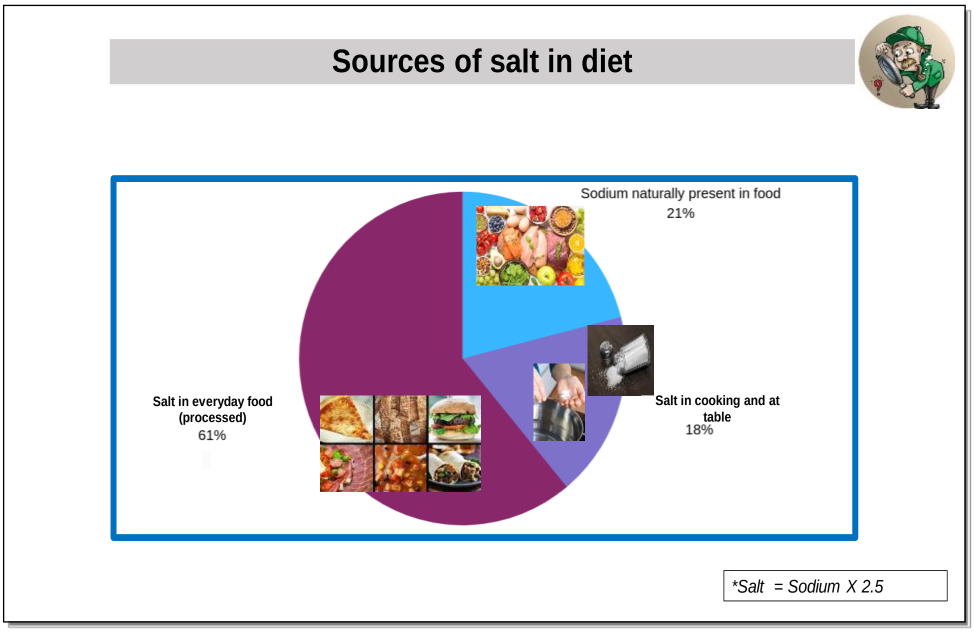
Slide 1



Slide 2



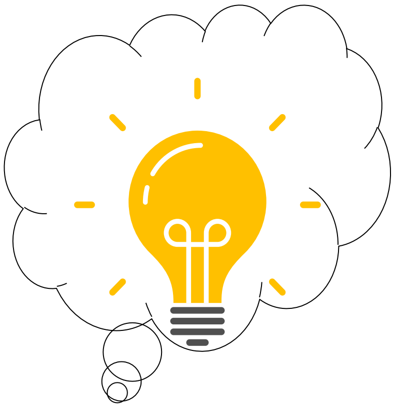
Slide 3



Slide 4

Slide 5

Steps for reducing dietary salt intake



- ✓ **Reduce portion size**
- ✓ **Reduce frequent usage**
- ✓ **Reduced salt food products**
- ✓ **Read nutrition label**

Slide 6

Reducing portion size

Salt content: 0.94g/100g

Avg. slice (wt. 50g) = 0.5g

4 slices/day = 1.9g salt

Salt content: 0.95g/100g

Avg. slice (wt.23.8g)=0.2g

4 slices per day = 0.9g salt

Slide 7

Reduced salt food products

Salt content:
1g per serving

Salt content:
0.6g per serving

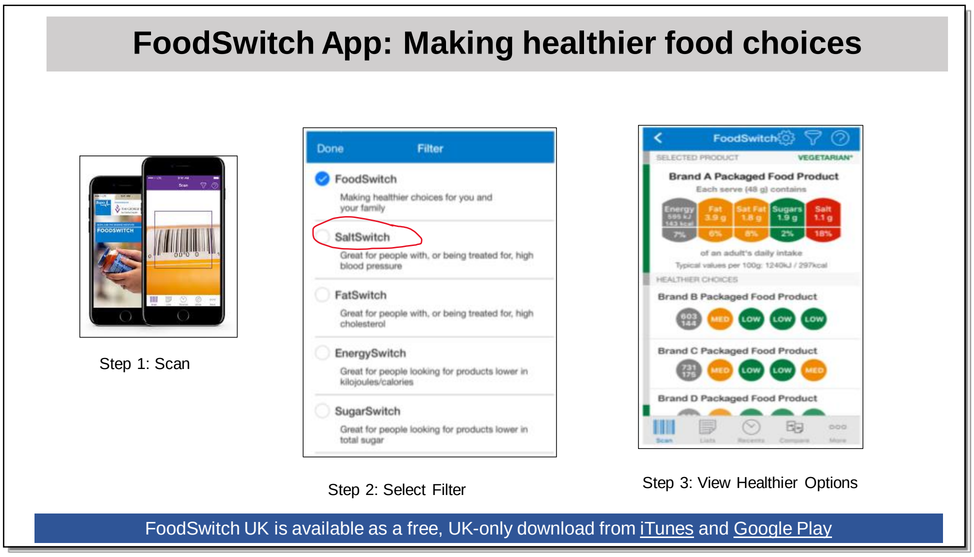
Slide 8

Nutrition Label: Interpretation

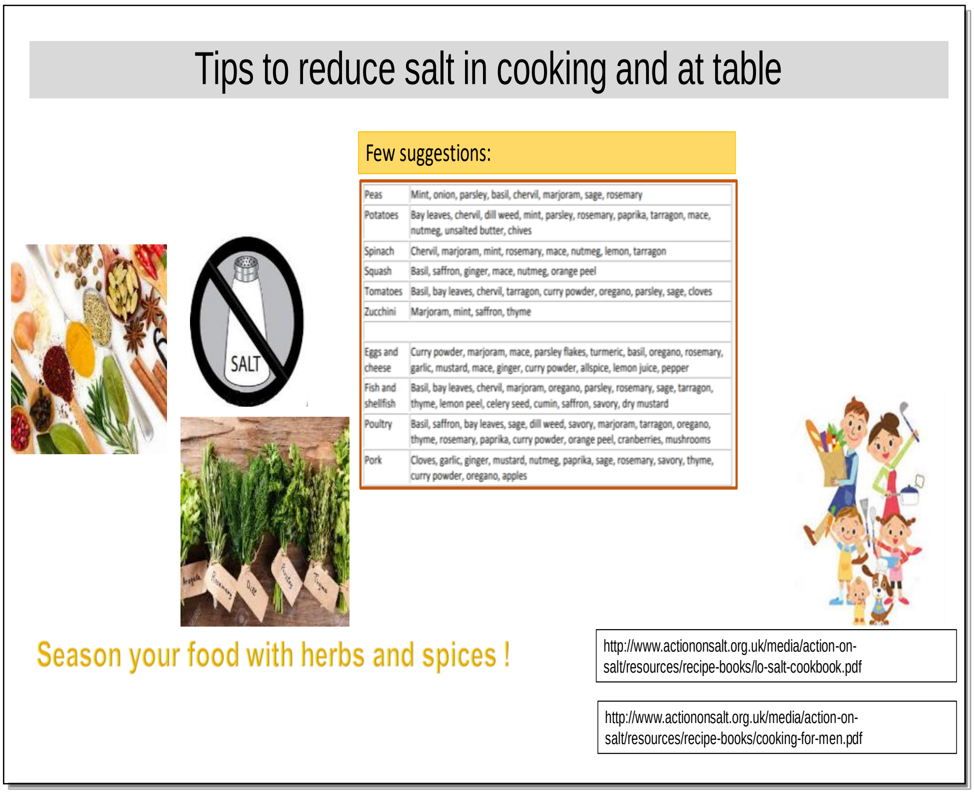
Nutrient	Reference Intakes	Low	Medium	High	Portion>100g High
Salt	6g	≤0.3g/100g	>0.3g to ≤1.5g/100g	>1.5g/100g	>1.8g per portion

Slide 9

Slide 10

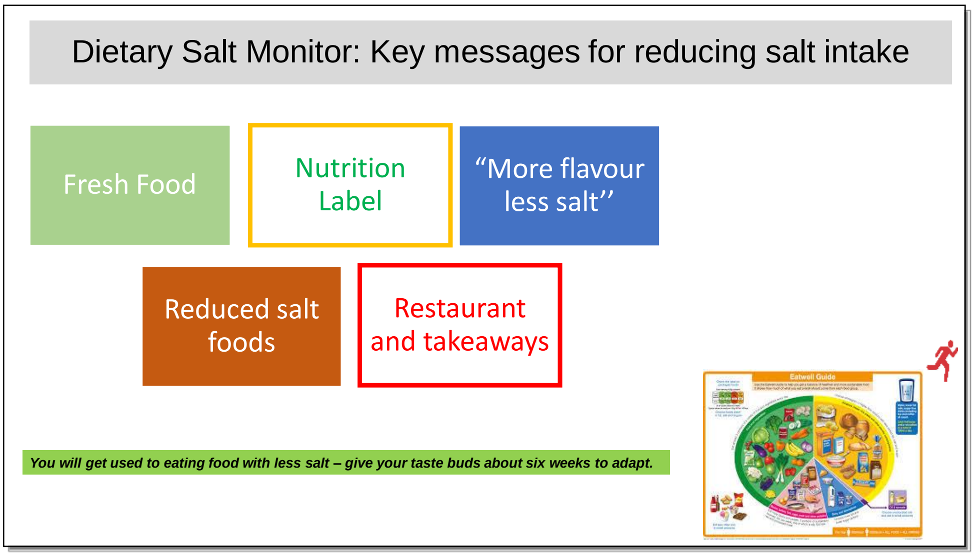


Slide 11



Peas	Mint, onion, parsley, basil, chervil, marjoram, sage, rosemary
Potatoes	Bay leaves, chervil, dill weed, mint, parsley, rosemary, paprika, tarragon, mace, nutmeg, unsalted butter, chives
Spinach	Chervil, marjoram, mint, rosemary, mace, nutmeg, lemon, tarragon
Squash	Basil, saffron, ginger, mace, nutmeg, orange peel
Tomatoes	Basil, bay leaves, chervil, tarragon, curry powder, oregano, parsley, sage, cloves
Zucchini	Marjoram, mint, saffron, thyme
Eggs and cheese	Curry powder, marjoram, mace, parsley flakes, turmeric, basil, oregano, rosemary, garlic, mustard, mace, ginger, curry powder, allspice, lemon juice, pepper
Fish and shellfish	Basil, bay leaves, chervil, marjoram, oregano, parsley, rosemary, sage, tarragon, thyme, lemon peel, celery seed, cumin, saffron, savory, dry mustard
Poultry	Basil, saffron, bay leaves, sage, dill weed, savory, marjoram, tarragon, oregano, thyme, rosemary, paprika, curry powder, orange peel, cranberries, mushrooms
Pork	Cloves, garlic, ginger, mustard, nutmeg, paprika, sage, rosemary, savory, thyme, curry powder, oregano, apples

Slide 12



APPENDIX Q

Working example for calculating salt intake with Dietary Salt Monitor (v.2.2021

Male	0
Female	1

Food Category	**Weight per standard serving (g)**	**Salt content per serving**	**State no. of servings eaten per meal**	**Frequency of consumption (choose the option that best suits your average intake and ENTER '1' in the column)**							**Reduced salt variety**	**Daily salt intake**
				2-3times a day	**Once/day**	**5-6 times a week**	**2-4 times a week**	**Once a week**	**1-3times a month**	**Never**	**Yes (1)/ No (0)**	
Bacon	65	1.8	1				1				0	**0.8**
Ham	20	0.5	1					1			0	**0.1**
Sausages	64	1.2	1						1		0	**0.1**
Other processed meats			1					1			0	**0.0**
Cheese	30	0.5	1		1						0	**0.5**
Salted butter and buttery spreads	10	0.2	1	1							0	**0.4**
Marmite	9	1.0	0							1	0	**0.0**
Bread and rolls	39	0.4	2	1							0	**2.0**
Breakfast items	68	0.7	2					1			0	**0.2**
Baked beans in tomato sauce	205	1.4	1				1				0	**0.6**
Soups	220	1.5	1				1				0	**0.7**
Ready meals	350	2.1	1					1			0	**0.3**
Pizza	300	3.0	0.5					1			0	**0.2**
Bought Sandwiches	173	1.6	1				1				0	**0.7**
Pasta Sauces	114	0.9	1					1			0	**0.1**
Table sauces	15	0.3	2			1					0	**0.5**
Crisps	35	0.6	0.5					1			0	**0.0**
Salted Nuts	30	0.3	1				1				0	**0.1**
Savoury Biscuits/ Crackers	8.5	0.1	1					1			0	**0.0**
Meat Substitutes	85	1.0	1						1		0	**0.1**
Stock			1						1		0	**0.0**
Gravy			1						1		0	**0.0**
Salt based rubs/seasonings.	7.4	1.3	1						1		0	**0.1**

Eating out									
Starters	[redacted]	0.51	[redacted]		1			[redacted]	0.4
Main Course	[redacted]	2.5	[redacted]		1			[redacted]	0.4
Dessert	[redacted]	0.21	[redacted]			1		[redacted]	0.1
Salt usage in cooking and at table. Mention (1) for YES and (0) for NO									
Adding salt during cooking.	[redacted]							1	[redacted]
Adding salt at table	[redacted]							1	[redacted]

Estimated Salt intake /g day:11 and limit is 6g/d

Columns marked as grey are input fields, these include data as gender (M/ F), no. of portions of food categories, frequency of consumption and if reduced salt variety is chosen most times for each category. Fields marked as amber are output field and include formulas for the calculation. Estimated daily salt intake is total salt contributed from all 23 processed food categories, eating out and account for discretionary salt.

Based on the above computation, each participant was sent individualized report stating their estimating salt against the recommended limits and top sources of salt in diet. Here is the sample of individualized report emailed to the participants.

Sample

Dear Participant (……………………)

Thank you for filling out our research study's 'short food frequency questionnaire'. Based on your responses, we have estimated your daily salt intake using our research's dietary salt monitor.

Your estimated salt intake is …. / day
Recommended salt intake is ≤6g/day

Top sources of salt in your diet are ………………………………………………………………………………………

You can watch our educational video for practical tips to reduce dietary salt intake.
Here Link: Bit.ly/reducingsaltintake

If you have any further questions, please contact at rab0805@my.londonmet.ac.uk.
We shall be in touch next week and request you to fill another dietary survey. This shall also help us to receive your feedback about participation in this research study.

Best regards
Ranjana Babber
Research Student
London Metropolitan University

APPENDIX R
Copy of Published Abstracts

Proceedings of the Nutrition Society (2020), **79 (OCE3)**, E773 doi:10.1017/S0029665120007594

Nutrition Society Live 2020, 14–15th July 2020

Barriers in adherence to dietary salt intake recommendations in participants with type 2 diabetes and co-morbid hypertension

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Hypertension is present in up to two-thirds of the patients living with type 2 diabetes [1]. Management of high blood pressure plays a vital role in reducing the risk of macrovascular and microvascular complications in patients with type 2 diabetes [2]. A meta-analysis of randomized controlled trials in diabetes patients, concluded that reducing salt intake lowers blood pressure in type 2 diabetes [3].

We conducted a dietary survey to determine the knowledge, attitudes, and practices (KAP) regarding dietary salt intake in participants with type 2 diabetes and co-morbid hypertension. A total of fifty participants within the age group of 20 -75 year, were recruited from the Diabetes Foot Clinic, Basildon & Thurrock University Hospital. An interviewer-administered questionnaire was used to assess awareness level on varying aspects of dietary salt intake. The Multiple Pass Recall method was used to obtain dietary data, for determination of food sources of salt [4] and estimate daily salt intake.

The mean KAP score for the study group participants was 22.6 (6.1) out of a maximum achievable score of 40. Only 12% of the study participants achieved a KAP score above 32 corresponding to >80% KAP score achievement. The mean KAP score of the participant group consuming >6g/day salt was lower compared to the group consuming <6g/day (21.6 (5.4); 22.9 (6.3) respectively, NS). The majority of the participants (98%) were not aware of UK government recommendation of '<6 g salt/day'. Lack of understanding of food sources of salt; poor self-perception of salt intake; non-practice of reading salt content on nutrition label and frequent addition of salt to food during cooking were identified as other potential barriers in adherence to the recommended salt intake. The nutritional analysis of the dietary data indicated 28% of the participants consumed >6 g/day of salt and nearly half of the participants consumed >5g/day i.e. above WHO salt intake recommendation. Pivot tables were used to determine the top food contributors to salt intake as: bread, added salt during cooking, canned beans, bacon, ham, processed meat and meat dishes as beef burgers, pork or chicken based chinese takeaway, ready meals, salted butter, cheese and soups.

The findings of our study indicate low level of awareness related to varying aspects of dietary salt intake among the hypertensive type 2 diabetes participants and describes the specific barriers in adherence to the recommended salt level. We hope to use this data to formulate a salt calculator as an educational tool to increase awareness and ideally decrease salt intake in this, at-risk population.

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Proceedings of the Nutrition Society

Proceedings of the Nutrition Society (2022), **81 (OCE5)**, E216 doi:10.1017/S002966512200249X

Summer Conference 2022, 12–15 July 2022, Food and Nutrition: pathways to a sustainable future

Dietary salt monitor – a novel nutrition education intervention for reducing salt intake in Type 2 Diabetes

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The risk of cardiovascular morbidity and mortality increases markedly in type 2 diabetes, owing to the higher prevalence rates of hypertension(1,2). The role of dietary salt intake has been well established in the prevention as well as management of high blood pressure(3). However, there is paucity of interventions and education programmes aimed at lowering dietary salt intake in population with type 2 diabetes. This research study was aimed at the development, validation, and implementation of a novel dietary salt monitor. A 24h dietary recall using multiple pass recall method was obtained from the participants with type 2 diabetes and concomitant hypertension (n = 50), attending outpatient diabetic foot clinic at NHS hospital in Basildon, Essex. This dietary information was further analysed for development of a short food frequency questionnaire, namely dietary salt monitor. This novel dietary tool was validated against the gold standard - 24h urinary sodium excretion method since dietary assessment methods are subjected to measurement errors related to recall bias, misreporting and lack of updated food composition databases(4). The study design included collection of 24h urine samples for two days from university students. The effectiveness of dietary salt monitor was pilot tested in an online nutrition education intervention, where type 2 diabetes participants (n = 22) were recruited from various online platforms including the Diabetes UK website. The top ten contributors of salt were identified as bread and rolls, processed meats, added salt, ready meals, meat dishes, spreading fats, canned beans, soups, cheese, and sandwiches. A total of 23 food categories were shortlisted for the food frequency questionnaire component of the dietary salt monitor, and these categories were finalised based on the factors as salt density, contribution of salt to the diet, non- achievement of Public Health England's 2017 salt targets, food categories unrecognized as high in salt by consumers, sustainability, change in cooking practices during COVID-19 and overall nutritional composition of the food category. The Bland and Altman method for agreement between dietary salt monitor and urinary sodium excretion method suggested a bias of 1.5g/ d (upper LOA 7.68 and lower LOA -4.72, n = 9). This dietary salt monitor was further integrated in a web form and supported by a short educational video highlighting the salt content of the food categories and key strategies as 4'R's - **R**educing portion, **R**educing frequent intake, **R**educed salt food, **R**ead nutrition label, for lowering salt intake. This short-term intervention study (6 weeks) resulted in a statistically significant reduction in median salt intake for the group, with baseline of 7.9 g/d shifting to 5.2 g/d post the intervention (p = 0.001, effect size = 0.6). This study marked the development of UK's first dietary salt monitor for use in type 2 diabetes and was effective in reducing dietary salt intake.

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