# Understanding non-adherence to diabetes complications screening in a multi-ethnic Asian population using a mixed-methods design: protocol and baseline participant profile

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## *Abstract*

**Background:** Yearly screening for microvascular complications of diabetes mellitus (DM), namely retinopathy (DR), nephropathy (DN), and foot complications (DFC), is recommended to reduce their incidence, and delay or prevent their progression. However, poor adherence to screening is common, but prospective data on the magnitude and predictors of non-adherence to DR, DN and DFC screening in Singapore are unavailable.

**Objective:** The Understanding Non-Adherence to Diabetes Complications Screening (UNADS) study aims to determine the rates, predictors, clinical and economic impact of non-adherence to diabetic complications screening in patients with type 2 diabetes (T2DM) in Singapore. We describe the study methodology and participants' baseline characteristics that may be associated with non-adherence to DM complications screening.

**Methods:** In this prospective, mixed-methods, clinic-based study, patients who underwent DR, DN, and/or DFC screening and were offered an annual rescreening appointment, were recruited from six primary care centres. Patients' sociodemographic, medical, clinical, and patient-reported characteristics were recorded at baseline. Non-adherence to DR/DN/DFC screening is defined as not attending the annual rescreening appointment within 4 months of the scheduled rescreening date. Adherence and clinical data will be recorded at 16-months post-enrolment. Additionally, selected participants and healthcare professionals will undergo qualitative interviews to elicit barriers/facilitators of adherence to rescreening.

**Results:** 974 eligible patients (2,123 screenings, median [IQR] age 61.0 [55.0-67.0] years, 52.9% male, 64.1% Chinese) consented and completed the baseline assessment. Of these, 75.4%, 61.9%, and 80.7% attended DR, DN and DFC screening, respectively. Most (81.4%) attended >1 complication screening on the same day; had received secondary or lower education (71.9%); had hypertension (73.4%) and dyslipidemia (85.1%); and 43.1% were obese (BMI>27.5 kg/m2). Median DM duration and HbA1c levels were 6.3 years and 6.9%, respectively. Over half (55.1%) had not received prior DM education. Furthermore, participants reported low levels of diabetes-related self-efficacy (1.4 [IQR 1.0-3.9] out of 5).

**Conclusions:** At baseline, we have successfully enrolled almost 1000 patients with T2DM scheduled for annual DR/DN/DFC rescreening, and potential predictors of non-adherence to rescreening were systematically collected. Ongoing follow-up phases will focus on establishing the rates and associated modifiable predictors of non-adherence to DR/DN/DFC rescreening, which may inform programme initiatives.

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# Original Manuscript

# Understanding non-adherence to diabetes complications screening in a multi-ethnic Asian population using a mixed-methods design: protocol and baseline participant profile

**Short Title:** Non-adherence to diabetes complications screening

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## ABSTRACT

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namely retinopathy (DR), nephropathy (DN), and foot complications (DFC), is recommended to reduce their incidence, and delay or prevent their progression. However, poor adherence to screening is common, but prospective data on the magnitude and predictors of non-adherence to DR, DN and DFC screening in Singapore are unavailable.

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**Conclusions:** At baseline, we have successfully enrolled almost 1000 patients with T2DM scheduled for annual DR/DN/DFC rescreening, and potential predictors of non-adherence to rescreening were systematically collected. Ongoing follow-up phases will focus on establishing the rates and associated modifiable predictors of non-adherence to DR/DN/DFC rescreening, which may inform programme initiatives.

**Keywords:** Diabetes complications screening, diabetic retinopathy, diabetic nephropathy, diabetic foot complications, non-adherence, mixed-methods

## INTRODUCTION

Microvascular complications of diabetes mellitus (DM), namely retinopathy (DR), nephropathy (DN), and foot complications (DFC) are common, and impose a profound quality of life, health and economic burden on the individual and society.(1, 2) Regular screening for these complications can reduce their incidence and delay/prevent progression of blindness, end-stage renal disease, and diabetic foot ulcers.(3-7) In Singapore, guidelines recommend that individuals with DM have a dilated fundus examination, assessment of urine albumin excretion and serum creatinine, and foot examination/education annually. However, screening programs are only cost- and clinically-effective if uptake is high, and studies conducted overseas have shown poor adherence to screening, ranging from 20% to 60%.(8-10) At a population-based level, the Singapore Epidemiology of Eye Disease study (2004-2011, SEED) showed that 80% of individuals with DM had undiagnosed DR, a proxy indicator of non-adherence to DR screening.(11) However, current data on non-adherence to DR, DN and DFC screening in Singapore is lacking.

Several factors have been associated with non-adherence to DM complications screening including low educational attainment, issues with appointment access, and lack of social/family support.(8, 12-17) However, most existing research is limited by a retrospective study design, or only employing qualitative data collection, meaning that predictors of non-adherence to DM complications screening remain largely unknown. Additionally, non-adherence to screening has been associated with poor DM control,(6, 18) more severe disease,(19, 20) and frequent treatment(21) and hospitalization needs.(6) Indeed, a systematic review exploring patients' non-attendance at eye screening programmes revealed that repeated non-attendance was associated with increased risk of sight threatening DR (STDR).(20) However, the studies included were conducted mostly in

Western populations and may not be applicable to Asian populations due to different screening guidelines, and regional, political, social, economic, cultural, and healthcare systems.

To date, there are no prospective and contemporary population data on the rates; predictors; and clinical and economic impact of non-adherence to DM complications screening in Singapore. Furthermore, our understanding of the barriers/facilitators to screening adherence faced by DM patients is limited. Such information is crucial for healthcare professionals and policy makers to make decisions on resource allocation and for informing interventions to improve adherence to DM screening programs. Against this background, we are conducting a prospective, multi-centred clinic-based study (**U**nderstanding **N**on-**A**dherence to **D**iabetes Complications **S**creening [**UNADS**]) to ascertain the rates (Aim 1); associated predictors (Aims 2a and 2b); and clinical (Aim 3) and economic impact (Aim 4) of non-adherence to DM complications screening in primary care 'polyclinic' patients with Type 2 DM (T2DM) in Singapore using a mixed-methods approach. In this paper, we provide a detailed description of the study design, data collection tools and protocols, and associated analytical plans. Furthermore, we present the patients' baseline characteristics, and suggest factors that may potentially be associated with non-adherence to DM complications screening.

## METHODS

### Conceptual framework

We used Green and Kreuter's PRECEDE-PROCEED model(22) to inform our mixed-methods study design. This model has been widely used to identify and conceptualize barriers to healthcare screening in other health fields.(23-26) Our study utilized the first five 'PRECEDE' phases (**Supplementary Figure 1**): 1. social assessment, 2. epidemiological

assessment, 3. behavioural and environmental assessment, 4. educational and ecological assessment and 5. administrative and policy assessment (see **Supplementary materials**). Based on our consultations with senior healthcare professionals from the SingHealth [SHP] and two National Healthcare Group [NHGP] Polyclinics, and data from the NHG DM registry and SEED, non-adherence to DM complications screening was already identified as a major public health issue in Singapore.(11, 27) Therefore, in this current study, we focus on the implementation of Phases 2-5 via a prospective, mixed-methods study that combines a quantitative data collection phase followed by in-depth qualitative interviews.

**Study setting and design**

In Singapore, DM complications screening is performed mainly at 23 primary healthcare government polyclinics. Of these, four SHP and two NHGPs were involved in our study, based on high attendance by minority ethnic groups i.e., Malays (Geylang, GY [NHGP]) and Indians (Hougang, HG [NHGP]), and high patient volume to maximize recruitment potential (i.e., Bedok, BK; Bukit Merah, BM; Outram, OT; and Pasir Ris, PR [SHP]).

Standardized and uniform research protocols were applied at all sites. Each participant completed a baseline assessment on the day of enrolment and will be followed up at 16-months post enrolment (**Figure 1**). Baseline assessments involved collection of quantitative data including clinical and sociodemographic information, and patient-reported outcomes. At 16 months following the baseline assessment (i.e. up to four months after the scheduled annual rescreen appointment), a trained clinical research coordinator (CRC) will determine if the participant attended the annual rescreening appointment from polyclinic records. Participants who attend/don't attend rescreening will be deemed 'adherent'/'non-adherent', respectively. The CRC will then arrange a follow-up visit for all participants (both adherent and non-adherent) at the study site to collect study-related clinical information that

are not available in the electronic medical records (EMR). Furthermore, purposively selected participants will be invited to participate in focus groups or semi-structured interviews regarding barriers/facilitators to adherence with DM complications screening. In addition, semi-structured interviews will also be conducted with healthcare professionals (e.g., polyclinic doctors and allied health professionals) to elicit their perceptions on why some patients do not comply with their screening visits.

Recruitment commenced on 6th June 2018 at HG, 11th June 2018 at BK, 19th June 2018 at OT, 25th September 2018 at GY, 21st November 2018 at PR and lastly at BM on 8th February 2019 and baseline quantitative data collection ended at all six sites on 31st January 2020. The follow-up quantitative and qualitative phase is currently ongoing.

**Ethics Approval**

The study was approved by the SingHealth Centralized Institutional Review Board (CIRB, Reference #2016/3041), and all patients enrolled in this study provided written informed consent prior to participation. All healthcare professionals who will be enrolled in qualitative interviews will be verbally consented prior to participation. The study was conducted in accordance with the Declaration of Helsinki.

**Study population and procedures**

Quantitative Phase

*Population:* Patients with T2DM who underwent DM complications screening at one of the study sites and received a referral for an annual rescreen at the participating sites, were eligible. All eligible participants were Singaporean citizens or permanent residents of Chinese, Malay, Indian, or Eurasian ethnicity; aged ≥21 years; free of significant hearing impairment that could affect the study protocol, and cognitive impairment assessed using the six-item Cognitive Impairment Test.(28) Patients who had type 1 DM (T1DM) or with complications necessitating referral to tertiary care (e.g., presence of moderate or worse

DR, overt proteinuria, neuropathy) were deemed ineligible to participate. Each patient was assigned a unique study identification number for each type of screening attended and enrolled under this study. For example, a patient attending DR and DN screening appointments on the same or different days (bundle screening) were assigned two unique study identification numbers.

*Sample size determination:* Assuming the non-adherence rate for DR, DN and DFC is 50%, 30%, and 40%, a sample size of 1111 for DR, 933 for DN and 1067 for DFC was needed to obtain a 95% confidence interval of ±3% around the rates of non-adherence estimates with 80% power. Accounting for non-response and loss to follow-up of 20%, a sample size of 1444 for DR, 1213 for DN, and 1387 for DFC was needed. Furthermore, assuming a non-adherence rate of 50% and a probability of exposure (barriers/facilitators) of 15% among those who are adherent, these proposed sample sizes would be able to detect an odds ratio (OR) of 1.47, 1.6 and 1.5 of non-adherence to DR, DN and DFC screening, respectively, for a barrier/facilitator. Additionally, assuming that the effect of bundle screening would be 30% on DN and DFC screening where DR screening (n=1444) was treated as a constant, we required 849 and 971 for DN and DFC, respectively. In total, we required a sample of 3264 patients.

*Data collection:* All study assessments (summarised below) were undertaken by trained project members. A full description of all study procedures is provided in **Supplementary Table 1**.

- *Socio-demographic, medical, and diabetes-related information and social history* were collected via an in-house questionnaire and from EMR.
- *Anthropometric parameters*: Height and weight were measured on the day of assessment if not available in the participant's EMR.
- *Clinical parameters:* BP was assessed using a digital automatic BP monitor(29) Dinamap model

Pro Series DP110X-RW, 100V2; GE Medical Systems Information Technologies, Inc., USA) on site if not available in EMR. Participants' HbA1c, lipids [low/high density lipoprotein cholesterol (LDL/HDL), triglycerides (TG), total cholesterol (TC)], serum creatinine, UACR, and estimated glomerular filtration rate (eGFR) were collected from EMR if assessed ≤12 months ago. Otherwise, a venous blood sample drawn via venepuncture and a mid-stream urine sample were sent to Innoquest Laboratories Pte Ltd or National Healthcare Diagnostics, in Singapore for same-day analysis. The eGFR was calculated using the Chronic Kidney Disease Epidemiology Collaboration formula.(30)

- *Ocular parameters:* Retinal graded results of participants who attended the Singapore Integrated Diabetic Retinopathy Programme (SiDRP), a tele-opthalmology based screening programme, were obtained from participants' EMR.
- *Patient-reported outcomes* hypothesized to be associated with screening adherence were assessed using the following validated questionnaires: Revised Diabetes Knowledge Test(31, 32); Health Literacy Test for Singapore (HLTS) questionnaire(33); 3 item Health Literacy Questionnaire(34); Diabetes Empowerment Scale (Short form) – Self Efficacy (DES-SF)(35); Problem Areas in Diabetes Questionnaire (PAID-5)(36); Questions on Social Support.(37, 38)
- Specially crafted items designed to elicit barriers from the patient's perspective based on known barriers from the literature and expert panel input were also included (e.g., history of adherence/ non-adherence to DM complications screening, time taken to reach screening appointments, DM-related education needs and experiences, and attitudes towards diabetes control).

All baseline quantitative data were collected in hard copy format and subsequently entered in the Research Electronic Data Capture software (REDCap, Singapore) system (**Supplementary materials**).

*Analytical plan:* Basic proportions will be utilized to assess the rate of non-adherence to each DM complications screening (**Aim 1**). Baseline sociodemographic, medical, clinical, and patient-reported factors will be analysed continuously or categorically where

appropriate and logistic regression models will determine the associations between the various factors with non-adherence to each of the three DM complications screening visits (**Aim 2a**). Linear and logistic regression models will be utilized to examine the relationships between non-adherence to each individual DM complications screening with intermediate pre-post changes in clinical outcomes collected at the follow-up visit (**Aim 3**). To model the economic burden of non-adherence to DM screening, we will estimate and compare the cost of patients who are adherent versus non-adherent (**Aim 4**). We will focus on long-term costs of non-adherence (time horizon: 40 years) as there is unlikely to be any substantial cost-saving in the short term. To estimate long-term costs of non-adherence, a decision tree model will be used, which captures possible benefits of screening adherence in terms of lower risk of developing complications and timely detection and treatment if complications occur which, in turn, would lead to lower costs in the long term. All analyses will be performed using Stata/SE, version 15 (StataCorp, College Station, Texas).

Qualitative Phase

Our qualitative methodology aligns with the Consolidated criteria for reporting qualitative research (COREQ) checklist. (39)

*Population:* Focus groups or individual semi-structured interviews will be conducted with both adherent and non-adherent participants for the three DM complications screenings. Participants will be purposively selected across the spectrum of age, gender and language spoken (i.e., English, Mandarin, Malay, or Tamil) to ensure applicability of results. In addition, healthcare professionals, including advanced practice nurses, nurse care managers/educators and family physicians, will be invited to participate in semi-structured interviews.

*Sample size estimation:* Non-adherent participants will be oversampled to focus on barriers to screening adherence as these are amenable to intervention. Interviews will be offered in

English, Mandarin, Malay, or Tamil to capture issues applicable to English or non-English speakers. We estimate that 8 focus groups (3 ‘adherent’ and 5 ‘non-adherent’) with five to seven participants per group, and 15-20 semi-structured interviews will be required, resulting in a total of 55-76 participants. We estimate that 8-10 health care professionals will also be needed for the semi-structured interviews. Sampling will continue until thematic saturation is reached (i.e., no new themes emerge).

*Data collection:* Patient focus groups and semi-structured interviews will be conducted by trained interviewers and note-taker face-to-face at Singapore Eye Research Institute or over the phone, after completion of the 16-month follow-up. Sessions will be conducted according to an interview guide developed from a thorough literature review and based on expert panel opinion. The interview guide will comprise open-ended questions targeting predisposing (e.g., beliefs about illness and Western and Chinese medicine), reinforcing (e.g., role of family members in DM care), and enabling (e.g., importance of screening) factors guided by the PRECEDE component (**Supplementary materials**). Different guides will be used for adherent and non-adherent participants.

We will use the Theoretical Domains Framework (TDF) to inform our interview guide for healthcare professionals and synthesize our qualitative data (**Supplementary materials**).(40) The TDF covers 12 domains (e.g. knowledge; skills; beliefs; motivation etc.) that cover potentially modifiable barriers that can inform intervention.(41) We will include open-ended questions like *“What factors do you think patients consider when they are deciding whether or not to be screened?”* as well as questions about knowledge of screening guidelines, referral practices, and information provided to patients regarding the referral during the consultation.

All qualitative interviews will be audio-recorded using a digital recorder. Audio files will be transcribed (and translated into English where necessary) by a professional transcription and translation company and will be checked by the research team for

accuracy (**Supplementary materials**).

*Analytical plan:* An inductive analytical approach will be adopted based on the constant comparative method whereby broad themes will be developed from the raw content of the transcripts.(42) New or improved themes that emerge from later transcripts will be incorporated into the coding hierarchy, and earlier transcripts will be updated to reflect these modifications. Themes will be categorized as predisposing, enabling, and reinforcing barriers/facilitators based on Phase 4 of the PRECEDE component. From the healthcare professionals' interviews, data relating to factors influencing behaviour during complications referral will be coded using the 12 TDF domains. The computer program QSR NVivo 12 will be used to code the data. Transcripts will be analysed by two different coders and disagreement in coding will be resolved by discussion or a third, independent coder (**Aim 2b**).

Preliminary Analyses

In this preliminary report, we compared the characteristics of participants and those who refused to participate (non-participants) using t-test or chi-square statistics, as appropriate. Furthermore, we present baseline characteristics that may be associated with non-adherence to DM complications rescreening using descriptive statistics (mean/median and standard deviation [SD]/interquartile range [IQR], counts, and percentages). All preliminary analyses were performed using Stata/SE, version 15 (Stata Corp, College Station, Texas).

## RESULTS

### Recruitment and retention

A total of 3,546 patients were screened across the six polyclinics. Of these, 830 (23.4%, **Supplementary Figure 2**) were excluded because (i) they received a <12-month (~3-6 months) review referral at the polyclinic (n=604, 72.8%), (ii) had significant hearing

impairment (n=63, 7.6%), (iii) had complications requiring referral to tertiary care (n=39, 4.7%), (iv) had cognitive impairment (n=38, 4.6%), (v) or were not Chinese, Malay, Indian, or Eurasian (n=35, 4.2%). Of the remaining 2,716 (76.6%) eligible patients, nearly two-thirds refused (n=1,742, 64.1%) participation. Reasons for refusal included not interested (n=901, 51.7%), lack of time (n=512, 29.4%), >1 study related visits required (n=287, 16.5%), and 'other' reasons (e.g., does not want to share confidential information, caregiver does not approve, does not believe in research etc., n= 42, 2.4%). The remaining 974 (35.9%) eligible patients agreed to participate.

The response rate ranged from 9.5% in BK and 33.9% in PR, to 85.0% in GY (**Table 1**). There were no significant differences in age and gender between participants and non-participants. Compared to participants, non-participants were more likely to only attend DR screening (51.9%), not attend 'bundle' screening appointments (64.6%) and be from the BK site (28.6%) (all p<0.001).

**Baseline profile of study participants**

Of the 974 enrolled patients at baseline, 75.4% (n=734), 61.9% (n=603), 80.7% (n=786) attended DR, DN, and DFC screening, respectively. Over four in five (81.4%) attended ≥1 complication screening on the day of enrolment.

Patient characteristics potentially associated with non-adherence to DM complications screening

*Sociodemographic*

The baseline cohort was 61.0 median [IQR 55.0-67.0] years old, with over two-fifths <60 years (42.4%); and primarily male (52.9%, **Table 2**). Most participants were Chinese (64.1%), followed by Malay (21.4%), Indian (13.9%), and Eurasian (0.6%). A majority had received secondary or lower education (71.9%), were employed (60.5%), had a monthly household income of >S$2000 (62.5%) and lived in public housing (86.6%). Furthermore,

most were married (75.7%) and reported taking <30 minutes to access the polyclinic site (74.3%).

*Medical and clinical*

Co-morbidities were common overall, with a high prevalence of hypertension (73.4%), dyslipidaemia (85.1%), and obesity (43.1%, **Table 3**). Most participants rated their health status as 'good to excellent' (79.7%). Participants reported a median DM duration of 6.3 [IQR 3.0-12.0] years, and most were on diet control (94.2%). Participants had median HbA1c, and systolic and diastolic BP values of 6.9 [IQR 6.4-7.6]%, and 130.0 [IQR 120.0-138.0] mmHg and 70.0 [IQR 65.0-78.0] mmHg, respectively. The median LDL cholesterol and eGFR was 2.1 [IQR 1.7-2.6] mmol/L and 88.5 [IQR 73.8-98.3] mL/min/1.73m$^2$, respectively.

*Patient-reported*

In general, most study participants (95.0%) had adequate *health literacy* (**Table 4**). More than half (55.1%) reported not having received *DM education* either at the time of diagnosis of DM or in the past year. Most reported receiving 'quite a lot/great deal' of *DM support* (69.7%). The median baseline *diabetes knowledge* scores of those on insulin and not on insulin were 16.0 [IQR 13.0-18.0] out of 22 and 9.0 [IQR 8.0-11.0] out of 14, respectively. Over 10% and 20% of the participants on insulin and not on insulin answered <50% of the questionnaire correctly, respectively. Participants reported low levels of *diabetes-related self-efficacy* (1.4 [IQR 1.0-3.9] out of 5), and more than half rated their *diabetes control status* as 'okay' (56.6%). Almost one-fifth reported *diabetes related-distress* (17.6%).

## DISCUSSION

We established the UNADS study to provide urgently needed data on the rates;

predictors; and clinical and economic impact of non-adherence to DM complications screening in a multi-ethnic Asian primary care population with T2DM using a mixed-methods approach. A total of 974 patients with T2DM who completed 2,123 DM complications screening visits across six polyclinics in Singapore were enrolled and have completed the baseline assessment. Most (81.4%) were recruited while attending >1 complication screening on the same day. A spectrum of sociodemographic (e.g., age, ethnicity, education and income levels, and housing, and accessibility to nearest polyclinic), medical (e.g.presence of comorbidities, and HbA1c and lipid levels), and patient-reported factors (e.g., DM-specific self-efficacy and knowledge levels, and self-rated DM control) which may potentially predict non-adherence to DM complications screening, were systematically collected. Completion of longitudinal quantitative and cross-sectional qualitative data collection and analyses will provide insights into the rates and modifiable risk factors of non-adherence to DM complications screening in this population; and contribute to the design of evidence-based interventions addressing those factors at patient, provider, and system levels in the public sector.

We found that more than two-fifths of our study participants were aged <60 years, and were mostly Chinese, had secondary or lower education and received a monthly household income of >S$2000. These characteristics have been reported to be linked to non-adherence to DM complications screening by previous studies exploring factors related to attendance to DM related screening programmes.(8, 43) For example, a large cohort study (n=24,832) of individuals with DM by Alice and colleagues reported that those aged <60 years and receiving a higher income were associated with the greatest risk (-1.3-fold) of non-adherence to eye examination guidelines in New South Wales.(8) Furthermore, a mixed-methods study investigating the barriers/facilitators of uptake of DM health screening conducted in Singapore showed that those of Chinese ethnicity (vs. Indians), and those

with lower education had lower odds of attending regular DM health screenings.(43)

Our baseline analysis also showed a high prevalence of comorbid conditions such as hypertension, dyslipidemia and obesity, which may be associated with an increased likelihood of not attending screening appointments. Comorbidity is common among people with DM and can create a number of challenges that affect a patient's ability to participate in regular screening.(44) Indeed, Baumeister and colleagues studied trends of barriers to receiving recommended eye care among individuals with DM in Germany using population-based data collected between 1997-2001 and 2008-2012(45) and found that eye care utilization declined over the 10-year period in those diagnosed with DM for >5 years, and in those with obesity, dyslipidemia and multiple co-morbid conditions.

We found that more than half of our baseline study sample had not received any DM-related education prior to DM complication screening. This is important, as evidence suggests that lack of information on DM may predict non-adherence to regular annual screening. For instance, in a nationwide survey of 1,288 individuals with DM conducted in Korea, Byun and colleagues found that those who had not received education about DM care were more likely to be screened less often for DR and DN.(12) At baseline, our participants reported low levels of DM-specific self-efficacy, which may be important in predicting non-adherence to DM complications screening. Indeed, studies exploring screening attendance in other healthcare fields (e.g. cancer) have shown that low self-efficacy is an important determinant of non-adherence to screening programmes.(46) Nevertheless, full analysis of the follow-up data using regression models is essential to identify and confirm the modifiable predictors of DM complications screening in this population and to inform appropriate intervention in this multi-ethnic primary care population.

A key strength of the UNADS study is the application of the PRECEDE-PROCEED

model, which offers a systematic classification of factors at individual, provider, and system levels by their relative importance and capacity for modification. This facilitates consideration of the determinants for change at individual-, provider-, and system-levels and allows for the development of more efficient and effective programmes. Other strengths are its large sample size involving six polyclinics across two different healthcare clusters and the collection of rich longitudinal quantitative and qualitative data covering a wide range of exposures and outcomes.

The UNADS study has some important limitations. Firstly, the Coronavirus Disease (COVID-19) outbreak and related restrictions had serious implications on its implementation. Due to the restrictions on face-to-face research activities, study enrolment was severely impacted, and the estimated target sample size was not achieved. However, as far more of our study participants attended bundle screening (81.4%) than originally estimated in our sample size calculations (30%), our final sample size was deemed adequate to accomplish our study's objectives. Secondly, our overall baseline response rate was low (35%) and this could lead to selection bias affecting the validity of our results. There were several reasons for this: survey fatigue experienced by patients attending busy sites like BK and BM with several ongoing research projects; need for biological sample collection at baseline and follow-up (if unavailable in the EMR); and impact of restrictions imposed during the COVID-19 outbreak as explained above.(47, 48) Lastly, the use of self-reported measures may be subject to social desirability and recall bias.

The UNADS study is the first longitudinal mixed-methods study to investigate the rates, independent predictors, and the clinical and economic impact of non-adherence to DM complications screening in multi-ethnic polyclinic patients with T2DM in Singapore. Our baseline data are comprehensive including several sociodemographic, clinical, health and patient-reported characteristics that may predict non-adherence to DM complications

screening. Completion of the follow-up phase will provide empirical evidence on the rates, and modifiable barriers/enablers of non-adherence to DM complications screening. Furthermore, the study results may inform public health interventions to develop culturally appropriate intervention programs to improve screening adherence in multi-ethnic populations. Finally, this study may contribute to reducing unnecessary disease burden with timely screening, monitoring and treatment; improving health outcomes for Singaporeans with T2DM at the primary care level; and demonstrating significant cost-savings to the patient and society over time.

**Figure 1.** UNADS mixed-methods study design

**Supplementary Figure 1.** Application of PRECEDE component in the UNADS study

**Supplementary Figure 2.** UNADS Study Screening and Recruitment



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**Author Contributions:** AA:formal analysis, investigation, project administration, supervision, visualization, writing-original draft, review and editing; EF: conceptualization, formal analysis, investigation, project administration, supervision, visualization, writing-original draft, review and editing; AW: formal analysis; EL, RM, CS: conceptualization,

writing – review and editing;

NC, WE, CJ, LP, WT, WF, SW: writing – review and editing; EL was the senior study investigator and author. The final version of the paper has been seen and approved by all co-authors.

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**Table 1. Response rates of eligible patients to the UNADS study by polyclinic sites**

| Polyclinic sites | Eligible patients, n | Participants, n | Response Rate (%) ^ |
|---|---|---|---|
| SHP – Bedok | 550 | 52 | 9.5 |
| SHP – Outram | 638 | 197 | 30.9 |
| SHP – Pasir Ris | 322 | 109 | 33.9 |
| SHP – Bukit Merah | 365 | 57 | 15.6 |
| NHGP – Hougang | 494 | 264 | 53.4 |
| NHGP – Geylang | 347 | 295 | 85.0 |
| Total | 2716 | 974 | 35.9 |

^Calculated as participants as a percentage of eligible patients



**Table 2. Baseline socio-demographic and lifestyle characteristics of UNADS study participants**

| Characteristics | n (%) or Median (IQR) |
|---|---|
| Screening attended | |
| Diabetic Retinopathy | 734 (75.4) |
| Diabetic Nephropathy | 603 (61.9) |
| Diabetic Foot complication | 786 (80.7) |
| Bundle screening on the same day | 793 (81.4) |

| | |
|---|---|
| Socio-demographic factors | |
| Age (years) | 61.0 (55.0-67.0) |
| <=49 years | 118 (12.11) |
| 50-59 years | 295 (30.29) |
| 60-69 years | 420 (43.12) |
| 70+ years | 141 (14.48) |
| Male gender | 515 (52.9) |
| Ethnicity | |
| Chinese | 624 (64.1%) |
| Malay | 208 (21.4%) |
| Indian | 136 (13.9%) |
| Eurasian | 6 (0.6%) |
| Educational attainment | |
| Primary or lower | 153 (15.7) |
| Secondary or A-level | 548 (56.3) |
| Tertiary | 273 (28.0) |
| Marital Status | |
| Single | 117 (12.0) |
| Married | 737 (75.7) |
| Divorced/Separated | 61 (6.3) |
| Widowed | 59 (6.1) |
| Housing type | |
| Public | 843 (86.6) |
| Private | 131 (13.5) |
| Monthly Household Income | |
| ≤ S$2000 | 311 (37.5) |
| > S$2000 | 518 (62.5) |
| Employment status, yes | 589 (60.5) |
| Accessibility to Polyclinic | |
| < 30 min | 720 (74.3) |
| 30 min to 2 hours | 249 (25.7) |
| Lifestyle/Health Behaviour factors | |
| Smoking | |
| Never/Past smoker | 870 (89.3) |
| Current smoker | 104 (10.7) |
| Alcohol status | |
| Never/Past drinker | 763 (78.3) |
| Current drinker | 211 (21.7) |

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**Table 3. Baseline medical and clinical characteristics of UNADS study participants**

| Characteristics | Median (IQR) or n (%) |
|---|---|
| Diabetes Management | |
| Diabetes duration | 6.3 (3.0-12.0) |
| Diabetes Treatment | |
| Insulin | 68 (7.0) |
| Oral anti-diabetic medications | 789 (81.3) |
| Diet | 915 (94.2) |
| Exercise | 780 (80.3) |
| Health Status | |
| Comorbidities | |
| None | 54 (5.6) |
| 1-2 conditions | 640 (66.5) |
| ≥ 3 conditions | 268 (27.9) |
| Hypertension, yes | 711 (73.4) |
| Dyslipidaemia, yes | 828 (85.1) |
| Asthma, yes | 51 (5.2) |
| BMI (kg/m2)[a] | 26.9 (24.1-30.3) |
| Obesity, yes | 419 (43.1) |
| Arthritis, yes | 96 (9.9) |
| Self-rated Health Status | |
| Excellent/Very good | 281 (28.9) |
| Good | 494 (50.8) |
| Fair/Poor | 198 (20.4) |
| Clinical Factors | |

| | |
|---|---|
| Blood pressure (mmHg), | |
| Systolic | 130.0 (120.0-138.0) |
| Diastolic | 70.0 (65.0-78.0) |
| HbA1c (%) | 6.9 (6.4-7.6) |
| Lipids | |
| Total cholesterol (mmol/L) | 4.1 (3.6-4.7) |
| HDL (mmol/L) | 1.3 (1.1-1.5) |
| LDL (mmol/L) | 2.1 (1.7-2.6) |
| TGL (mmol/L) | 1.4 (1.0-1.8) |
| eGFR (ml/min/1.72m2) | 88.5 (73.8-98.3) |

UNADS - Understanding Non-Adherence to Diabetes Complications Screening; BMI – Body Mass Index; HbA1c – Haemoglobin A1c; HDL – High Density Lipoprotein; LDL – Low Density Lipoprotein; eGFR – Estimated Glomerular Filtration Rate

[a]BMI was calculated as weight in kilograms divided by height in meters squared (Wt[kg]/Ht[m]2)

**Table 4. Baseline patient-reported characteristics of UNADS study participants**

| Characteristics | Median (IQR) or n (%) |
|---|---|
| Health literacy[a] | |
| Not adequate | 41 (5.1) |
| Adequate | 764 (95.0) |
| Health literacy (3-item)[b] | 10.0 (7.0-12.0) |
| Diabetes knowledge[c] | 9.0 (8.0-11.0) |
| Not on insulin treatment | 9.0 (8.0-11.0) |
| On insulin treatment | 16.0 (13.0-18.0) |
| Diabetes education[d], no | 532 (55.1) |
| Diabetes support, yes | |
| No/a little bit of support | 295 (30.3) |
| Quite a lot/ a great deal of support | 678 (69.7) |
| Satisfaction with diabetes support | |
| Not at all/ a little satisfied | 143 (14.7) |
| Somewhat satisfied | 180 (18.5) |
| Very satisfied/Extremely satisfied | 648 (66.7) |
| Self-rated diabetes control | |
| Very good | 255 (26.4) |
| Okay | 547 (56.6) |
| Not good | 80 (8.3) |
| Variable | 84 (8.7) |
| Attitude towards glycaemic control | |
| Very important | 916 (94.2) |
| A little/Not important | 56 (5.8) |
| Self-efficacy[e] | 1.4 (1.0-3.9) |
| Diabetes related distress, yes[f] | 171 (17.6) |

[a]Adequate health literacy was defined as 75% correct response in both sections i.e., 3 numeracy items and 27 reading comprehension sections
[b]Higher score indicates higher health literacy level
[c]Higer score indicates higher level of diabetes knowledge
[d]Have you ever attended any diabetes education programs focusing on diabetic retinopathy/diabetic nephropathy/ diabetic foot complications management?
[e]Higher score indicates higher self-efficacy level
[f]A total score of $\geq$ 8 suggests 'possible' diabetes distress
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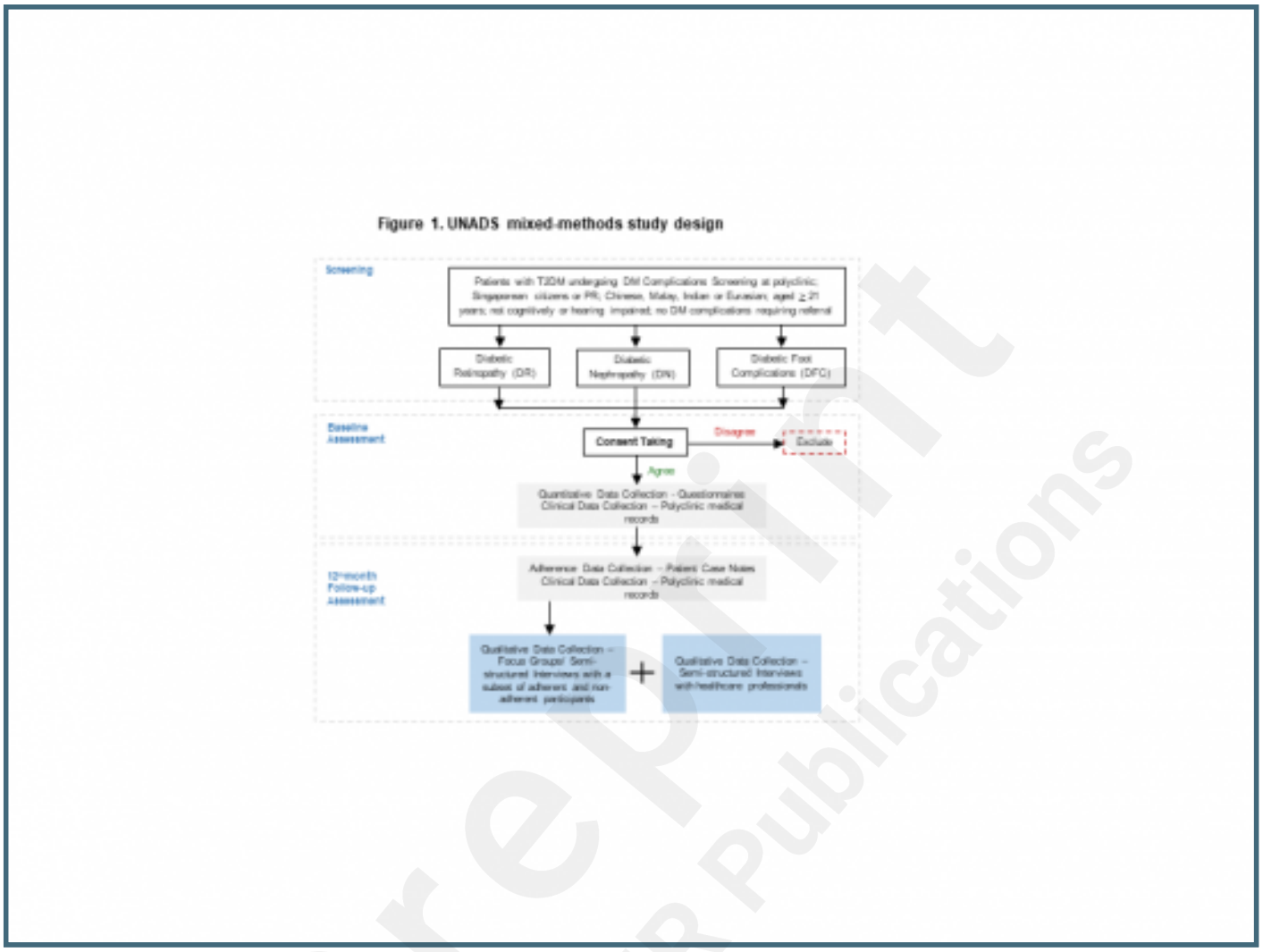
# Supplementary Files

# Figures

UNADS mixed-methods study design.



# CONSORT (or other) checklists

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