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Abstract

In Catalonia (Spain), population-based colorectal cancer (CRC) screening offers biennial fecal occult blood testing to men and women aged 50-69 years old. The program is organized in screening hubs, most of which use a pharmacy-based model to distribute and collect fecal immunochemical test (FIT) kits The comprehensive evaluation of CRC screening programs, which include the role and implications of pharmacy involvement, is essential to ensure program quality and identify areas for further improvement. The present study aimed to assess the adherence of community pharmacies to the CRC screening program and to analyze data on FIT kit distribution and collection in the Metropolitan area of Barcelona (Catalonia, Spain). Time to FIT completion was assessed by Kaplan-Meier estimation, and with the log-rank test. A Cox regression model was used to adjust for other variables associated with the completion of FIT such as sex, age, deprivation score index and previous screening behavior. Overall, 82.4% of pharmacies adhered with CRC screening program. Out of 82,902 FIT kits distributed to screening invitees 77,524 completed FIT kits were returned to pharmacies (93.5%) with a participation of 39.8% among the 193,766 invitees. From those who completed a FIT, the median time to return the kit was 3 days. FIT completion time was significantly lower among women, older age, high deprivation score index and previous CRC screening ($p<0.005$). Our findings highlight the large involvement of community pharmacists with CRC screening program as well as a high quality in the process of FIT distribution and collection.

Keywords: Mass Screening, Community pharmacy, Colorectal Cancer

Abbreviations: CRC, colorectal cancer; FIT, fecal immunochemical test; DS, deprivation score.

Background

Screening for the early detection of colorectal cancer (CRC) is widely recommended and is associated with improved survival outcomes [1]. Despite these evidenced-based recommendations, CRC remains the second most incident cancer and represents the second cause of cancer-related death in high-income countries [2]. In Catalonia (Spain), CRC incidence ranks second in males and females, with approximately 5,128 new cases (3,558 men, 2,570 women) diagnosed each year, leading to 2,616 deaths annually (1,591 men, 1,025 women) [3]. Guidelines and recommendations on how best to deliver screening in a population are diverse [1]. In Europe, the approach is to implement population-based cancer screening programs. In the United States (USA), CRC screening is mainly opportunistic giving general recommendations to the population on screening practice and being offered during contact in primary healthcare or in other healthcare settings [4]. Different screening tests have been shown to be effective and have been implemented worldwide; however, participation rates are highly variable between countries and settings [1,5–7].

One challenge for the population-based CRC screening approach is the insufficient screening participation and low longitudinal adherence of the target population, even though screening is covered by a single-payer healthcare system at no cost to the screened individuals [8]. In such context, accessibility and awareness are the main barriers to participation [9,10], so the involvement of healthcare settings is essential to develop effective methods to enhance screening.

The role of community pharmacies in health promotion and prevention has been expanding across different countries [11]. A systematic review, which included 11 studies, concluded that pharmacies could make a significant contribution to early detection of cancer, including promotion of screening for colorectal and breast cancer [12]. The wide accessibility of community pharmacists and their understanding of, and relationships with the communities they serve, offer unique opportunities to improve patient involvement in a population-based CRC screening program. Patients frequently visit pharmacies for health information and have for long sought advice from pharmacists as one of the most entrusted health care professionals. Moreover, pharmacies may be effective at engaging hard to reach groups, including lower socioeconomic groups, who might be at increased risk of cancer but less likely to participate in screening [13].

Catalonia launched a population-based CRC screening program among women and men aged 50–69 years, using fecal occult blood testing in 2000 [14]. Currently, ten

hubs provide the screening service for the CRC screening program in Catalonia. Following the positive experience of the inclusion of pharmacies in the CRC screening program in Italy [15], in 2010, the hub of Metropolitan Area of Barcelona and Barcelona city decided to include pharmacies in its CRC screening program with satisfactory acceptance by pharmacists [16]. Afterwards, pharmacy-based model became widely used by most screening offices to distribute and collect the fecal immunochemical test (FIT) kits [17]. The comprehensive evaluation of CRC screening programs is essential to ensure program quality and identify areas for further improvement. In this context, the evaluation of the involvement of pharmacies in the CRC screening can provide information on new opportunities for targeted interventions and quality improvement.

The main objectives of this study were to assess the adherence of community pharmacies to the CRC screening program and to analyze data on FIT kit distribution and collection in the Metropolitan area of Barcelona during 2017-2018.

Methods

Setting/Screening procedure

The screening hub of the Catalan Institute of Oncology, as part of the Catalan CRC screening program, covers a target population of 494,085 men and women aged 50-69 years (1st January, 2017) in the Metropolitan area of Barcelona. The Institute identifies individuals due for screening from the Central Register of Insured Persons of the Catalan Health Service. All eligible individuals receive an invitation letter where they are asked to pick up a FIT kit at any nearby community pharmacy participating in the CRC program. Invitations are sent according to primary healthcare areas (territorial divisions through which primary health care services are organized). Individuals in a given geographic area are assigned to a primary care team along with a referral hospital for further examination. On the sixth week, non-participants receive a reminder letter. Community pharmacies are the mainstay for distributing and collecting FIT kits, checking eligibility criteria, providing information to get screened and instructions on how to complete the FIT. To adhere with the CRC screening program, pharmacists have to complete the Official College of Pharmacists' training program in CRC screening. Community pharmacists who adhere for the first time with the screening program have to complete a 5-hour online training course which includes content on epidemiology and prevention of CRC, functioning of the screening program as well as a step-by-step description of the process that is performed at the pharmacy. Those community pharmacists who have previously participated in the screening program, have to complete a 1 hour training session that focuses on the program updates as

well as a reminder of previous information. On a voluntary-basis, pharmacists can access to some additional contents (videos). The FIT kits as well as the educational material are provided by the screening program. The Catalan health service remunerates pharmacies with one euro per delivered kit. Completed kits are sent to the reference laboratory for analysis. Tests must be analyzed within 14 days of the sample collection; otherwise FIT must be repeated. Participants with negative FIT are informed of their results via email, with a recommendation for biennial screening. Individuals with positive FIT are contacted by telephone and invited to schedule a diagnostic colonoscopy at their referral hospital. Individuals with screen-detected cancer, inflammatory bowel disease or familial adenomatous polyposis are referred to specialized healthcare and definitely excluded from the screening program. All procedures are provided free of charge (**Supplementary Figure**).

Study design and data sources

The Official College of Pharmacists provided information on pharmacies located in the Metropolitan area of Barcelona and also which of them were adhered to the screening program during last biannual round (2017-2018). The Official College of Pharmacists Information System centralizes all the information related with the processing and the tracing of the FIT kits from the community pharmacies adhered with CRC screening and their allocated laboratory. Pharmacies located in the Metropolitan area of Barcelona with activity during 2018 were analyzed. The following variables were selected: pharmacy office number, FIT number identifier, distribution and collection dates, individual identifier, and primary healthcare area of reference. FIT kits collected with a distribution date out of the analysis period were excluded.

The Information System for Monitoring CRC Screening of Catalonia centralizes all the information in relation with the CRC screening process of the target population. The following variables of invitees were selected: individual identifier, sex, age categorized into four groups (50-54, 55-59, 60-64 and 65-69), FIT number identifier, FIT result (with a positivity threshold 20 μg Hemoglobin/g), FIT result date, and primary healthcare area of reference, previous screening (yes/no). Since no individual information on socioeconomic status was available, a deprivation score index (DS) calculated for primary healthcare areas of the Catalan territory was used. This score index uses aggregated indicators of income, employment, health and disability and education to generate a scale from 0 (least deprived) to 100 (most deprived) [18]. For this analysis, this score index was re-coded into a 3-category variable using the cut-off points of

tertiles of the Catalan distribution to enable comparisons between individuals living in the most and least deprived areas.

Data analysis

For the purpose of this analysis both Information Systems were merged to create a single dataset.

We performed a descriptive analysis of collaborating pharmacies during last biannual round of CRC screening in the Metropolitan area of Barcelona (2017-2018). The proportion of adhered pharmacies and pharmacy adherence rate by 1,000 target population was calculated globally and by healthcare areas. Pearson's rho correlation coefficient between DS, screening participation for CRC and proportion of adhered pharmacies by healthcare areas was calculated.

Pharmacy-based FIT distribution and collection data analysis was performed for individuals invited between January and October 2018 with pharmacy distribution and collection of FITs until December 2018. The FIT completion rate was calculated as the number of FIT kit returned divided by the number of kits distributed. Participation rate was calculated as the number of individuals with a test result divided by the total invitees. To determine the quality of information for collecting the fecal sample (FIT instructions), the proportion of inadequate FIT kits was calculated.

A time-to-event analysis was conducted from the FIT kit distribution date by pharmacists to the date of completed FIT was returned to the pharmacy. Individuals were censored at 30 days from the kit distribution date. Time to completion was described using nonparametric Kaplan-Meier estimates, and differences between groups within sex, age, DS and previous screening were initially estimated by log-rank tests, with graphical display through 30 days from FIT distribution. Cox proportional hazard models were performed to investigate the association of socio-demographic factors with the completion of FIT.

Statistical analysis was carried out using R statistical software (R Foundation for Statistical Computing).

Results

In 2017-2018, out of 643 affiliated pharmacies to the Official College of Pharmacists within the Metropolitan area of Barcelona, 528 adhered with the CRC screening program, representing an 82.4% of total pharmacies. **Figure 1** shows collaborating pharmacies by primary healthcare areas. In half of the primary healthcare areas, the

proportion of collaborating pharmacies with CRC screening was greater than 85%. On the other hand, we observed that in one third of primary health care areas the proportion of collaborating pharmacies were less than 80%. There was no linear correlation between pharmacy adherence and screening participation for CRC (r= -0.06; p=0.59) nor socioeconomic deprivation (r= -0.07; p=0.48). The rate of pharmacies that adhered with the CRC screening program was 1.1 per 1,000 target population, ranging from 0.36 to 2.73 pharmacies per 1,000 target population.

Figure 1. Pharmacy adherence (%) by primary healthcare areas in the Metropolitan Area of Barcelona, Catalonia (Spain), 2017-2018

1.5-column fitting image.

During the study period, 193,766 individuals were invited to the CRC screening program. Regarding the pharmacy activity (distribution and collection of FIT kits), 82,902 kits were distributed to the screening invitees, with an average of 286.9 kits distributed per pharmacy.

The 82,902 FIT kits were distributed to 82,030 individuals who received invitation letters from the program. Overall, 860 individuals (1%) picked up more than one kit, representing 1,732 kits (2%). A total of 77,524 completed FIT kits were returned to pharmacies and sent to the laboratory. Most of the FIT kits were conclusive (77,114), but 410 kits (0.5%) could not be analyzed in the laboratory because of inadequate sample collection, delays in return of the kit or technical failure. Of the 5,378 kits not returned to the pharmacy as of 31 December 2018, 782 (14.5%) individuals later completed CRC screening (**Figure 2**). The completion of FIT was 93.5% (77,114/82,030) with a participation of 39.8% among 193,766 invitees.

Figure 2. Flow chart of delivered and collected fecal immunochemical test at community pharmacies

2-column fitting image.

Among patients who completed a FIT, the median time of return of the kit was 3 days. Globally, the 90% return time of the FIT kits was up to 14 days. **Figure 3** shows the Kaplan-Meier curves on FIT completion (from picking up to returning the kit) by sex, age groups, DS and previous screening behavior. FIT completion time was significantly lower among women, older age, high DS and previous screening (*P<0.001*). In the Cox proportional hazards analysis (**Table 1**), being women had a statistical significant association with decreases in FIT completion. Older age (compared with youngest age group) and no previous screening had statistically significant associations with

increased FIT completion. Compared with living in an area with low DS, living in areas with middle and high DS were significantly associated with improvements in FIT completion.

Figure 3. Kaplan-Meier Curves on the time to fecal immunochemical test completion by sex, age, deprivation score index and previous screening behavior, 2018
2-column fitting image.

Table 1. Multivariable Cox Regression of factors associated with fecal immunochemical test completion, 2018.

Individual characteristics	N (%)	Events*	HRa† (95%)
Sex			
Women	45,199 (54.5)	42,651	1
Men	37,696 (45.5)	34,866	0.92 (0.91-0.94)
Age groups in years			
50-54	22,289 (26.9)	20,370	1
55-59	21,022 (25.4)	19,495	1.03 (1.01-1.05)
60-64	20041 (24.2)	18,972	1.16 (1.14-1.19)
65-69	19543 (23.6)	18,680	1.3 (1.27-1.32)
Previous screening			
No	33,413 (40.3)	29,986	1
Yes	49,482 (59.7)	47,531	1.17 (1.15-1.19)
Deprivation Score Index			
Low	16,811 (20.3)	15,548	1
Medium	25,777 (31.1)	24,024	1.06 (1.04-1.09)
High	40,307 (48.6)	37,945	1.19 (1.17-1.21)
Total††	**82,895 (100)**	**77,517**	

Events are the number of individuals that complete FIT; †HRa: adjusted hazard ratio; ††Missing (N=7) excluded

Discussion

Our findings highlight the large involvement of community pharmacists with CRC screening program, along with demonstrating a high quality in the process of FIT distribution and collection. Globally, eight out of ten pharmacies adhered with the CRC screening program providing broad accessibility for the individuals who are invited to the screening, regardless of aggregate socioeconomic status. Previous studies reported lower pharmacy adherence to CRC screening (20%-52%) [19,20].This

discrepancy may be explained by several unique features of our program: 1) Community pharmacy CRC screening service is centrally coordinated by the Official College of Pharmacists. 2) Pharmacists are certified by completing a training package. 3) Pharmacies are remunerated for the screening service they provide. These requirements ensure that pharmacists were ready to implement screening services into their practices. Despite the successful and widespread involvement of community pharmacies reported, there are some suboptimal areas in which improvement interventions can be designed.

In our study, six out of ten individuals who received an invitation letter to participate in CRC screening did not pick up a FIT kit at a pharmacy. Low participation jeopardizes the benefits of the screening program and actions to improve participation should be taken to achieve a participation rate of at least 45%, as recommended by the European Guidelines for Quality assurance in CRC Screening and Diagnosis [21]. When compared with other programs that use community pharmacy for the distribution and collection of FIT kits, such programs have shown higher participation rates. A study in the Emilia-Romagna Region of Italy showed a participation rate of 52.5% [22] while a study performed out in the city of Barcelona with an organization of pharmacies similar to our area showed a participation rate of 44.7%. Certainly, multiple factors may affect individual's decision to participate in CRC screening, not just only the role of pharmacy in the screening process [9]. We found no correlation between pharmacy adherence and participation in the CRC screening. However, we believe it would be interesting to go beyond correlational analysis. For instance, a spatial analysis to identify the most appropriate small geographic areas in which to pilot targeted CRC screening interventions could be performed. Participating pharmacies would be one of many variables to take into account in the analysis. In addition, more research is needed to identify how pharmacists can raise awareness on CRC and explore their role promoting inform participation in screening. Merely giving information about CRC is not enough; the way the information is presented to the individuals makes a big difference.

Among those individuals who picked up a FIT kit the compliance with FIT completion was remarkably high. This may indicate that instructions for performing FIT kit by pharmacists are accurate and appropriate. Although only a small proportion of those who picked up a FIT kit did not return it (5.5%), implementing strategies targeted to individuals who demonstrate concern for screening by picking up a FIT kit at the pharmacy are more likely to be successful than strategies addressing to all non-participants [23]. It would be useful as a first step to conduct a qualitative study from

individuals who picked the FIT kit at the pharmacy to assess what led them to either complete or not complete a FIT kit.

A study performed in USA reported a median time of 13 days to complete a FIT kit from a physician order [24], which was larger than the 3 days found in our study. When it comes to understanding determinants of FIT completion, similar to the USA study, we identified several characteristics as recent CRC screening and older age associated with higher completion of FITs, which highlight population subgroups that may need additional support to complete screening. The evidence on the time for return the FIT kits together with the determinants of FIT completion, may contribute to enhance pharmacists' health promotion activities to improve the return of FIT kits.

Strengths and limitations

To the best of our knowledge, this is the first study evaluating the time between distribution and collection of FIT kits through community pharmacies after an individual receives an invitation letter to participate in an organized, population-based CRC screening program. Another strength of this study is that the evaluation of the pharmacies results could allow designing targeted interventions to assess the feasibility of their implementation to improve screening. However, we are aware of some limitations of the study. Our findings cannot be generalized to other settings where the organizational structure of CRC screening is different. A proportion of individuals who did not return the kit within the study period participated later (14.5%). In addition, we were unable to discern if the returned kits were the same or if additional kit(s) were required.

Conclusions

A comprehensive evaluation of the different steps in the CRC screening is crucial for maximize benefits of screening [19]. In programs where pharmacies are an essential mainstay of the screening process, assessing their results is paramount to identify areas for improvement. Our findings demonstrate a high pharmacy adherence with CRC screening despite noting some sub-optimal geographical areas to focus on. While showing high quality in FIT kits distribution and collection data at pharmacies and with large compliance to complete FIT kits in a short time by individuals who pick up a FIT kit, we have identified issues to be enhanced by implementing new strategies such as SMS reminders for FIT completion.

Declaration Section

Supplementary Figure. Algorithm of the population-based colorectal cancer screening program, Metropolitan Area of Barcelona, Catalonia, Spain

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Figure 1

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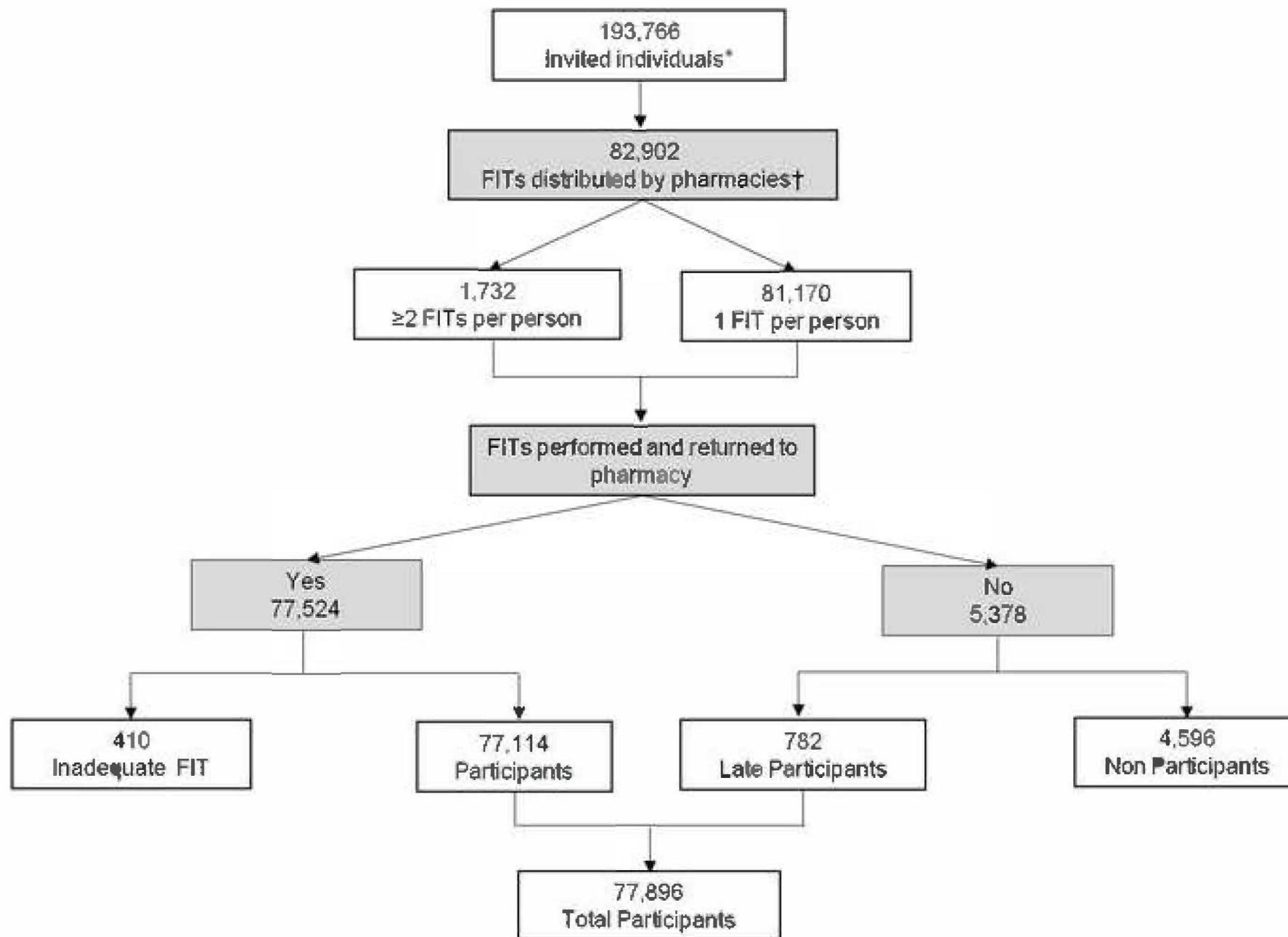
Figure 2

*Invitations letters sent from January to October, 2018; †82,030 individuals picked up FITs at the pharmacy
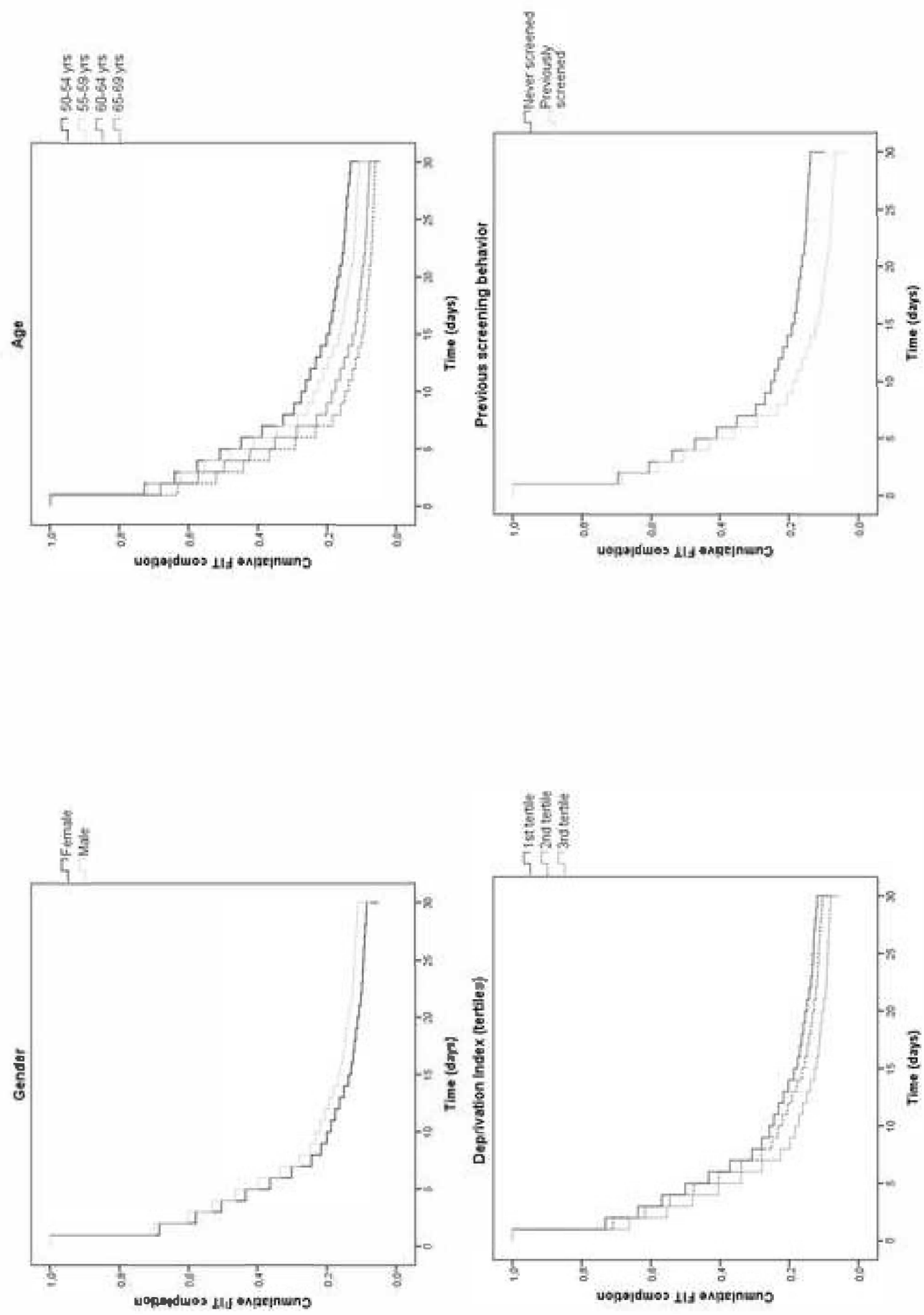
Figure 3

Tables

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