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D4.4 Midterm Recruitment and Implementation Progress Report – Study 1

Deliverable No.	D4.4	**Due Date**	30/04/2026
Description	This deliverable presents the midterm recruitment and implementation progress of Study 1 within the SUNRISE project. It provides an overview of recruitment performance across pilot sites, assesses progress against planned targets, and describes how the common recruitment pathway has been implemented under different national and institutional conditions. The report also identifies key barriers, implementation challenges, and deviations from the original plan, and documents the mitigation strategies applied across sites. Finally, it discusses implications for study feasibility, comparability, and subsequent evaluation activities.		
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Abstract

This deliverable (D4.4) presents the midterm recruitment report for Study 1 of the SUNRISE project, which evaluates SmartCoach, a school-based digital life-skills intervention for adolescent substance use prevention. The report summarises recruitment progress across the nine pilot sites, describes how the common recruitment pathway has been carried out in different national and institutional contexts, and identifies the main implementation issues and adjustments observed during the first phase of delivery.

By late March 2026, all nine pilot sites were in the recruitment phase and baseline data collection had reached 2,219 students out of 3,417 currently targeted, corresponding to approximately 65% of the current pooled target. Progress, however, is uneven across countries. Switzerland and the Basque Country have already exceeded their current targets, Romania is among the sites contributing the highest number of completed baselines at this stage, and several other sites continue to move forward at different speeds depending on school organisation, consent requirements, and local delivery conditions.

The report shows that midterm recruitment has depended not only on school willingness to participate, but also on the practical management of consent, registration, baseline completion, timetable constraints, technical onboarding, and policies concerning smartphone use in schools. In response, several sites introduced practical adjustments, including simplified consent procedures, broader school outreach, replacement or additional schools, and more direct in-class support during onboarding and baseline completion.

Given the slower pace observed in some settings, the consortium agreed to extend the recruitment window through October 2026. This adjustment is presented as a practical implementation measure that remains compatible with the overall project timetable and is expected to facilitate continued recruitment where a further school cycle is needed. Overall, the midterm picture indicates that Study 1 is progressing across all sites, while also showing that recruitment outcomes are strongly shaped by local implementation conditions.

Overall, the midterm results indicate that Study 1 is progressing across all sites and has already reached a substantial proportion of the planned recruitment. While variability across countries is evident, the observed differences are primarily linked to contextual implementation conditions rather than to inconsistencies in the study design. From a project perspective, recruitment remains on a feasible trajectory, with mitigation measures already in place to support completion within the extended recruitment window

These findings confirm that recruitment is feasible at scale, while also highlighting the importance of context-sensitive implementation strategies in achieving consistent results across diverse educational settings.

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Acronyms

Acronym	Meaning
AMEU	Alma Mater Europaea University
BBHRI	Biobizkaia Health Research Institute
FAVO	Federazione Italiana delle Associazioni di Volontariato in Oncologia
FISABIO	Foundation for the Promotion of Health and Biomedical Research of Valencia Region
HMU	Hellenic Mediterranean University
IOCN	Oncology Institute "Prof. Dr. Ion Chiricuță"
ISGF	Swiss Research Institute for Public Health and Addiction
OSA	Osakidetza / Basque Country pilot site lead
PASYKAF	Cyprus Association of Cancer Patients and Friends
UGENT	Ghent University
SUNRISE	Sustainable interventions and healthy behaviors for adolescent primary prevention of cancer with digital tools.
GDPR	General Data Protection Regulation
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance

1. Introduction

Recruitment is a central methodological component in school-based prevention research because it directly affects representativeness, feasibility, implementation quality, and the interpretability of study findings [1,4]. In school settings, recruitment rarely depends on a single decision point; rather, it usually involves a sequence of linked steps including school engagement, institutional agreement, teacher coordination, parental and student consent, student registration, and baseline completion [1]. This makes recruitment especially challenging in cluster and school-based trials, where organisational procedures, consent requirements, and the practical realities of school life can all affect whether participation is achieved as planned [1,4].

Recent work on adolescent health research also shows that strong recruitment and retention depend on reducing burden, lowering procedural barriers, and building positive relationships with participants and families, particularly when data collection includes digital components [2]. This implementation perspective is especially relevant for school-based digital interventions. A recent systematic review of digital health interventions for adolescent substance use prevention found that adoption and implementation factors influencing school participation are reported less often than reach and effectiveness, even though they are critical to the success and sustainability of programmes in real educational settings [3]. Taken together, this literature suggests that recruitment should not be treated simply as an early administrative step or as a numerical target. It is better understood as part of implementation itself, shaped by organisational, ethical, technological, and contextual factors that influence whether an intervention can be delivered under real-world conditions [1–4].

Within this context, Study 1 of the SUNRISE project evaluates SmartCoach, a mobile phone-based life-skills intervention designed to prevent substance use among adolescents through tailored digital coaching delivered over 16 weeks. The study is implemented as a multicentre, multinational, two-arm cluster randomised controlled trial across eight countries and nine pilot sites, with a target sample of 3,500 students aged 14 to 18 years. Participation depends on successful progression through school recruitment, consent, registration, and in-class completion of the baseline survey before the intervention can begin. Against this background, D4.4 provides a structured midterm account of how recruitment is progressing across the participating pilot sites, which implementation barriers have emerged so far, and how the consortium has adapted procedures in response.

2. Recruitment progress overview

Recruitment progress in Study 1 is summarised in Table 1. The table is intended to provide a concise midterm overview of where each pilot site stands in relation to its current recruitment target. For this reason, it focuses on a small set of indicators that are available across most sites and that are directly relevant to implementation progress: schools contacted, schools recruited, students targeted, baseline completed, and recruitment progress expressed as the proportion of completed baselines relative to the current site target.

Table 1. Recruitment progress across pilot sites

Country	Partner	Schools contacted	Schools recruited	Students targeted	Baseline completed	Recruitment progress (%)
Greece	HMU	5	3	280	159	56.8
Belgium	UGENT	52	3*	150	25	16.7
Slovenia	AMEU	6	3	233	82	35.2
Spain – Valencia	FISABIO	7	3	93	45	48.4
Spain – Basque Country	OSA	15	8	467	504	107.9
Italy	FAVO	72	3	560	215	38.4
Romania	IOCN	17	6	933	513	55.0
Cyprus	PASYKAF	25	4	140	84	60.0
Switzerland	ISGF	n/a**	35	561	592	105.5
Total		**199 + n/a**	**68**	**3,417**	**2,219**	**64.9**

* Belgium: by late March 2026, baseline completion had been achieved in three schools. The Belgian site report also describes broader outreach to additional schools and boarding schools, but these contacts are not counted here unless participation had already translated into completed baselines or confirmed recruitment within Study 1.

** Switzerland: the Swiss site uses a decentralised recruitment model based on regional addiction prevention centres. Schools are not approached through one centrally monitored outreach process, so the number of schools contacted cannot be reported in the same way as in other countries. What is available centrally is the number of schools or classes that entered the study and the number of students who completed baseline assessment.

By late March 2026, 2,219 students had completed the baseline survey out of 3,417 currently targeted, corresponding to 64.9% of the pooled target. The midterm picture is clearly uneven across sites. Switzerland and the Basque Country are already above their current targets. Romania also reports one of the highest numbers of completed baselines at this stage, while Greece and Cyprus show substantial progress. Belgium, Italy, Slovenia, and Valencia remain at earlier or more constrained stages of recruitment.

These differences are not surprising in a complex multi-country school-based study. Recruitment progress depends not only on initial school interest, but also on the timing of approvals, the complexity of consent procedures, the organisation of school schedules, and the level of support needed to

complete registration and baseline assessment in class. At midterm, the variation observed across sites therefore reflects differences in implementation conditions more than differences in the underlying study design.

The figures in Table 1 should be read as the main recruitment progress indicators for Study 1. They are not intended to match exactly the counts presented in Section 3, which refer specifically to schools that were contacted but did not enter the study. In addition, some indicators are not generated in exactly the same way across all sites, especially in Switzerland, where recruitment is decentralised and not centrally tracked from first contact onwards.

From an implementation perspective, recruitment efficiency varies substantially across sites. While some countries (e.g. Switzerland and the Basque Country) show completion rates above 100% of their current targets, others remain below 50%. This variation reflects differences in consent requirements (e.g. parental vs adolescent-only consent), school-level organisational constraints, and the level of direct support provided during onboarding and baseline completion.

Across sites, the main operational bottleneck is not initial school agreement, but the transition from consent to completed baseline assessment, which requires coordinated interaction between schools, families, and students.

Figure 1. Baseline completions against current target by pilot site

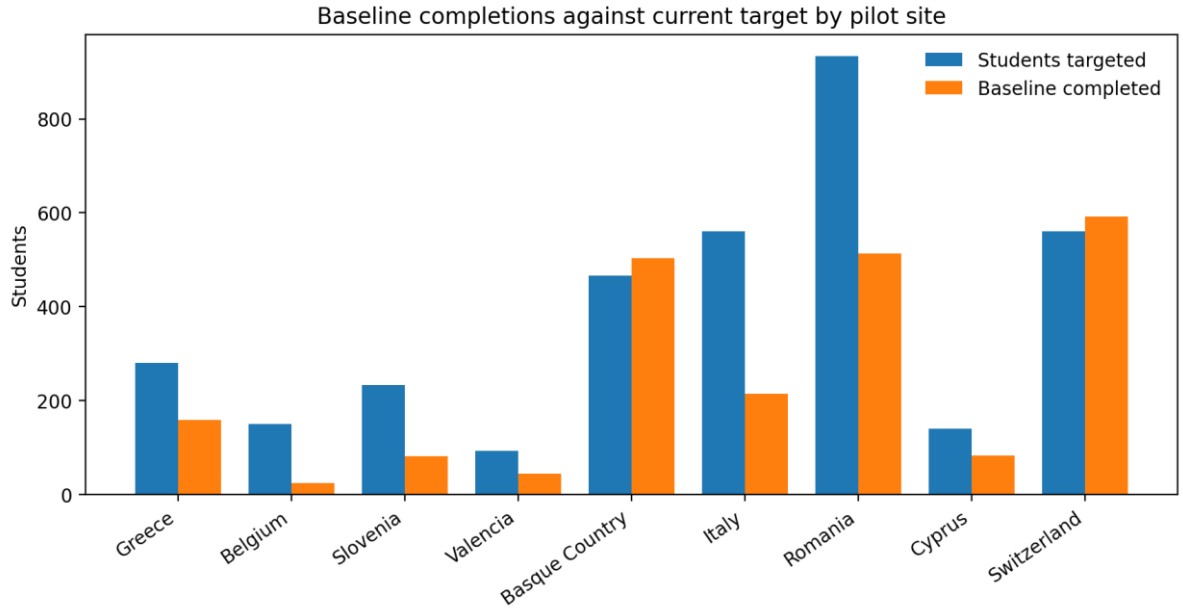
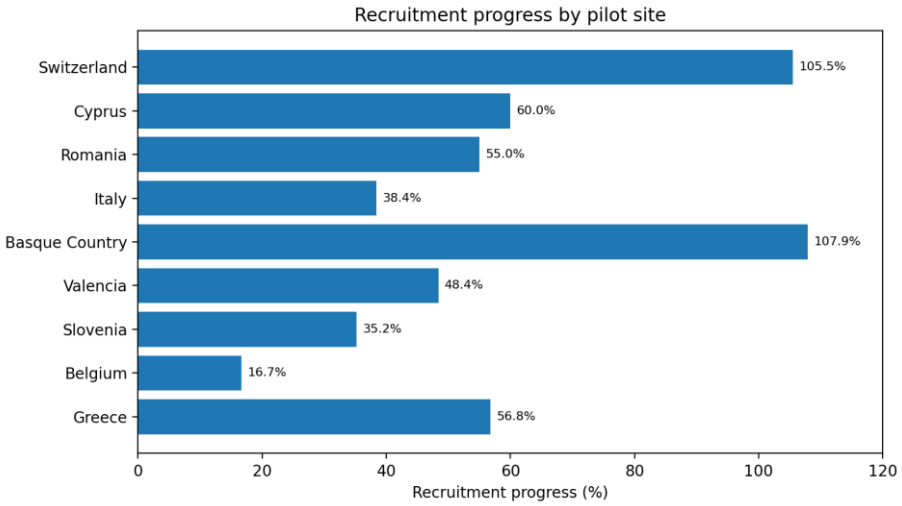


Figure 2. Recruitment progress by pilot site



The figures indicate that Study 1 has already reached a substantial volume of baseline completion, but that the remaining recruitment effort will depend heavily on how successfully each site can continue working within its own school and administrative context.

To better contextualise recruitment performance, Figure 3 illustrates the recruitment pathway in Study 1, identifying critical transition points and associated operational bottlenecks. The figure also summarises the mitigation strategies implemented across sites, reflecting the adaptive and context-sensitive nature of the implementation process.

Figure 3. Recruitment pathway and key operational bottlenecks in Study 1

Recruitment progression depends on successful transition across sequential steps. Key bottlenecks occur during the consent and registration stages. Targeted mitigation strategies were implemented to facilitate progression and improve recruitment efficiency.

3. Schools contacted for Study 1 that did not enter the study

In addition to the schools that eventually participated in Study 1, the pilot teams also contacted a wider group of schools that did not enter the study. In the cases reported below, schools were approached and follow-up efforts were made by the local teams, but participation was not secured. This section therefore highlights the part of recruitment work that did not translate into enrolment, despite the efforts made by the pilots to engage schools and move them into the study.

Table 2. Schools contacted for Study 1 that did not enter the study

Country	Schools contacted that did not enter Study 1	Comments
Belgium	40	Forty schools were contacted and followed up but did not enter Study 1. The Belgian material also indicates that the smartphone bans complicated recruitment, but the available documentation does not support a single closed count for refusals specifically linked to this factor.
Romania	3	Three contacted schools did not enter Study 1 because they did not respond after follow-up.
Spain – Basque Country	6	Six contacted schools did not enter Study 1. Two did not respond after contact, and four declined because mobile phone use conflicted with school policy.
Cyprus	3	Three contacted schools did not enter Study 1 because they did not respond after contact.
Italy	64	Sixty-four contacted schools did not enter Study 1. Most of these cases correspond to schools that did not respond despite contact and follow-up.
Greece	0	No schools are counted here. The Greek material describes

		implementation difficulties within participating schools rather than contacted schools that refused or failed to respond.
Spain – Valencia	1	One contacted school did not enter Study 1 because it did not respond after contact.
Switzerland	n/a	Comparable school-level refusal data is not centrally available because recruitment is organised through regional prevention centres rather than through one centrally tracked outreach process.

Across sites, the main pattern is not active refusal following extensive engagement, but rather the fact that schools were contacted and, despite follow-up efforts by the pilot teams, did not proceed to participation. This is particularly noticeable in Belgium and Italy, where a considerable number of contacted schools never joined the study. In the Basque Country, the most relevant additional factor was resistance to the use of mobile phones in the classroom. Greece is not included in the same way, as the available data relates to implementation problems in schools that had already agreed to participate, rather than to contacted schools that subsequently declined. Switzerland also requires separate interpretation, given that the decentralised recruitment model does not generate refusal figures that are comparable at the central level.

4. Recruitment procedures across pilot sites

Recruitment in Study 1 has followed a broadly shared sequence across sites: identification of schools, first contact, institutional agreement, class selection, consent collection, student registration, and in-class completion of the baseline survey before the start of the 16-week SmartCoach intervention. What differs across countries is not the overall structure of this pathway, but the way each step has been carried out in practice. These differences reflect national consent frameworks, local school organisation, approval procedures, and the degree of direct support needed to move from school agreement to completed baseline participation.

1. Greece (HMU)

In Greece, recruitment began through direct contact with school principals in the Municipality of Malevizi and through an existing collaboration with Gouves Art High School. After school agreement, the team notified the relevant secondary education authorities and coordinated implementation with the school administrations. Consent forms were initially managed by email, but this approach proved impractical for many families, so paper forms were subsequently distributed through students and returned via the schools. Baseline sessions were then carried out in class with the support of HMU team members, teachers, and social work students. To strengthen final recruitment, Tylissos Junior High School was added as an additional site.

2. Belgium (UGENT)

In Belgium, recruitment has been based on repeated outreach to schools and boarding schools through email, follow-up phone calls, and online meetings. The first phase led to participation from two schools, after which a second round of outreach was launched to broaden the pool of potential schools. The main practical challenge in Study 1 concerned the consent and registration pathway: parents were initially asked to complete consent through the Authoring Tool using QR codes, but this process generated considerable friction and low completion rates. The Belgian team therefore complemented this approach with paper forms and Smartschool-based communication, and also simplified the consent documentation. Baseline sessions were then organised in class with direct support from the research team, which allowed student assent and questionnaire completion to be guided more closely and made the process easier to manage in practice.

3. Slovenia (AMEU)

In Slovenia, schools were recruited mainly through existing contacts with principals and teachers. Once a school agreed to participate, meetings were held with class teachers to explain the study and organise the next steps. The main challenge was not initial school agreement, but helping students complete the digital registration process and proceed to the baseline survey. QR codes were first distributed through teachers or sent home, but this often led to delays because some students lost the codes, forgot whether they had already registered, or were unable to continue the process on their own. The procedure worked better when registration was completed directly in class, with the researcher present to guide students step by step. In some cases, students were also asked to call or text their parents during the session so that consent could be addressed immediately. This more direct, classroom-based approach made the process more manageable and improved completion of registration and baseline procedures.

4. Spain – Valencia (FISABIO)

In Valencia, schools were identified through a regional mapping strategy that sought to include urban, semi-urban, and rural settings, while also prioritising schools already connected to FISABIO networks. Initial contact was followed by meetings with school management and teaching staff, and the study was then introduced to students in class. Consent forms were distributed through the schools, with teachers helping to manage return. Under Spanish regulations, students aged 16 and above could participate without parental consent. Baseline data collection was then carried out in person during tutoring periods or regular class time. Recruitment is ongoing in two schools, with a third school entering the process.

5. Spain – Basque Country (OSA)

In the Basque Country, recruitment has been supported by a broad mix of contact channels, including direct approaches to school management, former alumni links, family contacts, and public health networks connected to Osakidetza. After initial contact, meetings were held with school directors and teachers to explain the project and define the participating classes. Once consent had been obtained, the research team scheduled in-class visits and supported students directly through registration and baseline completion. The Basque team also had to address hesitation around mobile phone use in the classroom by framing the digital tools as part of a health and prevention intervention rather than as general screen use. This close involvement appears to have facilitated a relatively smooth transition from school agreement to active participation.

6. Italy (FAVO)

In Italy, schools were identified through a structured review of the local educational landscape, combining regional school authority databases with an internal mapping of eligible institutions. Initial contact was made by phone and followed by a documentation package containing ethics and partnership materials. Once schools agreed, parental consent was collected on paper and baseline assessment was conducted in group sessions led by the FAVO team. Although the underlying procedure remained clear and structured, its implementation was affected by the late timing of national ethics approval, which meant that many schools had already finalised their plans for the academic year before recruitment could properly begin.

7. Romania (IOCN)

In Romania, schools were identified through education authorities and local mapping of eligible high schools. Selection depended on accessibility, willingness to collaborate, and scheduling feasibility. Initial contact was made by phone and followed by email with the relevant documentation. Once a school agreed, coordinating teachers were designated and the eligible classes were identified. Schools could choose between paper and electronic consent procedures. Baseline surveys were conducted in classroom sessions of around 40 to 50 minutes with the research team present throughout, which helped maintain a consistent and well-supported process across schools.

8. Cyprus (PASYKAF)

In Cyprus, recruitment combined broad geographical coverage with direct engagement of schools in both urban and rural areas, especially schools already familiar with European projects. Contact was made by email and telephone and then followed by face-to-face meetings. The Cypriot procedure

involves several formal steps before implementation can start, including ethics approval, Pedagogical Institute approval, and school inspector approval. After agreement, teachers were registered on the platform, educator consent was completed, parental consent forms were distributed in paper format, and the baseline survey was administered on site with direct support from the PASYKAF team. Students also activated SmartCoach during the same visit, which helped ensure that the transition from baseline to intervention start was immediate.

9. Switzerland (ISGF)

Switzerland follows a different recruitment model from the other sites. Schools were not approached through a single centrally coordinated outreach strategy. Instead, recruitment was embedded in existing prevention structures and carried out through regional addiction prevention centres that already collaborate with schools in several regions. In some cases, schools or teachers also approached the centres or the study team directly on the basis of prior collaborations. Once a school or class agreed to participate, the next steps were coordinated directly with the responsible teacher, including scheduling, logistics, and baseline administration. For this age group, parental consent was generally not required, and the baseline survey was typically completed during one regular school lesson, either with members of the study team or with trained prevention-centre staff present. This explains why Swiss recruitment figures are strong, but some school-level outreach indicators are not available in the same form as in other countries.

5. Participant profile

Participants enrolled in Study 1 are adolescents recruited from secondary and upper secondary schools across the nine pilot sites. In line with the study protocol, the intended population consists primarily of students in mid to late adolescence, although the exact age range varies somewhat across countries depending on school structure and local recruitment opportunities. Overall, the sample reflects routine school populations rather than narrowly selected groups, since participation has depended mainly on school agreement, class availability, and progression through the recruitment pathway at each site.

Across sites, the participating schools cover a mix of urban, peri-urban, and rural settings, although the balance differs by country. Romania describes a mainly urban sample with mixed socio-economic backgrounds. Valencia reports schools that are predominantly urban or peri-urban and students from varied sociocultural backgrounds. Greece combines urban schools with schools serving suburban and rural areas, and includes the rural case of Tylissos. Slovenia also reports participation from both urban and rural environments. Taken together, this indicates that Study 1 is being implemented in a range of educational contexts rather than in one narrow type of school setting.

The current participant pool is also socially heterogeneous. Several sites explicitly refer to mixed socio-economic or sociocultural backgrounds, and the Swiss report further notes diversity in migration background and school type, with participation from different parts of Switzerland and a substantial proportion of students from upper secondary academic track schools. This does not mean that the sample was designed to oversample specific disadvantaged groups, but it does suggest that the study is reaching a varied school-based population that is consistent with the broader multicountry implementation logic of SUNRISE.

At midterm, the participant profile can therefore be described as broad, school-based, and pragmatically assembled through real-world implementation. This is important for interpreting the recruitment results, because it means that current enrolment reflects not only the formal study criteria, but also the practical conditions under which schools, classes, students, and families have been able to participate in Study 1 so far.

6. Consent process

The consent process has been one of the main factors shaping the pace of recruitment in Study 1. Across all sites, participation required student assent or consent and, where applicable, parental consent in line with national and ethical requirements. Although this common principle applied throughout the study, the way consent was managed differed substantially across countries, and these differences had a direct effect on how quickly students could move from school agreement to registration and baseline completion.

In practical terms, the most demanding situations were those in which consent depended on several linked steps involving schools, parents, and students. In Belgium, the initial procedure relied on the Authoring Tool to support parental and student registration through QR codes. This created considerable friction: parents were unfamiliar with the tool, the process was perceived as too complicated, and early registration errors were difficult to correct. As a result, the Belgian team complemented the original digital procedure with paper-based consent forms and, later, with a digital option through Smartschool, while also shortening and simplifying the consent form itself.

A related issue appeared in Slovenia, although in a somewhat different form. There, the main difficulty was not a lack of school willingness to participate, but helping students complete the digital registration process and proceed smoothly to the baseline survey. When registration depended too heavily on codes being taken home or managed indirectly, delays became more frequent. The process worked better when registration and baseline steps were guided directly in class, with immediate support available when students had difficulties continuing the digital sequence.

In several other countries, paper-based consent remained the most workable option. In Cyprus, paper consent was required by the Ethics Committee, and the process depended heavily on teachers to distribute and collect forms. In Romania, schools could choose between paper and electronic formats depending on local preference, while in Italy the paper-based consent pathway was clear but slow, contributing to a consent period of several months. Valencia and the Basque Country reported a comparatively smoother process in Study 1 because students aged 16 and above did not require parental consent under Spanish regulations, although long information sheets and low family engagement still affected return rates. Greece also found that paper circulation through students worked better than email-based return when the original approach proved impractical for families.

Switzerland represents a structurally different case. For this age group, parental consent was generally not required, and students could provide informed consent independently. As a result, the Swiss team did not face the low return rates or prolonged parental follow-up reported elsewhere, and this substantially reduced administrative friction during recruitment.

These experiences show that recruitment speed in Study 1 depended less on school interest alone than on how easily consent could be integrated into normal school practice. Where the consent pathway was straightforward, the transition to registration and baseline completion was also smoother. Where consent required multiple handovers, unfamiliar digital steps, or prolonged follow-up with families, recruitment slowed accordingly.

7. Ethics and institutional approvals

Ethics and institutional approvals were in place before recruitment activities started at all pilot sites. This provided the necessary framework for Study 1 to proceed in line with the ethical and legal standards set out in the project documents and in the relevant national procedures. In that sense, recruitment has taken place on an approved basis across countries, and no site began implementation without the required authorisations.

At the same time, the approval pathway was not equally demanding in all settings. In some countries, ethics approval was only one element within a broader administrative sequence that also involved education authorities or school-level permissions. This meant that, even where the study itself had ethical clearance, the practical start of recruitment still depended on additional institutional steps.

Italy provides the clearest example of how timing in the approval process affected implementation. The National Ethics Committee procedure took longer than expected, and by the time approval was received many schools had already finalised their academic planning for the year. As a result, the study entered schools later than originally intended, which reduced the room available for recruitment within the school calendar.

In Cyprus, the process also extended beyond ethics approval itself. In addition to ethical clearance, approval from the Pedagogical Institute was required, and each participating school also had to inform or obtain approval from the relevant school inspector before implementation could proceed. This created a more layered administrative pathway, which helps explain why recruitment depended heavily on school-level coordination and could not move forward immediately after initial agreement.

Greece followed a somewhat different route. There, ethics-related requirements were in place, but the implementation sequence also included formal notification of the relevant secondary education authorities as part of local coordination with schools. This did not prevent recruitment, but it shows that the administrative route into schools was not identical across countries and had to be managed in line with local educational structures.

Overall, these differences did not compromise the feasibility of Study 1, but they did affect how quickly recruitment could begin and how easily the study could be integrated into each school system. The midterm experience therefore suggests that ethical clearance alone is not always the best indicator of implementation readiness; in several settings, the practical start of recruitment depended just as much on the surrounding institutional pathway.

8. Barriers and challenges

Recruitment in Study 1 has progressed under different practical conditions across sites. Overall, the experience to date indicates that the recruitment pathway is workable, but that its pace depends heavily on how well study procedures can be aligned with school organisation, family communication, and the practical demands of in-class implementation. The barriers identified at midterm should therefore be understood less as isolated problems than as part of the operational complexity of delivering a school-based digital intervention across different national settings.

The most consistent challenge has been the consent process. In several countries, progress depended on repeated follow-up with schools, teachers, students, and families before baseline sessions could be scheduled. This was especially visible in Belgium and Italy, where parental consent created substantial delays, but similar effects were also reported in Greece, Cyprus, Romania, and Valencia whenever the process required several handovers before forms were returned. Once consent had been obtained, recruitment generally moved more smoothly into registration and baseline completion.

A second set of barriers concerned registration and technical onboarding. Some sites reported difficulties linked to QR codes, passwords, platform use, connectivity, or the practical time needed to guide students through digital steps before they could complete the baseline survey. In Belgium, the initial parent-and-student registration flow through the Authoring Tool created avoidable friction. In Greece and the Basque Country, network quality and platform stability affected some sessions. Romania also noted that on-site guidance was important to ensure consistent completion of the digital tools, and similar observations were made in Cyprus and Slovenia, where implementation worked better when support was available directly in the classroom.

School scheduling constraints were also common across sites. Schools work within fixed timetables, exam periods, internal projects, and pre-planned annual calendars, so integrating an external study required constant negotiation. In Cyprus, this issue was particularly important because the exam period and the end of the school year created a clear interruption in the recruitment pathway. Switzerland also highlighted the importance of aligning recruitment with long-term school planning cycles, even though Study 1 itself progressed well there. Similar constraints were reported in Romania and in the consolidated draft more broadly, where baseline sessions sometimes had to be reorganised because of overlapping priorities, attendance variation, or timetable changes.

A further challenge concerned hesitation around smartphone use in schools. This was most clearly reported in Belgium, where the recently introduced smartphone ban made some schools reluctant to participate in a WhatsApp-based intervention. Similar concerns also appeared in Italy, the Basque Country, Valencia, and Cyprus, where schools sometimes needed reassurance that the digital tools formed part of a supervised health and prevention activity rather than unrestricted phone use. These concerns did not make participation impossible, but they did increase the amount of explanation and coordination required before implementation could proceed.

These experiences suggest that the main challenge in Study 1 was not whether recruitment could take place, but how much coordination, clarification, and in-class support were needed to make the process work under real school conditions. Sites generally progressed better where schools were closely involved, where study procedures could be fitted into normal classroom routines, and where the research team could provide direct support during the key transition from consent to baseline completion.

9. Deviations from the original plan

During the recruitment period, several pilot sites introduced targeted adaptations to the operational delivery of early study procedures within schools. These adaptations were implemented to improve feasibility, reduce procedural delays, and better align the recruitment pathway with local school practices and administrative constraints, while preserving the core design and methodological integrity of Study 1.

A first group of adaptations concerned the consent and registration process, which emerged as a key operational bottleneck across multiple sites. In Belgium, the initial digital consent and registration pathway proved more complex for families than anticipated; as a result, the process was simplified and complemented with paper-based options and Smartschool-supported communication. In Greece, email-based return of consent forms was replaced by paper circulation through students to improve response rates, and the registration step was streamlined by removing the need for parental involvement at that stage. In Slovenia, indirect management of registration codes led to lower completion rates, prompting a shift towards direct, classroom-supported onboarding with step-by-step guidance.

A second group of adaptations related to recruitment coverage and school-level organisation. Belgium expanded its recruitment strategy through a second outreach wave including boarding schools. Greece incorporated an additional school (Tylissos Junior High School) to strengthen recruitment capacity, while Slovenia included a replacement school to maintain implementation continuity. In Romania and Italy, baseline data collection was adapted to local constraints by organising sessions in larger spaces or across multiple classes. In several sites, including the Basque Country, Valencia, Cyprus, and Belgium, the role of the research team in classroom-based implementation became more prominent over time, particularly in supporting the transition from consent to registration and baseline completion.

These adaptations are best understood as context-driven implementation refinements rather than deviations affecting the study design. The target population, overall recruitment pathway, intervention delivery, and evaluation framework remained unchanged across all sites. However, the specific operationalisation of these procedures was adjusted to ensure feasibility under real-world school conditions.

While these adaptations may introduce some variability in implementation processes across sites, they do not compromise the internal consistency or scientific objectives of Study 1. On the contrary, they reflect the pragmatic nature of the study and provide valuable insights into how school-based digital interventions can be effectively implemented across diverse educational and regulatory contexts. These aspects will be explicitly considered in the interpretation of results and in subsequent evaluation activities (WP5).

10. Extended recruitment window

According to the SUNRISE Description of the Action, recruitment for Study 1 was planned between months M18 and M32. However, the operational start of recruitment coincided with the end of the 2024–2025 academic year (June 2025), when most schools had already finalised their teaching schedules and were no longer able to incorporate additional activities. As a result, effective recruitment could only begin with the start of the following academic year (September 2025), leading to a later-than-planned operational initiation across several sites.

In addition, the planned end of the recruitment period (M32, August 2026) coincides with the summer break in most participating countries, when schools are closed and recruitment activities cannot be conducted. This creates a structural constraint that limits the ability to complete recruitment within the originally defined timeframe, particularly in sites requiring additional school cycles.

An additional factor contributing to the adjusted recruitment timeline relates to the ethical and regulatory requirements associated with working with minors and implementing digital interventions in school settings. Given that Study 1 involves adolescents and the use of mobile-based technologies, several countries required detailed ethical review processes addressing data protection, informed consent procedures, and the use of digital tools within educational environments. In some settings, this resulted in slightly longer timelines for obtaining full approvals from ethics committees and institutional bodies.

These processes were handled with strict adherence to Good Clinical Practice principles, GDPRrequirements, and national regulations, ensuring that participant protection, data security, and informed consent procedures were fully robust before recruitment started. Rather than representing a limitation, this reflects the necessary level of scrutiny when conducting research in vulnerable populations and contributes to the overall scientific and ethical quality of the study.

In response to these constraints and based on ongoing monitoring of recruitment progress across sites, the consortium agreed to extend the recruitment window until October 2026. This extension is a targeted and proportionate adjustment that allows recruitment activities to be aligned with the school calendar, including the start of the 2026–2027 academic year where necessary.

Importantly, this adaptation does not reflect a change in the study design, target population, or evaluation framework. Instead, it ensures that the study can reach the planned sample size required to maintain sufficient statistical power and support robust, high-impact results. Achieving an adequate sample size is particularly critical for Study 1, given its role in generating evidence on adolescent health behaviour change in line with current European public health priorities and policy recommendations.

From a project implementation perspective, the extension remains fully compatible with the overall SUNRISE timeline (ending in April 2028). The intervention period, follow-up assessments, and subsequent evaluation activities (WP5) can still be completed within the available timeframe without compromising study integrity or delivery of downstream tasks.

Furthermore, the extension does not introduce risks for the implementation of other work packages. The sequencing of activities remains coherent, and no dependencies are negatively affected. On the contrary, the extended recruitment window strengthens the feasibility of the study by ensuring that all sites can complete recruitment under realistic operational conditions, thereby supporting the achievement of the project's scientific and policy objectives.

Overall, the extension should be understood as a pragmatic, context-driven adjustment that preserves methodological robustness, ensures adequate statistical power, and enhances the quality and interpretability of Study 1 outcomes, without compromising the overall objectives or timeline of the SUNRISE project.

11. Updated timeline

Table 3 sets out the current expected completion dates for recruitment in Study 1 by pilot site. At this stage, the timetable is clearer than at the beginning of implementation, although it remains open in a small number of settings. Two sites, Switzerland and the Basque Country, have already completed recruitment and exceeded their current targets. Several others are expected to complete recruitment during spring 2026, while a smaller number remain dependent on additional school recruitment or on continuation into the next academic cycle.

The timeline should be read as a planning framework rather than as a fixed forecast. Recruitment completion depends not only on school interest, but also on the timing of consent collection, school schedules, registration, and baseline completion. For this reason, some movement in expected completion dates is normal in a multicountry school-based study and does not in itself indicate a change in the study model.

Table 3. Updated expected recruitment completion by pilot site

Country	Expected recruitment completion	Operational status / note
Greece	April 2026	Registration at Tylissos planned for 1–4 April 2026
Belgium	April–October 2026	Recruitment ongoing; continued efforts to expand participation
Slovenia	April–October 2026	Dependent on additional school recruitment
Spain – Valencia	May 2026	Third school entering recruitment
Spain – Basque Country	Completed	Target reached and exceeded (504/467)
Italy	April–October 2026	Recruitment progressing; final enrolment likely to remain below target
Romania	May 2026	Progressing steadily
Cyprus	Pause in mid-April 2026; resume in October 2026	Exam period and school year end require continuation in the next academic cycle
Switzerland	Completed	Target reached and exceeded (592/561); recruitment remains open

The revised timetable shows that most sites are expected to complete recruitment during spring 2026, but not all sites are working within the same time horizon. Cyprus is the clearest case in which the school calendar creates an unavoidable interruption, while Slovenia remains more open because final timing depends on the successful addition of further schools. The extension through October 2026 therefore functions mainly as a safeguard for the sites that still need more time, while remaining fully compatible with the overall project schedule.

12. Lessons learned

The midterm experience indicates that recruitment was most effective when the study was implemented as a supported school-based activity, rather than as a process managed independently by students or families. Across several sites, the transition from consent to baseline completion was more reliable when the research team or trained collaborators were present in the classroom, guiding students step by step and resolving practical issues in real time. This pattern was consistently observed in Romania, Cyprus, Greece, Valencia, and Switzerland, and helps explain the increasing reliance on classroom-based support across sites as implementation progressed.

A second key lesson concerns the design of the consent pathway. Recruitment proceeded more smoothly when consent procedures were integrated into routine school practices and presented in a simple, accessible format. In contrast, recruitment slowed when parents were required to complete multiple unfamiliar steps or when consent processes involved several handovers between schools, families, and students. Evidence from Belgium, Greece, Slovenia, Cyprus, and Italy supports this pattern, although the specific barriers varied by context. Importantly, these findings do not suggest that digital tools should be avoided, but rather that the full pathway, from information to consent, registration, and baseline completion, must be intuitive and easy to navigate.

In this context, engagement with families emerged as an additional key factor in facilitating recruitment across several sites. Direct interaction with parents, including dedicated information sessions, played an important role in clarifying key aspects of the study, particularly the use of mobile devices, data protection and security measures, and the overall purpose of the intervention. In several contexts, parents expressed awareness and concern regarding the potential negative effects of mobile phone use among adolescents. Addressing these concerns explicitly, by framing the intervention as a structured, supervised, and health-oriented use of digital tools, was essential to facilitate acceptance and participation. Building trust between families and the research team was therefore a critical component, further reinforced by clearly communicating the potential impact of the study both at individual and broader population levels.

The findings also highlight the importance of strong local coordination. Recruitment success depended not only on initial school agreement, but on sustained interaction with school management and teaching staff. Clear communication, realistic scheduling, and concise documentation improved feasibility across sites. Experiences from Romania, Belgium, Italy, and the Basque Country show that recruitment is not secured through initial engagement alone but requires continuous organisational effort to maintain momentum throughout the process.

A further lesson relates to longer-term implementation and scalability. Recruitment was more easily integrated in settings where time demands were limited and where existing relationships with schools could be leveraged. The Swiss model provides a clear example of this, combining established prevention networks, simplified consent procedures, and implementation formats that could be completed within a single lesson. More broadly, several sites indicate that reducing procedural burden and aligning study activities with school timetables are critical factors for uptake.

Overall, these lessons suggest that successful recruitment in Study 1 did not depend on a single optimal strategy, but on the effective combination of school engagement, streamlined consent procedures, classroom-based support, realistic timing, and trust-building with families. More broadly, the findings reinforce a key implementation principle: the closer study procedures are to routine school practice, the more likely large-scale delivery becomes feasible.

13. Implications for study validity and evaluation

The midterm recruitment experience highlights several aspects that are relevant for the interpretation of Study 1 outcomes.

Recruitment pathways differed across countries, particularly with regard to consent procedures and school engagement strategies. While these differences reflect real-world implementation conditions, they may influence participation patterns and should be considered when analysing cross-country comparability.

In addition, the pragmatic recruitment approach, based on school willingness and operational feasibility, implies that the sample is not fully random at the school level. This is consistent with the real-world implementation logic of SUNRISE but may have implications for representativeness in some settings.

Furthermore, variability in onboarding support and classroom implementation may have influenced baseline completion rates and early engagement with the intervention. These factors will be explicitly addressed in WP5 analyses, including subgroup analyses and implementation evaluation based on the RE-AIM framework.

Overall, these elements do not compromise the feasibility or integrity of the study, but rather highlight the importance of interpreting results within an implementation science framework, where context and delivery conditions are integral components of the intervention.

14. Conclusions

At midterm, Study 1 has reached a substantial level of recruitment and baseline completion across the consortium. Although progress has not followed the same pattern in all countries, the overall picture confirms that implementation is advancing in all pilot settings, with several sites already reaching or exceeding their current recruitment targets. Switzerland and the Basque Country are the clearest examples of this, while Romania, Greece, and Cyprus also demonstrate meaningful progress at this stage.

The findings show that recruitment performance is closely linked to how effectively study procedures can be integrated into routine school practice. While specific challenges varied across sites, the most critical point consistently concerned the transition from school agreement to completed baseline participation. Consent procedures, onboarding and registration processes, timetable constraints, and perceptions around digital tools all influenced the speed and efficiency of this transition. Where these elements were well aligned with school routines and supported in the classroom, recruitment progressed more smoothly.

Importantly, the consortium has demonstrated the ability to adapt implementation without altering the core design of the study. The adjustments introduced across sites represent context-driven operational refinements rather than methodological deviations. The target population, recruitment pathway, intervention delivery, and evaluation framework have remained consistent throughout. This balance between standardisation and flexibility has been essential to maintain both feasibility and methodological robustness in diverse educational settings.

The extension of the recruitment window until October 2026 should be interpreted within this implementation context. It represents a proportionate and necessary adjustment to align recruitment with school calendars and operational constraints, rather than a change in study objectives. At project level, this remains fully compatible with the overall SUNRISE timeline and does not compromise subsequent intervention or evaluation phases.

Overall, Study 1 demonstrates that large-scale, school-based digital interventions targeting adolescents are feasible across heterogeneous European contexts, but highly dependent on local implementation conditions. The variability observed across sites should therefore be understood not only as an operational challenge, but also as a source of valuable evidence on how context influences implementation.

These findings reinforce a key conclusion: successful delivery in this type of intervention depends on the ability to integrate research procedures into routine school practice, supported by clear coordination, manageable processes, and context-sensitive adaptation. This will be critical not only for the completion of Study 1, but also for the interpretation of its results and the future scalability of the SUNRISE approach.

This is particularly relevant in the context of current European public health priorities, where scalable, school-based interventions are key to addressing behavioural risk factors in adolescent populations.

15. References

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