PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Cohort profile: Monitoring Young Lifestyles (MyLife), a prospective longitudinal quantitative and qualitative study of youth development and substance use in Norway
AUTHORS	Burdzovic Andreas, Jasmina; Brunborg, Geir Scott; Scheffels, Janne; Tokle, Rikke; Buvik, Kristin; Kvaavik, Elisabeth

VERSION 1 – REVIEW

REVIEWER	Joanna Henderson Centre for Addiction and Mental Health Canada
REVIEW RETURNED	09-May-2019

GENERAL COMMENTS	The authors describe a protocol and sample description for an important topic, with a strong design and inclusion of mixed methods. The following comments are made with the goal of strengthening the manuscript: - Abstract is somewhat confusing with varying Ns and timelines - The manuscript should be reviewed for grammar, colloquialisms (e.g., under Strengths and Limitations – "very first …" - In the Introduction the authors make the case for the lack of studies contextualized by developmental psychopathology frameworks. Further explication of what is meant by this and how this study addresses this gap would strengthen the manuscript. - Page 6 title "Cohort Description" – seems misplaced - Research questions need to be further described – as it stands it seems the focus appears to be on data collection with determination of research questions and hypotheses to follow - Middle school students are the focus because they are reportedly of ages that precede the onset of the behaviours of interest. While this is generally true, it is important to acknowledge that for a highly vulnerable subset of children, substance related behaviours may start before the study period. - It would be helpful to include description of some key ways in which the pilot informed the current study - The connection between data collection in 2014/2015 and 2017 is not clear, especially across quantitative and qualitative approaches - Sampling description only includes a very small amount of information about QL sampling and the timing is not clear, and the timing of the two components relative to each other is not clear. - The section "The Mylife Cohort" is largely repetitive with the previous section - Discussion will need to be re-reviewed once the research questions and methods are clearer - Figure 4 – title/label incorrect - References need attention

REVIEWER	Katherine Tassiopoulos, DSc, MPH Senior Research Scientist, Department of Epidemiology Harvard T. H. Chan School of Public Health U.S.
REVIEW RETURNED	31-May-2019

GENERAL COMMENTS	This overall is a well-written and well-constructed manuscript, and the goal of the study - to evaluate factors associated with substance use, and consequences of this use, among youth in Norway - is an important one. I have a few comments for the authors' consideration: 1. My main comment is that it difficult to follow the development and timeline of the QL group. I think this is because some members of the QL group in the pilot study continued on into the 'main study'. The discussion of the QL could be therefore clarified more in the body of the paper. The flow chart in Figure 4 could be revised and expanded to help clarify the timeline. In the abstract, inclusion of the year of the baseline QL assessment is especially confusing since it is first stated that the cohort was recruited in 2017, but the baseline QL assessment was completed in 2014. 2. The rationale for asking for the return of all informed consent forms, including those where the parent declined participation, should be stated. I assume this was requested to help determine whether students actually gave the forms to their parents. 3. The authors state that retention in the first follow-up was strong and that they expect low attrition in the subsequent rounds. However, the response rate for those in high school was only 72.3%, and as the cohort ages and more youth enter (and complete) high school, the overall rate will likely decrease. This could certainly affect the ability to look at trajectories of substance use over time, and should be stated in the limitations. 4. There are a few typos throughout the paper so some additional proofreading is warranted. (For example, the terms 'online' and 'on-line' are both used, the word 'constraint' is misspelled as 'constrains' (line 52, page 5). Also, the figure legend for Figure 4 states that it is the flow chart for the quantitative arm and it should say qualitative.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

1. Abstract is somewhat confusing with varying Ns and timelines

Response: We are aware of the somewhat confusing design and varying timelines, which proved challenging in terms of study and cohort description not only in the Abstract but throughout the manuscript. As now clarified in this revision, these different timelines were not part of the original design but resulted from an unusually long administrative review by the Norwegian Data Protection Authority (DPA) – we have noted this in the main text and again as one of the key limitations of the study. The revised abstract is hopefully less confusing now, as it simply states the following:
“Participants: The MyLife cohort was recruited from middle schools in Norway, which were selected from low, medium, and high standard of living areas in both rural and urban regions of the country. A total of 3,512 8th, 9th, and 10th graders (55% girls) from 33 schools were enrolled in the quantitative

project arm (QT), while a total of 120 8th graders (52% girls) from 6 schools were enrolled in the qualitative project arm (QL).
Findings to date: QT baseline was conducted in the fall of 2017, when 2,975 adolescents completed an on-line questionnaire during a regular class time. A total of 2,857 adolescents participated in the first QT follow-up one year later. QL baseline was conducted across the Fall semesters of 2014 (1 class) and 2015 (5 classes), when a total of 118 8th graders completed face-to-face interviews. QL follow-ups were conducted in the spring of 2015 and fall of 2017 (n = 98) for group interviews, and in the spring of 2017 and 2018 (n = 95) for individual interviews. In terms of additional data sources, a total of 3,035 parents consented to own participation, of which 1,899 completed a brief on-line questionnaire at QT baseline in late 2017. School principals completed brief surveys at the same time."

2. The manuscript should be reviewed for grammar, colloquialisms (e.g., under Strengths and Limitations – "very first …"
Response: We have edited this revision to the best of our abilities. We are also open to the BMJ language proofreading services, if further assistance is needed.
3. In the Introduction the authors make the case for the lack of studies contextualized by developmental psychopathology frameworks. Further explication of what is meant by this and how this study addresses this gap would strengthen the manuscript.
Response: Thank you for this comment. We have substantially expanded this section, to include better explanation of these theoretical approaches, and the lack of coordinated quantitative and qualitative studies exploring substance use using developmental psychopathology frameworks. Specifically, this section was added to the manuscript, p. 3-4:
"The relevant research no longer seeks to simply identify the most important risk and protective factors1-3; instead, it increasingly aims to understand their complex contribution to varied patterns and developmental trajectories of early drinking, smoking, and drug use4-11. Indeed, understanding the developmental course of substance use has become central to understanding the causes, onset, timing, duration, and consequences of these behaviors. More importantly, understanding how different substance use patterns develop and progress over time and across various sub-populations ultimately informs not only our understanding of the associated risk and protective factors, but also of the potential prevention and treatment strategies1 2 12.
Such questions are best explored within the developmental psychopathology and epidemiology frameworks and social-ecological theories of human development13-21. These approaches study developing individuals within their social contexts (i.e., families, schools, cultures, etc.) and focus on causal mechanisms underlying developmental shifts towards or away from pathological outcomes and problem behaviors such as substance use14-16 21-24. And while these fields have been traditionally dominated by quantitative approaches and statistical analyses, integration of qualitative methods into core developmental psychopathology frameworks can offer unique advantages25 26.
Specifically, qualitative methods address the "why" questions and provide insights into the larger socio-cultural contexts in which individuals develop27 28; the results from the integrated studies therefore offer both depth and breadth in understanding of youth development and cultures. For example, repeated interviews with adolescents can help us map and describe the complex social and cultural processes underlying their use of alcohol, tobacco, or drugs. Yet, multidisciplinary and mixed methods studies of early substance use remain few and far between, constrained by the high-risk samples, cross-sectional designs, and general non-reliance on developmental framework29 30."

4. Page 6 title "Cohort Description" – seems misplaced
Response: This section has also been substantially revised, to first describe our study design and procedures, then sampling and recruitment strategies, data collection techniques, and finally, findings to date (including core cohort characteristics). We also more closely followed the BMJ formatting guidelines, hopefully resulting in the improved overall report structure.

5. Research questions need to be further described – as it stands it seems the focus appears to be on data collection with determination of research questions and hypotheses to follow.
Response: Thank you for drawing our attention to this issue. We were initially following the general BMJ guidelines for "Cohort Profile" reports, which state that "Cohorts described should be long-term, prospective projects and not time-limited cohorts established to answer a small number of specific research questions." By doing this, we have unintentionally omitted to state even the basic research questions to be addressed in the MyLife project.
This revision specifies these for both the quantitative and qualitative arms, p. 5-6:
"Given the above-identified gaps, the MyLife project was initiated as a large-scale multidisciplinary and mixed-methods prospective investigation of early substance use and other addictive behaviors, their normative and non-normative developmental courses, their varied causes and consequences, putative comorbidities, and underlying psychological and social processes and mechanisms. Our primary research questions will therefore focus on identification and examination of risk and protective factors associated with substance use patterns across adolescence. Closer examination of sensitive developmental periods and larger contextual factors in relation to changes both across and within individuals will also be prioritized.
These questions will be examined both quantitatively (i.e., examination of adolescents' repeated surveys, parental surveys, and various administrative data sources) and qualitatively (i.e., examination of adolescents' repeated individual and group-based interviews using thematic content and narrative analyses). Further, we aim to both quantitatively and qualitatively explore numerous under-studied and emerging questions, including the problematic use of social media and video games31-34, the role of alcohol and drug use opportunities35-37, putative gender, ethnic, and socio-economic variations and differences9 38 39, resilient outcomes in face of multiple risk factors40, and shifting cultural norms and behaviors surrounding early substance use41-45.
Finally, a wider range of research questions and outcomes extending beyond adolescence can eventually be addressed through various secondary projects and data analyses and the planned individual-level linkages of quantitative data with other administrative and health data sources readily available in Norway46. The study ultimately aims to narrow the existing research gap, to inform relevant public health policies, and to improve prevention and intervention strategies concerning early substance use and other addictive behaviors. This report describes the MyLife project, its design and sampling, recruitment and data collection for quantitative and qualitative project arms, core cohorts, and selected preliminary results."

6. Middle school students are the focus because they are reportedly of ages that precede the onset of the behaviors of interest. While this is generally true, it is important to acknowledge that for a highly vulnerable subset of children, substance related behaviors may start before the study period.
Response: Indeed, this is one of the key shortcomings of our selected sample. This is now noted in the revised Limitations section, together with a related concern of self-selection into the study (where adolescents with high-risk characteristics may have been less likely to even inform their parents about the study), p. 24-25:
"Next, because of the privacy and confidentiality concerns, the participating schools were not able to share parental contact info with the MyLife team. For this reason, distribution of the project information booklets and consent forms was outsourced to schools and ultimately to students themselves. Given this reliance on young adolescents as liaisons, it is not known how many parents were properly informed about the MyLife study. It is possible that the more vulnerable or high-risk adolescents were less likely to share this info with their parents, thus affecting the core sample characteristics. This also suggests that the utilized consent strategy, albeit the only ethically feasible one in our case, might have been less than optimal.
The related limitation concerns inferences and generalizability of our results. For example, given our inclusion criteria and sampling strategies, we may have missed the onset of substance use before

grade 8th and among adolescents who may be particularly vulnerable for a range of negative outcomes. However, we can still identify those "early starters" in the core sample."

7. It would be helpful to include description of some key ways in which the pilot informed the current study.
Response: This information was omitted from the original submission due to the word limit concerns. We have now added the requested details for both study arms, p. 11-12:
"Pilot study: A small scale mixed-methods pilot study including 4 middle schools and 1 high school (N = 851) was conducted in 2014 to test recruitment strategies, modes of data collection, and questionnaire/interview content for both study arms. The QT pilot involved 5 cohorts: 8th, 9th, and 10th grade middle school students, and first and second year high-school students. The results informed several key aspects of the main study. For example, high-school cohorts were eliminated from baseline inclusion as scientifically and logistically non-efficient; questionnaires were simplified to be appropriate for younger adolescents and several sensitive items were removed (e.g., suicidality module); reimbursement strategies were fine-tuned to include gift cards of meaningful value for individual participation in combination with random lottery drawings of highly prized items such as iPhones; and National Identity Numbers were selected as the primary means of participant identification and data linkages.
The QL pilot included two 8th grade classes (n = 36), and it also tested recruitment strategies, interview topics, and assessment techniques. The pilot informed the main study decisions concerning the timing and balance of individual and group interviews, group sizes and composition, etc. Importantly, one of the pilot classes (n = 13) continued participation, and is included in the core QL sample even though its baseline was completed one year ahead of the main study schedule. Specifically, interviews with these participants continue to inform the decisions on how to proceed with the rest of the core sample, including the selection of emerging topics for both QT surveys and QL interviews.
The pilot characteristics and selected results are described elsewhere31 39 43 44.

8. The connection between data collection in 2014/2015 and 2017 is not clear, especially across quantitative and qualitative approaches.
Response: This unfortunate separation was caused by administrative delays in the Data Protection Authority (DPA) review, as now noted in the revised manuscript. In short, even though the school sampling and recruitment was finalized by 2015 and both study arms were slated to start their baseline data collection in the Fall semester of 2015, only the QL arm was allowed to proceed in the fall of 2015 as planned whereas the QT arm was initiated in the fall of 2017. This shortcoming is now stated at the end of the revised design section, p. 7-8:

"Study design, all participants, data sources, and planned timelines are shown in Figure 1.
It should be noted that the original MyLife design proposed overlapping QL and QT samples, as well as the common baseline for the Fall semester of 2015. The separation of data collection schedules for the two arms resulted from a lengthy evaluation process by the Norwegian Data Protection Authority (DPA). Nevertheless, the MyLife project still facilitates mixed methods analyses, albeit not at the individual student level28 45."

9. Sampling description only includes a very small amount of information about QL sampling and the timing is not clear, and the timing of the two components relative to each other is not clear.
Response: We agree that the information on QL sampling (both the schools and students) was limited. For further clarification, we have separately delineated all QT and QL procedures, and QL info was expanded to now specify sampling of the schools as follows, p. 9:
"This procedure resulted in 42 schools with upwards of 9,500 middle school students (see Figure 2 for details) suitable for both QT and QL arm participation. Two additional schools previously identified in the pilot project were eligible for QL.

The enrollments in the identified schools ranged from 54 to 529 middle school students. All 42 schools were contacted and invited to participate in the QT arm. Nine schools declined, leaving 33 schools with about 7,000 middle school students potentially available for study inclusion. A total of 7 schools were invited to participate in the QL arm; 5 schools identified through the procedure above were eligible for new participation, while 2 schools identified during the pilot study were eligible for continued participation. One school declined, leaving a total of 6 QL eligible schools. The ultimate aim was to enroll full 8th, 9th, and 10th grade cohorts from each school if possible (for QT) and one 8th grade class/cohort per school (for QL). These school recruitment procedures were completed in 2015 and are shown in Figure 3 (for QT) and Figure 4 (for QL).

QL consent procedures as follows, p. 10:
"QL consent: A subgroup of 143 students from 6 schools (one 8th grade class/cohort per school) were approached in 2015 following the main school recruitment procedures. Similar to the QT procedures above, parents were asked to consent to their child's participation in the QL arm involving both individual and group interviews over time. Parental consent for the QL arm participation was obtained for 120 students (see Figure 4)."

and the separation of data collection timelines, as stated in the response to #8 above.

10. The section "The MyLife Cohort" is largely repetitive with the previous section.
Response: These sections were substantively re-organized and consolidated, as noted above.

11. Discussion will need to be re-reviewed once the research questions and methods are clearer.
Response: These sections were substantively re-organized and consolidated. Please see the revised manuscript.

12. Figure 4 – title/label incorrect.
13. References need attention.
Response: Figures and references were corrected for previous omissions and typos.

Reviewer: 2
This overall is a well-written and well-constructed manuscript, and the goal of the study - to evaluate factors associated with substance use, and consequences of this use, among youth in Norway - is an important one. I have a few comments for the authors' consideration:

1. My main comment is that it difficult to follow the development and timeline of the QL group. I think this is because some members of the QL group in the pilot study continued on into the 'main study'. The discussion of the QL could be therefore clarified more in the body of the paper. The flow chart in Figure 4 could be revised and expanded to help clarify the timeline. In the abstract, inclusion of the year of the baseline QL assessment is especially confusing since it is first stated that the cohort was recruited in 2017, but the baseline QL assessment was completed in 2014.
Response: As noted in the responses to the Reviewer 1 (questions #1, #8, and #9), this challenging design resulted from the delays associated with the Data Protection Authority (DPA) administrative review. These issues are now noted in the revised manuscript; both the design and limitations section, p. 7-8, and p. 24:
"Study design, all participants, data sources, and planned timelines are shown in Figure 1.
It should be noted that the original MyLife design proposed overlapping QL and QT samples, as well as the common baseline for the Fall semester of 2015. The separation of data collection schedules for the two arms resulted from a lengthy evaluation process by the Norwegian Data Protection Authority (DPA). Nevertheless, the MyLife project still facilitates mixed methods analyses, albeit not at the individual student level28 45."

“As with all studies, there are important limitations. First, the non-alignment of the QT and QL baselines resulted from administrative delays; nevertheless, the project largely retained its multidisciplinary and mixed-methods character.”

We aimed to clarify this as much as possible in this revision. For example, the school recruitment (finalized by 2015) vs. individual student recruitment (2017 for QT) is now explained in the main text. The revised Abstract now states that the QL baseline was staggered across 2014 and 2015:
“QL baseline was conducted across the Fall semesters of 2014 (1 class) and 2015 (5 classes), when a total of 118 8th graders completed face-to-face interviews.”

Finally, as requested by Reviewer 1 as well, we added more information concerning the QL procedures; please see the responses to questions #8 and #9 above.

2. The rationale for asking for the return of all informed consent forms, including those where the parent declined participation, should be stated. I assume this was requested to help determine whether students actually gave the forms to their parents.
Response: Indeed, this was the rationale behind this procedure, as now specifically stated in the revised text, p. 8-9:
“Informed consent, General procedures: Because of the respondents’ young age, informed parental consent was required before the children could be invited to participate, or give assent for own participation in the MyLife study. The schools were provided with information packages containing a printed booklet describing the project in plain language, explicit consent form, and a secure return envelope; this package was administered to all students during regular class time.
Students were asked to take the package home, share it with their parents, and to return sealed envelopes with completed consent forms to their teachers by a deadline. In order to estimate as accurate as possible response and consent rates, we asked that the forms be returned even if no consent for study participation was granted. Those with parental consent were asked to assent for own participation immediately preceding the QT and QL baseline assessments.”

3. The authors state that retention in the first follow-up was strong and that they expect low attrition in the subsequent rounds. However, the response rate for those in high school was only 72.3%, and as the cohort ages and more youth enter (and complete) high school, the overall rate will likely decrease. This could certainly affect the ability to look at trajectories of substance use over time, and should be stated in the limitations.
Response: Thank you for this comment, as it made us take a closer look at this key challenge facing prospective cohorts. Consequently, we have refrained from speculations related to our retention rates; the original section was entirely deleted and replaced with a bit more cautious calls for examination of factors associated with attrition, p. 25:
“Finally, identification of the factors associated with attrition may improve future retention rates, especially for those participants followed-up individually.”

To further clarify this issue, we have now noted that chosen QT design (i.e., accelerated longitudinal design) was selected, among other reasons, due to its relative robustness to missing data, p. 6-7:
“Data collection windows for all 5 annual assessments were set during the Fall semester, with closing at the last day of that calendar year (i.e., September through December 31). The chosen QT design fully reflects our key theoretical models and scientific aims while optimizing data collection time and robustness to dropout47 48.”

4. There are a few typos throughout the paper so some additional proofreading is warranted. (For example, the terms 'online' and 'on-line' are both used, the word 'constraint' is misspelled as 'constrains' (line 52, page 5). Also, the figure legend for Figure 4 states that it is the flow chart for the quantitative arm and it should say qualitative.
Response: Figures and references were corrected for previous omissions and typos. We are also open to the BMJ language proofreading services, if further assistance needed.

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VERSION 2 – REVIEW

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GENERAL COMMENTS	The authors have addressed my previous comments satisfactorily. The revised paper is well-written and clearly describes the development of the cohort, its aims, and the limitations of the design.